Implantable left ventricular assist devices as initial therapy for refractory postmyocardial infarction cardiogenic shock†

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Abstract

OBJECTIVES: Recently, the initial therapy for refractory cardiogenic shock has largely been based on use of short-term mechanical devices with later conversion to durable options. The premise is that such patients cannot tolerate cardiopulmonary bypass and the extended surgery needed for implantable left ventricular assist device (LVAD) placement. We have adopted an alternative strategy to implant long-term LVADs as the initial device therapy in such patients.

METHODS: Over a 3 year period, we used implantable LVADs (Jarvik 2000, one; Ventrassist, one; Heartmate XVE, two; and Heartmate II, nine) in 13 patients (11 men and two women; mean age 54 years) with postmyocardial infarction shock without prior use of a short-term LVAD. The median time interval from myocardial infarction to LVAD implantation was 3.5 days. Eight patients were on a ventilator, two had unknown neurological status and four had suffered cardiac arrest in the preceding 24 h. Two had prior coronary artery bypass graft. Nine had received dual antiplatelet therapy postmyocardial infarction. The mean laboratory value of creatinine was 1.5 mg/dl, alanine aminotransferase 748 U/l, international normalized ratio 1.5 and lactate 3.2 mmol/l. One procedure was carried out off pump; for the others, the mean cardiopulmonary bypass time was 72 min. Right ventricular assist devices were used in two cases and were later explanted.

RESULTS: One patient died of progressive multiorgan failure. All others survived to hospital discharge. There were no re-explorations for bleeding or major infectious complications; two patients had perioperative stroke. The median duration of mechanical ventilation, intensive care unit stay and hospital stay was 3, 9 and 18 days, respectively. At 1 year, of the 12 survivors, eight have since had heart transplant, one patient underwent device explant, two remained alive on support and one died 7 months post-LVAD.

CONCLUSIONS: Our data challenge the notion that patients in refractory cardiogenic shock are too ill to tolerate immediate placement of implantable LVADs. Despite the surgical challenges, a one-stop implantable LVAD approach for cardiogenic shock is feasible and may offer unique advantages over the bridge-to-bridge approach because it avoids the incremental costs, hospitalization and morbidity associated with repeated interventions.

Keywords: Myocardial infarction • Cardiogenic shock • Ventricular assist device

INTRODUCTION

Cardiogenic shock complicates about 7% of cases of the myocardial infarction and has 6-fold higher mortality in comparison to myocardial infarction without cardiogenic shock [1]. The recent treatment paradigm for supporting the left ventricle during postmyocardial infarction cardiogenic shock refractory to maximal medical therapy and intra-aortic balloon counterpulsation therapy is typically the use of short-term mechanical assist devices or extracorporeal membrane oxygenation (ECMO) as a bridge to bridge, bridge to recovery or bridge to transplantation [2]. At our centre, since 2007 we have adopted an approach of inserting implantable left ventricular assist devices (LVADs) as the primary therapy for post-acute myocardial infarction cardiogenic shock (AMI-CS) as a single bridge approach and here we report our experience.

MATERIALS AND METHODS

We carried out a single-centre retrospective study of 13 patients, from September 2007 to August 2010, who were in cardiogenic shock after recent myocardial infarction and received implantable LVADs without prior use of short-term LVADs.

Cardiogenic shock was defined as cardiac pump failure leading to inadequate end-organ tissue perfusion, with systolic blood pressure of <90 mmHg and a reduction in cardiac index (<1.8 l/min/m²), in the setting of elevated left ventricular diastolic pressure (pulmonary capillary wedge pressure >18 mmHg) [3, 4]. If cardiac catheterization could not be performed, the
cardiogenic shock was defined as a systolic blood pressure of <80 mmHg in the absence of hypovolaemia and associated with cyanosis, cold extremities and changes in mental status, persistent oliguria or congestive heart failure [5].

