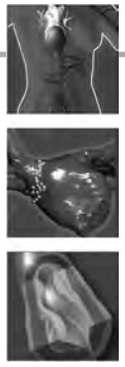

Percutaneous ventricular assist device TandemHeart™ in severe refractory cardiogenic shock

Evaluation of: Kar B, Gregoric ID, Basra SS, Idelchik GM, Loyalka P: The percutaneous ventricular assist device in severe refractory cardiogenic shock. *J. Am. Coll. Cardiol.* 57, 688–696 (2011). Mortality in patients suffering from cardiogenic shock remains high. The article by Kar *et al.* presents the results of the largest number of patients in a single-center experience receiving percutaneous ventricular assist device support in cardiogenic shock, despite intra-aortic balloon pump and/or high-dose vasopressors and inotropic therapy. Hemodynamic improvements with the use of the TandemHeart™ (Cardiac Assist Technologies, Inc., PA, USA) device were well documented. The salvage rate for this cohort of patients, the majority of whom would have died without rapid implementation of mechanical circulatory support, was remarkable. As would be expected for application in refractory shock, there was also a high rate of mortality and adverse events. Nonetheless, the authors have demonstrated that the rapid deployment of mechanical circulatory assistance can positively influence outcomes in refractory cardiogenic shock.

KEYWORDS: cardiogenic shock ▪ heart failure ▪ intra-aortic balloon pump ▪ percutaneous ventricular assist device ▪ TandemHeart™

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This article reviews the recent article by Kar *et al.* which demonstrates the results of a large number of percutaneous ventricular assist device implantations with TandemHeart™ (Cardiac Assist Technologies, Inc., PA, USA) in patients with severe refractory cardiogenic shock [1].

The device was approved for short-term left ventricular support by the US FDA in 2003 and has been implanted in more than 1500 patients worldwide. It is inserted in the catheterization laboratory or operating room under fluoroscopic guidance [2]. A 21-French cannula is inserted through the femoral vein, and the device is positioned via transseptal puncture into the left atrium. A centrifugal continuous-flow pump then delivers blood from the left atrium into the femoral artery via a second 15–17 French cannula usually inserted percutaneously in the common femoral artery. The device has a flow rate up to 4.0 l/min at 7500 rpm [3].

The device has been used for support during high-risk coronary interventions [4,5], in cardiogenic shock, acute myocardial infarction, decompensated heart failure as a bridge-to-bridge procedure [6,7], in acute myocarditis [8] and postcardiotomy shock [9].

The patient population used in the study by Kar *et al.* was mostly treated after intervention for acute myocardial ischemia with ongoing hemodynamic compromise as stabilization for a bridge to decision.

Methods

The retrospective single center study by Kar *et al.* included 117 patients with percutaneous ventricular assist device implantation between May 2003 and November 2008. Patients had severe refractory cardiogenic shock that was defined as systolic blood pressure less than 90 mmHg, a cardiac index of <2.0 l/min/m² and evidence of end-organ failure despite high-dose inotropic and/or vasopressor support. Over 80% of patients were supported with an intra-aortic balloon pump (IABP) before implantation.

In total, 68% of the patients suffered from ischemic cardiomyopathy with a previous myocardial infarction, and 32% from nonischemic cardiomyopathy. In total, 80% of the patients with ICM underwent revascularization before pump placement. A large number of patients arrested before the TandemHeart implantation, and 47.9% of patients received cardiopulmonary resuscitation (CPR) during device implantation. A continuous intravenous heparin infusion was administered during support for anticoagulation, with a target activated partial thromboplastin time of 60–80 s. Pre- and post-procedure data included hemodynamic and biochemical parameters.

Results

The patients in the study by Kar *et al.* demonstrated significant improvement in hemodynamic and end-organ function with an average

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duration of support of 5.8 ± 4.75 days. In spite of the significant increase in cardiac output from pre- to post-implant (0.52–3.0 l/min/m²), the 30-day mortality rate was 40.2% and the 6-month mortality rate was 45.3%. The multivariate analysis of the risk factors for mortality identified preimplantation CPR as a significant risk factor.

Complications due to emergent device implantation included perforation of the left atrium and a dissection of the femoral artery. In 3.4% of the patients, lower limb ischemia was observed despite an antegrade cannula for distal limb perfusion. Bleeding complications were common and included bleeding around the cannula (29%) and gastrointestinal bleeding (20%). Blood transfusions were necessary in 60% of the patients.

Ultimately, 26% of patients were bridged to a left ventricular assist device, 4% were bridged to heart transplantation, 11% were bridged to surgical revascularization and 55% were treated medically.

