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Strategies for Temporary Mechanical Support: Contemporary Experience with Pulsatile and Non-pulsatile Support Systems

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ABSTRACT

Despite advances in mechanical circulatory support, cardiogenic shock continues to have a high mortality. We reviewed our experience with pulsatile versus non-pulsatile temporary mechanical support at our institution to determine optimal strategy for survival.

From January 2001 to December 2003, mechanical support for cardiogenic shock was instituted in 38 patients.

Non-pulsatile devices (NP group) were used in 22 patients and pulsatile devices (P group) in 16 patients. Indications for the NP group were post-cardiotomy shock (PCS) in 17, myocardial infarction in 2, and isolated post-cardiotomy right ventricular failure in 3 patients. In the P group, 9 had the device placed for PCS, 3 for viral myocarditis, 1 after myocardial infarction, and 3 for right ventricular (RV) failure. Overall, bleeding, limb ischemia, and multi-system organ failure were higher in NP group with 5 weaned and 3 surviving to discharge (14%). In the P group, survivors included 7 weaned and 3 transplanted patients (63%).

With the exception of isolated RV failure, we obtained a dismal survival result with ECMO/centrifugal circuits for treatment of cardiogenic shock. For refractory pump failure, improved survival was achieved by using intermediate-term pulsatile devices with early transition to a chronic device and/or heart transplantation.

INTRODUCTION

Acute heart failure requiring mechanical circulatory support continues to be one of the most challenging tasks cardiac surgeons are facing. Despite significant advances in post-operative care, mortality associated with cardiac pump failure requiring mechanical support has remained high and complications in the peri-operative period continue to add to the overall morbidity of device support. As the complexity of cardiac operations increases, it is important to re-evaluate strategies for temporary mechanical support and device selection to optimize survival of post-cardiotomy shock.

In recent years there have been significant advances in the understanding of the neurohormonal and inflammatory response to extracorporeal circuits, particularly in relation to centrifugal circuits and membrane oxygenators [Peek 1999]. In addition, new devices have emerged and there have been extended application of chronic pulsatile devices in the acute cardiogenic shock setting [DeRose 1999]. In this report, we have reviewed our contemporary experience in the treatment of cardiogenic shock with temporary mechanical support to evaluate which strategies were associated with improved survival.

METHODS

A retrospective review of all patients who had received temporary mechanical circulatory support from January 2001 to December 2003 was performed at our institution. All entries that were coded as ventricular assist device, centrifugal pump, or Abiomed pump (Abiomed, Inc., Danvers, MA) were retrieved and the operative reports of all reviewed. The database also included all patients transferred to our institution for management of cardiogenic shock during this period. All patients who were placed on ECMO following lung transplantation or any other indication besides circulatory support were excluded. The patients were divided into two groups depending on the device type. The patients who received centrifugal support or ECMO were grouped as non-pulsatile (NP), and the patients who received the Thoratec device (Thoratec Corporation, Pleasanton, CA) or the Abiomed pump were considered together as the pulsatile (P) group. Choice of device used for support was at the discretion of the surgeon. In this retrospective study, it was difficult to determine if an oxygenator was necessary; however, at our center, ECMO has been used primarily instead of centrifugal pumps for circulatory support. In the last 3 years we have been using the Abiomed and Thoratec devices for treatment of cardiogenic shock as the devices of choice.

In both groups, transition to heart transplantation or a chronic assist device was considered if the patients were deemed appropriate transplant candidates. These criteria were based on determination of neurologic status by clinical

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Table 1. Patient Characteristics*

Pre-operative Characteristics	Pulsatile Group (%)	Non-pulsatile group (%)
Age, y	48.6 ± 12.7	55.3 ± 12.2
Male gender	9 (56.3)	12 (54.5)
NYHA III or IV	16 (100)	18 (81.8)
Myocardial infarction	10 (62.5)	10 (45.5)
Hypertension	6 (37.5)	3 (13.6)
Diabetes mellitus	4 (25.0)	3 (13.6)
Renal insufficiency	2 (12.5)	5 (22.7)
Renal failure requiring dialysis	1 (6.3)	2 (9.1)
Previous cardiac surgery	2 (12.5)	9 (40.9)

*NYHA indicates New York Heart Association classification.

examination and/or head CT scan, when possible. In addition, age and significant co-existent morbidity, which are generalized criteria for heart transplantation, were considered in this decision.

