Bridge to transplantation with the DeBakey VAD® axial pump: a single center report


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Abstract

Aims: To report our experience with a left ventricular assist device axial pump as a bridge to transplantation: the DeBakey Ventricular Assist Device (VAD).

Methods: From February 1999 to February 2002, nine patients (among which eight males), with a mean age of 47 years, all in NYHA functional class IV, were proposed for a bridge to transplantation with the DeBakey VAD. Five patients had primary dilated cardiomyopathy, four had ischemic cardiomyopathy. All the patients had inotropic support prior to the intervention (dobutamine with a mean dose of 12 mcg/kg per min), six had an intra-aortic counterpulsation, four presented ventricular rhythm disorders. Interventions were performed through sternotomy alone (no need for an abdominal pocket) under extra-corporeal circulation on beating heart (except in one patient suffering from an apical thrombosis for which cardioplegic arrest was performed) as followed: implantation of the apical inflow cannula, tunneling of the percutaneous cable, implantation of the outflow graft under aortic side clamping, starting of the DeBakey VAD during CPB weaning-off.

Results: Mean support duration was 81 ± 62 days (16–224 days). Eight reoperations were required (three for bleeding or cardiac tamponade, one for haemoperitoneum, one for aortic bifurcation thrombectomy, one for right ventricular assist device implantation, two for iterative replacements of the DeBakey VAD). A significant hemolysis was observed in two patients. No device infection or dysfunction were observed. Secondary recovery of a pulsed flow was observed either clinically or by Echo-Doppler in six patients. Five patients were transplanted, four died prior to transplantation (three from multi-organ failure on post-operative day 35, 16 and 50, respectively, and the last patient was found disconnected at day 109).

Conclusions: The DeBakey VAD is at the origin of renewed interest for continuous flow assist devices. Still under evaluation, the advantages of miniaturization and facility of implantation of this new device seem to be promising. © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Transplantation; Mechanical assist device; Heart failure; Non-pulsatile flow

1. Introduction

The ‘DeBakey Ventricular Assist Device (VAD)’ is an implantable left ventricular assist device axial pump with electromagnetic control. Its development was initiated in 1988 [1–6] by Michael DeBakey, MD, George Noon. In the scope of a left ventricular implantable assist device [6–14], the challenges taken up by the DeBakey VAD were: the choice for a non-pulsatile flow and miniaturization (diameter 30.5 mm, length 76 mm and weight 95 g).

2. Materials and methods

2.1. Description of the DeBakey VAD

The pump is totally implantable, made of titanium with an electromagnetic control. It has a 30.5 mm diameter, a 76.2 mm length and a total weight of 95 g. It consists of the following elements: an inflow cannula – a flow tube containing the flow straightener, the inducer/impeller and the diffuser – the motor stator in its housing – the outflow graft and the outflow control probe – the pump wiring.

2.2. Utilization method of the DeBakey VAD

The pump speed is the only parameter regulated by the clinician. When the left ventricle inflow level permits it, an increased pump speed will lead to an increased flow through the pump. The flow through the pump also depends on the pressure respective levels at the pump inflow and outflow. The pump inflow pressure reflects the left ventricular pressure. Likewise, the pump outflow pressure reflects the systemic pressure. Therefore, an improved flow through the pump can be achieved by increasing the left ventricle...
pre-load and by decreasing the left ventricle post-load without modifying the pump speed.

### 2.3. Patients

From February 1999 to February 2002, nine patients (eight males, one female) with a mean age of 47 years (range from 31 to 58 years) were assisted with a MicroMed\textsuperscript{\textregistered} DeBakey VAD for bridge to transplantation (Tables 1 and 2). Five patients suffered from primary dilated cardiomyopathy, four from ischemic cardiomyopathy. All were in New York Heart Association (NYHA) stage IV. All patients were under inotropic pharmacological support Dobutamine with a mean dose of 12 mcg/kg per min), six patients were under aortic counterpulsation and four had presented with ventricular rhythm disorders.

### 2.4. Implantation technique

Patients’ preparation and monitoring did not differ from other assist devices. A preoperative transoesophageal echocardiography (TEE) performed in all patients allowed to detect patent foramen ovale or intracavitary thrombi and to evaluate bilateral ventricular function. After cardiopulmonary bypass (CPB) weaning, a TEE was performed to verify the correct position of the inflow cannula, the efficiency of the de-airing procedures, the loading optimal level, the right ventricular function and the aortic valve freedom from opening.

In all cases, the operation was performed through a sternotomy, without any pocket in the abdominal wall. All implantations were performed under CPB with beating heart (CPB time 52 ± 19 mm) except for one patient who presented with a left ventricular (LV) apex thrombus, in the following order: implantation of the apical inflow cannula, tunneling of the percutaneous cable, implantation of the outflow graft under ascending aortic side clamping, air deairing, and starting of the DeBakey VAD during gradual CPB weaning-off. Over the first 48 h the pump speed was progressively increased without exceeding 10 000 rpm. During this period the objective was to maintain a minimal speed rotation while maintaining a satisfactory cardiac index.

### 2.5. Anticoagulation protocol

CPB anticoagulation was identical to any other CPB (Heparin 0.9 \( \times \) corporeal surface in mg, protamine at the same dose and aprotinin 1.5 MUI) Heparin was re-injected when bleeding stopped (4 – 6 h postoperatively) so as to obtain an activated clotting time (ACT) of 250, an automated partial thromboplastin time (APTT) equal to one and a half to two times the control, an heparinaemia between 0.2 and 0.3 UI/ml. From the 1st postoperative day, aspirin was introduced at a 100 mg/day dose (250 mg/day if platelets >250 000). Secondly an antivitamin K relay was introduced to obtain an International normalised ratio (INR) between 2.5 and 3.5.