Discussion & significance

A recent report by Thomas *et al*. describes the outcome of a smaller number of patients after implantation of TandemHeart [5]. This study described a promising outcome after implantation with 71% of patients in-hospital survival. Only 49% of the patients were in cardiogenic shock, 24% on IABP and 46% on vasopressors before implantation, compared with the patients in the study by Kar *et al.*, where 100% of the patients were in cardiogenic shock despite IABP and/or high-dose vasopressor. Historically, the in-hospital mortality of patients in cardiogenic shock is approximately 50% with conventional medical treatment [10,11]. Kar *et al.* demonstrate a reduction of the mortality rate to 40.2%, in a cohort of patients at the extreme end of cardiogenic shock, with nearly half receiving CPR at the time of device implantation.

In two existing randomized trials comparing IABP and TandemHeart in cardiogenic shock, both groups demonstrated a similar 30-day mortality, even though patients with a TandemHeart showed significantly better hemodynamic and biochemical parameters in comparison to the IABP support [12,13].

In these two studies, patients with an IABP had a 30-day mortality rate of 45 [12] and 36% [13] compared with 42 [12] and 47% [13] in the TandemHeart group.

In addition, the rate of adverse events, such as bleeding, was higher in the TandemHeart group and occurred in 42–90% of the patients [12,13]. In the patient population from Kar *et al.* with IABP and TandemHeart, an increase of the adverse event rate was not seen.

Despite these issues, the report from Kar *et al.* is promising. Patients who remain in profound cardiogenic shock despite IABP and inotropic support are at an exceedingly high risk of death. Salvage of these patients, many of whom were receiving CPR at the time of implantation, is an impressive achievement. However, the question is whether these results can be replicated at other centers with this device. To match the outcomes reported by Kar *et al.*, each center would need a dedicated team, that would need to be available at all times to allow rapid implantation of the device, which requires transseptal puncture, left atrial positioning and large bore cannula insertion into the femoral artery. The impressive salvage rates demonstrated by Kar *et al.* is a result of the dedicated team and their commitment.

An alternative method of emergent circulatory support would be extracorporeal membrane oxygenation (ECMO). ECMO is often used for cardiogenic shock but a randomized study to compare the use of a TandemHeart and an ECMO does not exist. As discussed by Kar *et al.*, a high complication rate in ECMO patients has also been observed, but in recent years an improvement of the tubing system, oxygenator and pump has occurred that has allowed less morbid and longer support with ECMO. For ECMO implantation, fluoroscopic guidance is not necessary and it is probably less technically demanding than TandemHeart implantation. Rapid resuscitation in cardiogenic shock with ECMO has also been documented [14]. It is unlikely that a trial will be performed to compare the TandemHeart with ECMO, and utilization of one or the other will likely be center specific.

Future perspective

The report by Kar *et al.* demonstrates the feasibility of TandemHeart for application in refractory cardiogenic shock. The study demonstrates a tangible advance for the worst prognosis. The majority of patients in the study by Kar *et al.* would not have survived without rapid mechanical circulatory support implementation and the 55% 6-month survival is an impressive achievement. Ideally, a multicenter trial designed to compare ECMO with TandemHeart and/or other rapidly deployed left ventricular assist devices in refractory cardiogenic shock would be performed to

demonstrate the best available therapy in this situation. Realistically, this is unlikely to happen. The clinical principle demonstrated in the study by Kar *et al.*, is that rapidly deployed mechanical support can salvage many patients with cardiogenic shock that is refractory to more conventional therapies. Whether this is achieved with TandemHeart or through other methods will likely remain center specific. The demonstrated hemodynamic success of TandemHeart for cardiogenic shock may ultimately justify its potential use in less sick patient populations. One such example would be to provide support during percutaneous aortic balloon valvuloplasty [15].

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The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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Executive summary

Background

- TandemHeart™ (Cardiac Assist Technologies, Inc., PA, USA), a percutaneous ventricular assist device, was implanted in more than 1500 patients but only several case studies and two randomized studies have been published.

Methods

- A retrospective study analyzed the largest number of patients (n = 117), with TandemHeart implantation in cardiogenic shock in a single center.

Results

- An impressive salvage rate in refractory cardiogenic shock was reported.

Significance

- The study reports a large number of patients who were successfully salvaged with TandemHeart implantation.

Future perspective

- Rapid deployment of mechanical support in refractory cardiogenic shock allows salvage of previously moribund patients. Future application of this technology may include support for transcatheter aortic valve implantation.

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