RESULTS

Overall, 22 patients with a mean age of 55 ± 12 years were in the NP group and 16 patients with a mean age of 49 ± 13 years in the P group. Patient demographics and preoperative co-morbidities are listed in Table 1.

The mean duration of support for the NP group was 3.2 (±2.2) days versus 8.3 (±4.4) days for the P group ($P < .05$). Indications and types of mechanical support are listed in Table 2. For the NP group, support was used for post-cardiotomy shock (PCS) associated with biventricular failure in 17, myocardial infarction in 2, and isolated post-cardiotomy right ventricular failure in 3 patients. For the 3 patients with isolated RV failure: one occurred after repair of ascending aortic aneurysm, one following cardiac transplantation, and another patient after a complex operation involving resection of an atrial myxoma. In all 3 of these patients, the RVAD was successfully weaned and the patients were discharged from the hospital. These 3 patients were the only survivors in this entire group. All other patients either failed to wean (n = 12), died shortly after weaning (n = 3), or had support terminated because of irreversible neurologic injury (n = 4).

In the P group, 9 had the device placed for PCS, 3 for viral myocarditis, 1 after MI, and 3 for right ventricular (RV) failure. For the 9 patients who received a pulsatile device for PCS support, 4 were weaned successfully, and 3 were transplanted. One of these patients was transplanted after 3 months of support with a HeartMate LVAD, and the other 2 were directly bridged to transplantation. All survived and were discharged from the hospital. Overall 30-day survival in the P group for PCS was 78%.

Table 2. Indications for Mechanical Support

Variables	Pulsatile Group (%)	Non-pulsatile group (%)
Post-cardiotomy shock	9 (56.3)	17 (77.3)
Right ventricular failure	3 (18.7)	3 (13.6)
Myocardial infarction	1 (6.3)	2 (9.1)
Viral myocarditis	3 (18.7)	0

Table 3. Outcomes of Mechanical Support

Variables	Pulsatile Group (%)	Non-pulsatile group (%)
Weaned from MCS	7 (43.8)	5 (31.3)
Heart transplant	3 (18.7)	0
Survived to hospital discharge	10 (62.5)	3 (13.6)

Other indications in the P group included 3 patients requiring Abiomed RVAD because of right ventricular (RV) failure following insertion of a HeartMate LVAD. One of these patients had a massive myocardial infarction (MI) and received a HeartMate LVAD as a bridge to transplantation. This patient died after 7 days of support from sepsis and multisystem organ failure. The 2 other patients were already listed for transplantation and presented with acute decompensation. One died on the first postoperative day following subarachnoid hemorrhage and cerebral herniation. The other patient was successfully weaned from RVAD support, discharged from the hospital, and transplanted after 1 year of support on the VAD.

One additional patient in the P group had mechanical support with the Abiomed pump after a massive anterior wall MI following acute thrombosis of a stent placed in the left anterior descending artery and had undergone 40 minutes of resuscitation following cardiac arrest. Despite excellent hemodynamics, 24 hours after VAD support, a CT scan of the head demonstrated diffuse anoxic encephalopathy and support was withdrawn.

Finally, 3 patients in the P group had the device inserted for viral myocarditis. Two were successfully weaned and are alive at 2-year follow-up. The third patient was transferred from an outside institution and suffered cardiac arrest prior to placement of VAD and required open cardiac massage. By intra-operative transthoracic echocardiography there was a large intraventricular thrombus and after 3 days of support, a CT scan demonstrated extensive thromboembolic cerebral infarcts and support was withdrawn.

Complications were common in both groups and included bleeding requiring re-operation in 7 patients (44%) in the P group and 10 (45%) in the NP group. Multisystem organ failure was the cause of death for 2 patients (13%) in the P group and 10 of the NP patients (46%). Limb ischemia developed in 2 (9%) patients on peripheral ECMO support.

Overall survival outcomes are listed in Table 3. Survival was significantly better in the P group.

DISCUSSION

Temporary circulatory support is generally applied to patients in cardiogenic shock unresponsive to high-dose inotropic support and other adjunctive treatments such as

nitric oxide and intra-aortic balloon pump counter pulsation. The criteria for considering instituting mechanical support have previously been published and the importance of early decision making in this process has been clearly established [Moazami 2001, Samuels 2001]. Generally, the vast majority of patients need temporary circulatory support due to complication of one of the following: (i) postcardiotomy shock, (ii) acute myocardial infarction, and (iii) acute myocarditis.

