Ventricular assist device implantation in patients on percutaneous extracorporeal life support without switching to conventional cardiopulmonary bypass system

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Abstract

OBJECTIVES: Ventricular assist device (VAD) implantation using cardiopulmonary bypass (CPB) is an established procedure. However, the well-described complications of CPB may exacerbate multiple organ failure and increase blood product transfusions especially in end-stage heart failure patients.

METHODS: We describe our successful experience in six consecutive patients with profound cardiogenic shock, who were provided on an emergency basis with a percutaneous extracorporeal life support (ECLS) system via the peripheral vessels. After stabilization, a VAD was implanted using ECLS without switching to a conventional CPB system to reduce its side effects. We compared the data with those of 11 patients in whom the VAD was placed with the aid of an additional CPB system.

RESULTS: The six patients demonstrated a shorter duration of operating room time compared with the patients requiring CPB for device placement. During and after surgery, blood loss and blood product transfusions were lower in these patients. The need for mechanical ventilation and inotropic support was shorter and the survival rate (100% at 30 days, 83.3% at 3 months and 83.3% at 6 months) was higher when compared with patients who were operated upon with CPB. Two patients were successfully bridged to transplantation. One patient died due to cerebral bleeding after 7 weeks.

CONCLUSIONS: Our experience suggests that VAD implantation using percutaneous ECLS without switching to conventional CPB is a safe alternative in the bridge to bridge concept, especially in high-risk patients with cardiogenic shock who would benefit from the avoidance of the adverse sequels associated with conventional CPB.

Keywords: Ventricular assist device • Extracorporeal life support • Cardiopulmonary bypass • Cardiogenic shock

INTRODUCTION

Implantation of ventricular assist device (VAD) is becoming a viable clinical alternative to heart transplantation, not only as a bridge to recovery or transplantation, but also as a destination therapy. However, these devices are associated with poor survival in patients with acute cardiogenic shock, severe haemodynamic instability and multi-organ failure who need rapid installation of circulatory assist [1–3]. Extracorporeal life support (ECLS) is a well-established technology that provides cardiorespiratory support to stabilize severely compromised patients, but is only designed for short-term use [4]. More than a decade ago, it had been shown that a VAD implantation after ECLS placement is quite possible and does not yield inferior results [5].

Cardiopulmonary bypass (CPB) is traditionally required for implantation of VADs. CPB has various advantages such as inspection of the left ventricle for thrombus, protection from air embolism, haemodynamic resuscitation and removal of fluid, including ultrafiltration on CPB. However, CPB is associated with adverse effects including activation of the systemic inflammatory response syndrome (SIRS), which can result in bleeding, arrhythmias, thromboembolism, neurological disorders and organ dysfunction [6]. Several reports of small series from several groups have described insertion of VADs, including off-pump or minimally invasive insertion [7–10]. VAD implantation without extracorporeal circulation has been advocated for small axial pumps as well as for paracorporeal devices, but did not get widespread acceptance as haemodynamic instability may occur during implantation [7, 8].

In this report, we describe our successful experience with a case series of patients with profound cardiogenic shock secondary to acute or chronic heart failure, who were provided with a percutaneous veno-arterial ECLS system on an emergency basis via the peripheral vessels using Seldinger’s technique. After
stabilization, a VAD was implanted through a median sternotomy using the percutaneous ECLS without switching to a conventional CPB system to reduce the side effects.

MATERIALS AND METHODS

Patient population

From January 2007 to June 2011, 71 adult patients were placed on percutaneous veno-arterial ECLS for cardiac failure or cardiopulmonary resuscitation in our institution. Aetiologies for conservatively intractable cardiogenic shock were acute coronary ischaemia, myocarditis, ischaemic or dilated cardiomyopathy and post-cardiotomy heart failure. Twenty-seven patients (38%) died during ECLS. Another 27 patients (38%) were successfully weaned, and in 17 patients (24%) a VAD was implanted (bridge to bridge). After approval by the local ethics committee, we reviewed six patients (group ECLS) with cardiogenic shock, who were provided with an ECLS system on an emergency basis. After stabilization, a VAD was implanted using the percutaneous ECLS without switching to a conventional CPB system. We compared the data with those of 11 patients (group CPB) in whom the VAD was placed in traditional fashion with switching to a conventional CPB system. The haemodynamic criteria for support were identical for both patient groups. In both groups, the pump was employed as a bridge to transplant.

Initial selection criteria included the following: profound cardiogenic shock, or cardiac arrest, no existing absolute contraindications to heart transplantation, or re-operative cases and age <65 years.