There were 13 patients (11 men and two women) in this study. The median duration from myocardial infarction was 3.5 days (ranging from 1 to 23 days). All were in Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) class I by definition. The mean age of the patients was 54 years. The mean pulmonary capillary wedge pressure was 26 mmHg and the mean right atrial pressure 15 mmHg. Preoperative variables for the 13 patients are presented in Table 1.

Devices used were one Jarvik 2000 (Jarvik Heart, NY, USA), one Ventrassist (Ventricor, Chatswood, NSW, Australia), two Heartmate XVE (Thoratec, Pleasanton, CA, USA), and nine Heartmate II (Thoratec). One implant was done off pump. The mean cardiopulmonary bypass time for the other implants was 72 min. No cardioplegia was used for any of the procedures. For suture of the inflow cannula sewing ring, we used eight 2/0 Ethibond sutures with large (36 mm half circle, taper point, cutting) needles (Ethicon, Somerville, NJ, USA), each with wide felt pledgets (approximately 15 mm × 10 mm). These were applied circumferentially in a mattress fashion, with the first arm of suture taken first epicardially from about 1.5 cm from the edge of the ventriculotomy into the ventricle and then a smaller bite coming from the ventricle to the epicardium about 1–2 mm from the ventriculotomy. The second suture was then passed in similar fashion, with sufficient travel such that each pledgeted suture occupied approximately one-eighth of the circumference of the ventriculotomy. Sutures were tied down gently to prevent disruption of ischaemic myocardium. Where the myocardium was very friable, we also placed a cerclage suture running circumferentially through all the pledgets and the underlying myocardium, and tied this after the inflow cannula was in place. With this method, there is a cushion of tissue between the pledgets and the sewing cuff, which aids in security and haemostasis (Fig. 1). We do not apply surgical glue to reinforce the suture line. The mean operative time was 326 min. Two operations were performed in a minimally invasive fashion as a combination of small anterior thoracotomy together with a small left subcostal incision, avoiding median sternotomy [6]. Three patients had additional cardiac procedures. Tricuspid valve repair was performed in two cases and aortic valve repair in one case. One patient also received ventral cardiac denervation for malignant ventricular tachycardia. Two patients underwent concurrent right ventricular assist device (RVAD) insertion using a centrally placed Centrimag device (Thoratec); these devices were successfully explanted at a later date via resternotomy, 3 and 6 days later, when sufficient right heart and hepatic recovery had occurred.

**RESULTS**

Postoperative outcomes are outlined in Table 2. The median intensive care unit stay was 9 days (range 2–85 days); median hospital stay was 18 days (range 5–101 days).

One patient died on the fifth postoperative day due to progressive multiorgan failure. He had preoperative cardiopulmonary resuscitation, mechanical ventilation, intra-aortic balloon pump, with renal dysfunction (creatinine 2.4 mg/dl) and severe hepatic dysfunction (aspartate aminotransferase > 3000 U/l, alanine aminotransferase > 3000 U/l, international normalized ratio 3.4 and lactate > 15 mmol/l). Two patients had postoperative strokes; one with complete neurological recovery. Pathological examination of the cored apex showed full-thickness or haemorrhagic infarction in seven of 13 patients.

All 12 survivors were discharged home. One patient died at 7 months due to disconnection of the pump controller. At time of this report, eight patients have undergone successful transplantation; two remained alive on support 12 months postimplantation; and one underwent device explantation 8 months postimplantation. Figure 2 shows the 1 year survival. Actuarial 1 year survival was 86%.