Fortunately, these complications are infrequent. Postcardiotomy cardiogenic shock occurs in about .5% to 1.2% of all cardiac operations, incidence of massive myocardial infarction has been reduced with early strategies aimed at rapid percutaneous revascularization, and most cases of myocarditis resolve with medical therapy [Moazami 2004]. As a result, most studies reported in the literature generally involve either small series of patients or vastly heterogeneous group of patients bulked together.

In this recent experience with temporary mechanical support, our results have shown a dismal survival for cardiogenic shock with systems involving centrifugal or ECMO support. In fact, the 14% survival in this group was primarily in the patients with isolated RV dysfunction, a group who have a better overall prognosis if circulatory support can be maintained for several days [Moazami 2004]. Our results with centrifugal support are worse than reported previously [Doll 2004, Hoy 2000, Ko 2002, Pae 1992]. The extracorporeal life support organization (ELSO) registry reported a 37% survival in patients receiving ECMO for PCS [ECLS 2001]. More recently, Hoy reported 68% wean and 44% survival to discharge with centrifugal pump support [Hoy 2000]. Ko and colleagues reported on 76 patients for whom ECMO was used for PCS. Survival to hospital discharge was 28% if patients bridged to VAD or heart transplantation were excluded [Ko 2002]. It is interesting that the disappointingly low salvage rate for this condition has hardly changed over the last decade despite significant advances in the management of these patients. How can these dismal results be improved upon?

Several pre-existing factors seem to adversely affect outcome including age, re-operation, emergent operations, higher creatinine, and worse LV dysfunction [Smedira 2001]. Unfortunately, these pre-existing factors are difficult to modify and encompass many of the patients that require cardiac operations. However, there are several other areas of potential improvement. First, it has been clearly shown that early institution of circulatory support is associated with improved outcomes. Second, a network concept relating easy transfer of patients from smaller hospitals (the spokes) to a tertiary care center (the hub) for bridging to chronic devices or transplantation has been shown to improve results [Helman 1999]. Institution of a similar referral network in various regions will likely improve results provided that the referring center have the primary responsibility of full stabilization of the patient, control of bleeding, correction of metabolic and hemodynamic abnormalities with delayed transfer within 24 to 48 hours to a tertiary care facility. Active bleeding, with the limited resuscitative ability of the transferring team, will lead to a period of continuous shock secondary to low flows or cardiac tamponade and this invariably is associated with poor outcome.

Finally, a question that we tried to address with our group of patients, does the device type make a difference? The various device choices have been previously described [DiGiorgi 2003]. In our experience, a better survival was achieved in patients with pulsatile devices. One of the primary problems with ECMO support continues to be the higher complications that have been reported by all groups included in this study. Smedira et al reported infection in 49%, dialysis in 40%, neurologic events in 33%, and limb complications in 25% of patients supported by ECMO [Smedira 2001]. Peripheral cannulation for ECMO is generally fraught with limb complications secondary to arterial and venous insufficiency unless a side graft is used [Moazami 2003]. Continuous requirement for heparin and the consumptive coagulopathy that is associated with the circuit and the oxygenator sets up a perpetual cycle of bleeding and large transfusion requirements. Furthermore, under the best circumstance ECMO flows achieved are generally in the range of 2.5 to 3.5 liters/minute [Ko 2002]. Low hemodynamic flows, open chest, limb ischemia, and the need for immobilization and ventilation undoubtedly contribute to the large number of infectious complications and multisystem organ failure that has been reported.

Another paramount complication leading to this high mortality in most reports is myocardial failure after weaning from circulatory support. The reason that weaning can be successful, but survival dismal, is likely multi-factorial. In cases of postcardiotomy shock, the majority of myocardial damage is likely to occur intraoperatively with poor preservation of the heart during the period of arrest. With advances in myocardial preservation including use of both antegrade and retrograde cardioplegia, this complication can be reduced, but poor distribution of cardioplegia and the unpredictable deleterious effect of ischemia-reperfusion injury can lead to a poorly functioning ventricle even in the most experienced hands. Golding and colleagues found that 69% of patients autopsied after postcardiotomy ventricular support had extensive myocardial injury [Golding 1992]. It is interesting that the literature suggests that even in most experienced institutions, mortality associated with PCS is also about 70%. It seems that it is the erratic nature, extent and distribution of myocardial damage that makes the clinical course of these patients unpredictable. What differentiates patients with irreversible myocardial necrosis from those with viable but stunned myocardium? What length of support is appropriate to make that decision?