Extracorporeal life support device

The ECLS system (Emergency Life Support or Cardiohelp, Maquet CP, Hirrlingen, Germany) is a lightweight, compact and portable extracorporeal perfusion system. As all blood contact surfaces of the system are heparin-coated, systemic anticoagulation can be kept at a minimum. The effect of heparin was measured via the activated partial thromboplastin time, ideally between 50 and 60 s. In all patients, a 23-Fr cannula (BE-PVS 2338, Maquet CP) was percutaneously inserted into the right femoral vein using Seldinger’s technique. The arterial return was achieved with a 17-Fr cannula via the left femoral artery or right subclavian artery.

Surgical technique

After stabilization, a VAD (either the implantable INCOR or the paracorporeal EXCOR, Berlin Heart, Berlin, Germany) was inserted. After general anaesthesia, a median sternotomy was performed. Accordingly, full systemic heparinization was not required; an activated clotting time of 200–250 s was deemed sufficient. The ECLS flow was increased to 4.5 l/min. The apex was exposed using pericardial sutures or lap pads. After circumferential placement of multiple buttressed non-resorbable sutures at the cannulation site, ventricular fibrillation was induced. An apical access to the left ventricle was created, and the apex cannula was inserted, fixed, and de-aired. The heart was immediately defibrillated thereafter. Then, a VAD arterial cannula was anastomosed to the ascending aorta with continuous 4-0 Prolene. Both cannulae were connected to the VAD pump. After the ventricle was de-aired, the VAD pump was started and the ECLS was weaned. The ECLS system was removed and, after haemostasis, the chest was closed. Removal of the ECLS cannulae was simple with manual compression of the groin.

Patients with right ventricular (RV) failure were supported with a temporary percutaneous right VAD (RVAD) using a centrifugal pump [11]. The indications for RV failure were determined clinically and included inadequate cardiac output and systemic pressure despite large doses of inotropes and vasopressor agents, increased central venous pressure and significant RV dysfunction seen by transthoracic echocardiography. The following echocardiographic parameters were defined as predictors for RV dysfunction after left VAD (LVAD) implantation: tricuspid valve incompetence, RV end-diastolic diameter > 35 mm, RV ejection fraction < 30% and right atrial dimension > 50 mm [11, 12].

After 12–24 h without significant bleeding, we started anticoagulation with heparin (PTT 50–60 s). Long-term anticoagulation consisted of coumarin, together with a platelet aggregation inhibitor at a low dosage.

Short-term follow-up

Variables analysed included haemodynamic parameters (mean pulmonary artery pressures, cardiac index and pulmonary capillary wedge pressure), and parameters of end-organ perfusion [levels of lactate dehydrogenases (LDH), glutamic-oxaloacetic transaminase (GOT), glutamate pyruvate transaminase (GPT), total bilirubin and creatinine].

Outcome definitions included peri- and post-operative clinical course. The post-operative documentation consisted of duration of ventilation, drainage loss, requirement of red blood cell transfusion, sepsis, respiratory insufficiency, temporary dialysis and length of stay at the ICU, 30-day, 3-month and 6-month mortality.

RESULTS

As shown in Table 1, patient characteristics did not differ between the two patient groups, particularly for age, gender, body surface area, disease and sequential organ failure assessment score. In addition, there was no difference between the two groups regarding pre-operative risk factors (ventilation, cardiopulmonary resuscitation and ejection fraction) with a trend towards longer ECLS support duration in the ECLS group [11 days (range, 9–13) vs. 4 days (range, 4–8)]. Prior to VAD implantation, nearly all patients required ventilator support and >50% of the patients required inotropic support (Table 1).

Intra-operatively, the patients who were implanted without the assist of CPB demonstrated differences with respect to the duration of operating room time (153 ± 39 vs. 218 ± 87 min), blood loss [400 ml (range, 300–500)] vs. 600 ml (range, 500–1000)] and number of blood product transfusions [two units (range, 2–4) vs. five units (range, 4–6)] compared with the patients requiring CPB for device placement. In all six patients, the VAD implantation was well supported by the ECLS without mechanical, thromboembolic or major bleeding complications. After LVAD implantation, temporary RVAD was required in two
patients in the ECLS group to avoid secondary RV failure after weaning from the ECLS (Table 2).