**DISCUSSION**

Left ventricular assist device implantation as a bridge to heart transplantation is the most effective therapy in AMI-CS patients and provides superior survival in comparison to inotrope and
intra-aortic balloon counterpulsation therapy or percutaneous coronary intervention or coronary artery bypass graft [7]. It is a general concern that patients with multiorgan failure do not tolerate extended cardiopulmonary bypass and long procedures [8]. For this reason, the mainstay of therapy has been implantation of short-term ventricular assist devices (VADs) or ECMO with later conversion to long-term implantable VADs or device explantation, as appropriate. We undertook an aggressive strategy of implantable LVAD placement in AMI-CS patients and experienced good results. Compared with series of short-term devices in AMI-CS patients [9–13], we have experienced excellent outcomes. Our 1 year survival (86%) is comparable to INTERMACS class 1 patients from the INTERMACS registry (about 71%) [14].

While there are several reasons why patients with AMI-CS are not suited to extended surgery for placement of an implantable LVAD, we have found that most of these can be overcome. There is a concern about bleeding in the AMI-CS situation in the setting of coagulopathy due to liver dysfunction and also the potent antiplatelet therapy. However, with meticulous technique and laborious haemostasis (our mean bypass time was 72 min, but the mean operative time was 327 min), bleeding complications and transfusions can be minimized in these patients. We had no re-exploration for bleeding in our series, challenging the notion that these patients cannot have implantable LVADs because of coagulopathy concerns.

The left ventricular apex is friable in AMI and traditionally regarded as unsuitable to use for inflow cannula insertion. We have found that we could safely anchor a VAD to the apex in all cases. Despite seven of our patients having full-thickness or haemorrhagic infarction at the apex, as demonstrated by pathological examination, we did not have any major problems with haemorrhage or disruption at the inflow cannulation site. Leshnower et al. and Park et al. independently demonstrated that left ventricular apical cannulation can be employed safely in the setting of AMI [15, 16]. Notably, however, Park et al. used cardioplegia to facilitate suturing of the apex [16]. We preferred to avoid cardioplegia in order to preserve right ventricular function and to avoid further ischaemic injury to the septum. This strategy seemed to be successful in our series, because only two of our patients needed RVADs.

There are unique advantages to definitive implantation of LVADs as opposed to a bridge-to-bridge strategy. The most notable of these is avoidance of repeated interventions in most patients. In our series, we avoided repeated interventions in all patients, except for the two who needed RVAD explants. In contrast, a bridge-to-bridge strategy involves at least one re-intervention during initial hospitalization [9–13]. Aside from the economic advantages of avoiding multiple interventions and the shorter intensive care unit stays and mechanical ventilator times, there is a potential advantage of reduced risk of device infection. Although it is generally held that bridge-to-bridge devices are less costly than implantable devices, the reality is that most of the cost for mechanical support as therapy for AMI-CS does not derive from the cost of the device, but from the prolonged hospitalization, hospital mortality and readmissions during first 6 months [17]. Paradoxically, using the more expensive implantable devices probably saves resources in comparison to use of short-term devices in cardiogenic shock. The incremental cost of the long-term device is likely to be less than the sum of additional postoperative stay, re-intervention cost, cost of multiple devices (a short-term device, sometimes pump head changes of similar cost if prolonged support is required, and then a long-term device if used later). There is also the cost for trained personal to support some devices, such as ECMO.

Although use of peripheral VADs and ECMO is felt to be the least invasive and most immediately effective way to treat AMI-CS, these devices are associated with lower limb ischaemic complications, which could be up to 11–33% [18,19]. The use of peripheral arteries may be detrimental, in particular, with the AMI-CS group, who are more likely to be vasculopaths than a non-AMI cohort. Extracorporeal VADs/ECMOs might have initial beneficial effects on haemodynamic parameters, but might further promote a systemic inflammatory response syndrome. In patients with revascularized acute myocardial infarction complicated by cardiogenic shock, patients with percutaneous ventricular assist devices have been shown to have higher rate of fever and higher white cell counts as compared to patients with intra-aortic balloon pump [18]. With newer generation ECMO