Patients with most forms of myocarditis have a better outcome because the myocardium continues to be viable, as long as extensive necrosis from the inflammatory response has not occurred. In our experience, 3 patients had viral myocarditis. All 3 stabilized with the pulsatile Abiomed device and were supported from 3 to 7 days. Two were weaned, survived to hospital discharge, and are currently in NYHA functional class I. The third patient could have been weaned if her postoperative course had not been complicated with a cerebral thromboembolism, which occurred prior to the device placement. Similarly, in patients with acute myocardial infarction, potential for recovery is clearly dependent on the extent of myocardial necrosis, and salvage of the viable myocardium by

revascularization will determine the ultimate course of the patients. In our patients, the device was inserted after myocardial infarction and emergency surgical revascularization in 4 patients. All patients received complete revascularization early after presentation. Three were successfully weaned from the device and discharged from the hospital. One patient could not be weaned and was bridged by a HeartMate device, and eventually transplanted. In this period, mechanical support is needed to maintain adequate circulation and preserve end organ function until myocardial recovery occurs. It is doubtful that with 2 to 3 days of support, the period that is generally "safe" with ECMO support is adequate. Although the number of patients reported is small and drawing firm conclusions difficult, we have attempted to raise the question of whether device type makes a difference in survival outcome. The primary limitation of ECMO/centrifugal pumps is the duration of support that these devices can be used. We propose that the unpredictable course of myocardial recovery should prompt the use of devices that allow longer duration of support and open the option for other therapies. For patients who do not recover, the potential for cardiac transplantation exists. In fact, results of PCS have been significantly improved in the subgroup of patients who have been transitioned to a chronic device and eventually transplanted with a 60% to 70% survival [Dembitsky 1999, Korfer 1999]. The University of Michigan group has used ECMO support to establish rapid circulatory support, effectively allowing time for identification of viable candidates who could be bridged to a chronic device and eventually to transplantation [Pagani 2000]. The group at Columbia University recently reported on their experience using the Abiomed device as a bridge to a more chronic device [Morgan 2004]. In their experience, using this "bridge to bridge" concept, 7 of 8 patients were successfully transplanted. Support in the form of pulsatile devices that cover the gray zone between temporary support (for several days) to a more chronic support (extending weeks to months) will bridge the gap between clinical uncertainty and successful outcome. We believe it is not the mode of support, that is pulsatile versus non-pulsatile, that differentiates devices, but the duration of support that can be established with less complications. In a recent review, 4 case scenarios were presented to a panel with a large experience in treatment of cardiogenic shock. Although it seemed that ECMO for support was considered on several occasions, the majority thought that pulsatile devices such as the Abiomed or Thoratec were more appropriate and provided better efficiency and effectiveness compared to centrifugal pumps [Pennington 2001].

We recognize the significant limitations of this report which include a retrospective review in a small, heterogeneous group of patients with cardiogenic shock. In addition, we recognize that our results with ECMO support have been worse than those reported by other investigators. Nevertheless, based on our experience, we suggest that the best strategy for temporary mechanical support to maximize survival is in the form of intermediate-term pulsatile devices. For patients who fail to wean, transition to a chronic device and eventual heart transplantation will improve survival. The ethical dilemma remains for patients who survive but cannot be weaned. In the era of destination therapy, this option will likely be explored. ECMO support continues to be the best strategy in situations of acute circulatory failure where rapid institution of circulatory support will provide time for initial stabilization and evaluation for other appropriate chronic support. ECMO support also allows for peripheral cannulation and is ideal for emergency situations when support needs to be established rapidly, including in patients with previous cardiac operations. In situations where implantation of an intermediate-term pulsatile device is feasible, such as in the post-cardiotomy setting with failure to wean from cardiopulmonary bypass, we suggest that use of ECMO/centrifugal pumps should be discouraged unless no other options exist.

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