After surgery, the post-operative blood loss was lower in the ECLS group as compared with the CPB group [800 ml (400–1600) vs. 1500 ml (1100–1800)]. Also, the post-operative transfusion of packed red blood cells [one unit (range, 0–2) vs. two units (range, 2–4)] and of fresh frozen plasma (FFP) [one unit (range, 0–4) vs. four units (range, 2–6)] was lower in these patients. Supported by substitution of FFPs and platelets, no post-operative exploration was required. The need for mechanical ventilation [3 days (range, 1–13) vs. 8 days (range, 7–19)] and inotropic support [8 days (range, 5–15) vs. 14 days (range, 11–18)] was shorter in ECLS patients when compared with patients who were operated upon with CPB (Table 2).

After recovery from the operative procedure, levels of LDH, GOT, GPT, bilirubin and creatinine returned to normal (Figs 1 and 2).

The survival in the ECLS group was higher compared with the CPB group (80% at 30 days, 83.3% at 3 months and 83.3% at 6 months). They have been listed for heart transplantation. Two patients were successfully bridged to heart transplantation. One patient died due to cerebral bleeding after 7 weeks.

**DISCUSSION**

VAD implantation as a bridge to recovery or transplantation is a widely accepted treatment modality. However, in patients with cardiac arrest or severe haemodynamic instability and multi-organ failure the outcome is poor [1–3]. In these patients, ECLS enables quick and easy circulatory assist and provides physicians with a buffer period to evaluate and select appropriate candidates for VAD support or transplantation, but does not provide acceptable long-term survival [4]. Previous studies have reported successful use of a combined ECLS and LVAD approach to cardiac salvage for circulatory collapse [5, 13, 14].

Insertion of VADs routinely requires access to the heart through a median sternotomy and circulatory support with CPB to avoid blood loss and to enable inspection of the left ventricle for thrombus. However, the well-described complications of CPB may exacerbate multiple organ failure and increase blood
product transfusions during and after the operation [6]. Previous reports have described several approaches for implantation of different VADs without CPB in an off-pump technique. Frazier et al. reported placement of the Jarvik 2000 through a left thoracotomy and substernal incisions without CPB [7, 15]. Selzman and Sheridan [8] have developed a similar approach to insertion through a thoracotomy without CPB. Despite encouraging results, off-pump VAD implantation is still a technically challenging procedure with potential for misadventure and did not get widespread acceptance as haemodynamic instability may occur and visual inspection of the left-ventricular cavity is not possible during implantation. Although these techniques are attractive in re-operative situations, they limit the surgeon’s ability to perform adjunctive procedures.

This report describes our successful experience with VAD implantation through a median sternotomy using a percutaneous ECLS in a case series of patients with profound cardiogenic shock, who were provided with a percutaneous ECLS system on an emergency basis via the peripheral vessels. The VAD implantation using percutaneous miniaturized veno-arterial ECLS without CPB is a novel concept. The basic idea is to reduce the side effects associated with conventional CPB. Patients with cardiogenic shock often demonstrate end-organ dysfunction, including liver congestion, renal insufficiency and pulmonary oedema. VAD implantation with CPB often exacerbates these pre-existing conditions, resulting in post-operative coagulopathy, bleeding and RV dysfunction [16]. This concept also saves additional vascular cannulation and full systemic heparinization, and offers less artificial surface and less priming volume. Thus, at least theoretically, the SIRS should be reduced. Another advantage of the median sternotomy is that the pulmonary artery can be easily dissected if severe, acute right heart failure occurs, and the need for an RVAD arises. In our case, the VAD implantation and the peri-operative anticoagulation management were rather simple. Cannulation for VAD was performed with the aid of the ECLS with the heart beating. A careful implant technique avoided significant blood loss from spilling. No air embolism or thromboembolism occurred. The only disadvantage is that visual inspection of the left-ventricular cavity is hardly possible. The ability to implant the VAD without switching to a conventional CPB should provide benefits for the patient and decrease both blood utilization and time spent in the operating room. Furthermore, we have shown that our concept can be used with various devices. Although this is a small group of patients, some advantages can be appreciated. These patients had shorter operating room time, lower blood loss, lower transfusion of blood products and shorter duration of mechanical ventilation, isotropic support and ICU stay times than the patients undergoing device implantation after switching to a conventional CPB. Also, the survival in the ECLS group was higher compared with the CPB group.

Despite our initial encouraging results, this study has a number of limitations. The report is a single centre experience and the number of patients is small. In conclusion, our experience suggests that VAD implantation using percutaneous ECLS without switching to conventional CPB is a safe alternative in the bridge to bridge concept. This novel approach is useful in high-risk patients with cardiogenic shock who would benefit from the avoidance of the adverse sequels associated with conventional CPB.

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