**Table 2: Outcomes**

<table>
<thead>
<tr>
<th>Postoperative outcome</th>
<th>Number of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-exploration for bleeding</td>
<td>0</td>
</tr>
<tr>
<td>Re-exploration for other reasons</td>
<td>2 (RVAD explants)</td>
</tr>
<tr>
<td>Mechanical ventilation &gt;1 week</td>
<td>3</td>
</tr>
<tr>
<td>ICU stay &gt;2 weeks</td>
<td>4</td>
</tr>
<tr>
<td>Hospital stay &gt;1 month</td>
<td>4</td>
</tr>
<tr>
<td>Stroke</td>
<td>2</td>
</tr>
<tr>
<td>Device thrombosis/malfunction</td>
<td>0</td>
</tr>
<tr>
<td>Drive-line infection</td>
<td>0</td>
</tr>
<tr>
<td>Sepsis</td>
<td>0</td>
</tr>
<tr>
<td>Deep sternal wound infection</td>
<td>0</td>
</tr>
<tr>
<td>Haemolysis</td>
<td>0</td>
</tr>
<tr>
<td>Limb complications</td>
<td>0</td>
</tr>
<tr>
<td>Alive at 1 month</td>
<td>12</td>
</tr>
<tr>
<td>Transplanted within 1 year</td>
<td>8</td>
</tr>
<tr>
<td>Device explantation within 1 year</td>
<td>1</td>
</tr>
<tr>
<td>One-year mortality with VAD</td>
<td>2</td>
</tr>
</tbody>
</table>

ICU: intensive care unit; RVAD: right ventricular assist device; VAD: ventricular assist device.

![Figure 2: Kaplan–Meier curve for implantable left ventricular assist device (LVAD) recipients after acute myocardial infarction cardiogenic shock, showing the percentage of patients surviving after LVAD implantation.](https://academic.oup.com/ejcts/article-abstract/44/2/213/439988/356418)
circuits using biocompatible surfaces and less traumatic centrifugal pumps, these effects may be less pronounced. The potential problems of left ventricular distension and pulmonary oedema seen with ECMO or left atrium-based LVADs are avoided with implantable LVADs. Implantable LVADs also provide more consistent and higher cardiac output (up to 10 l) compared with most of the percutaneous devices (up to 5 l). Implantable LVADs may also allow earlier mobilization.

Another argument made for the use of short-term devices applies to patients with questionable neurological status. In our series, the two patients with unknown neurological status had a cardiac arrest witnessed in hospital, with cardiopulmonary resuscitation. We think these candidates are more likely to regain neurological function in comparison to those who experience cardiac arrest outside hospital and can be offered an implantable device even without knowledge of their neurological function. Our two such patients had no postoperative neurological dysfunction.

There could also be reluctance concerning durable mechanical circulatory support in the setting of AMI-CS for a possible chance of myocardial recovery. In reality, there is no good predictive algorithm to discriminate likely survivors from non-survivors in this setting. Another potential option for managing these patients is the use of a total artificial heart. While likely to be effective, this is rarely a practical option in the USA, because funding for this therapy is more tightly restricted, such that many emergency cases would not get reimbursed. Furthermore, committing patients with AMI to cardiac excision eliminates the option of myocardial recovery. A total artificial heart, however, would be an excellent strategy in the setting of post-AMI-CS with mechanical complications, such as postinfarct ventricular septal rupture.

Drawbacks and limitations

This is a small, single-centre study, and our experience might not be generalizable to other centres. In particular, the techniques described in this study cannot be implemented in hospitals where expertise in implantable LVADs is lacking. In such a scenario, a bridge-to-bridge device provides the optimal strategy. There are situations where bridge to bridge is clearly a superior option, e.g. patients who need to be resuscitated on the cardiac catheterization table. During this study period, we had three such cases where we used short-term devices.

CONCLUSIONS

An implantable LVAD for AMI-CS as a one-stop strategy is an option worthy of consideration. Further studies are required to compare the differences in outcome between our approach and the bridge-to-bridge strategy.

Conflict of interest: none declared.

REFERENCES


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