### 3. Results

#### 3.1. Clinical outcome

**3.1.1. Mean implantation duration**

Mean implantation duration was 81 ± 62 days (from 16 to 224 days).

**3.1.2. Hospital discharge**

Only one patient (no. 6), was discharged home with DeBa-
key VAD before transplantation. This patient recovered extremely well and was discharged from the hospital on post-operative day 70. He had follow-up hospital visits weekly. He underwent transplantation on postoperative day 224.

3.1.3. Mortality

Four patients, despite DeBakey VAD, died prior to the transplantation. Three from multi-organ failure on post-operative day 35, 16, and 50, respectively. The last patient who died prior to the transplantation, although he was in a perfect haemodynamic state, developed a psychiatric syndrome. He was found unconnected from the support during the night at day 109.

3.1.4. Transplantation

Five patients (nos. 1–3, 6 and 9) were bridged to transplantation after 45, 76, 124, 224 and 47 days of support respectively. One (patient no. 2) died 3 days after transplantation from septic shock. One patient (patient no. 3) died 12 months after the transplantation from ethylic coma. The three other patients are still alive and doing well 42, 18 and 3 months after transplantation, respectively.

3.2. Bleeding complications

Four reoperations for bleeding complications were necessary. Three for cardiac tamponade (Patient no. 1 on post-operative day 1 and 8, patient no. 8 on post-operative day 9). Patient no. 5 underwent one exploring laparotomy for haemoperitoneum on post-operative day 10: no cause for this haemoperitoneum was found.

3.3. Tromboembolic events

Two patients underwent thromboembolic events. No one had sequelae from them. Patient no. 3 had developed clothing within the right vasalva sinus opposite a right occluded ostium. This thrombus has been detected during systematic TEE control on post-operative day 2 since the patient had a sufficient anticoagulation level according to our previously described anticoagulation protocol, and since the aortic valve was not opening. First, we decided to increase the anticoagulation (to reach an heparinemia level of 0.3–0.4). On post-operative day 4, the patient developed bilateral legs ischemia. Arterial Echo-Doppler study showed an aortic bifurcation obstruction, while TEE did not found any thrombus on the right vasalva sinus. The patient underwent successful aortic bifurcation thrombectomy. The patient had no after effects from this event. No other thromboembolic event was observed during follow-up.

Two DeBakey VAD replacements were required in patient no. 7 with no device dysfunction as such. This patient was known to have left appendage thrombosis. Nevertheless device implantation was performed with beating heart after the exclusion of left clotted appendage. On postoperative hour 2, a severe cardiac output collapse was observed with a maintained pump speed and an increase in power consumption. A second DeBakey VAD was implanted with beating heart. On postoperative day 7, the same event occurred, and a third DeBakey VAD was implanted with aortic cross clamping and warm blood cardioplegic arrest. A left atrial exploration revealed unexcluded left appendage thrombi. Such unexcluded thrombi could have migrated and hindered the pump functioning. Immediate intra-operative examination of the second explanted pump revealed thrombotic material inside the pump. Besides, a laboratory examination did not reveal any abnormal performance of the explanted DeBakey VADs.

3.4. Hemolysis

Plasma-free hemoglobin (physiologic range zero to 5 mg/dl), was tested daily, first in the 15th post-operative day and twice a week until explantation. All the patients presented biological signs of hemolysis, while two patients (nos. 2 and 4) showed clinical signs (jaundice, hematuria) (Table 3). These two patients had peak values of plasma-free hemoglobin of 2950 and 2080 mg/dl, respectively. Figs. 1 and 2 describe for patients nos. 2 and 4 the plasma-free hemoglobin rate, the pump speed, the VAD output and energetic consumption with respect to time.

3.5. Right ventricular dysfunction

Two patients (nos. 2 and 4) presented with a significant right ventricular dysfunction defined as a cardiac index below 2.2 l/

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Table 3

<table>
<thead>
<tr>
<th>Patient</th>
<th>Bilirubinemia (mg/dl)</th>
<th>Plasmatic free-hemoglobin (mg/dl)</th>
<th>Speed rotation (rpm)</th>
<th>VAD outflow (l/mn)</th>
<th>Transfused units</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. 1</td>
<td>28 ± 13</td>
<td>67 ± 49 (22–180)</td>
<td>9.6 ± 1</td>
<td>3.9 ± 0.9</td>
<td>5</td>
</tr>
<tr>
<td>No. 2</td>
<td>35 ± 24</td>
<td>454 ± 666 (20–2080)</td>
<td>9.5 ± 0.4</td>
<td>3.4 ± 0.6</td>
<td>23</td>
</tr>
<tr>
<td>No. 3</td>
<td>56 ± 24</td>
<td>52 ± 38 (20–118)</td>
<td>10 ± 0.6</td>
<td>4 ± 0.8</td>
<td>6</td>
</tr>
<tr>
<td>No. 4</td>
<td>46 ± 37</td>
<td>510 ± 802 (28–2950)</td>
<td>9.8 ± 0.9</td>
<td>4.9 ± 1.3</td>
<td>16</td>
</tr>
<tr>
<td>No. 5</td>
<td>68 ± 21</td>
<td>32 ± 8 (20–102)</td>
<td>8.7 ± 0.3</td>
<td>4.3 ± 0.7</td>
<td>9</td>
</tr>
<tr>
<td>No. 6</td>
<td>32 ± 19</td>
<td>96 ± 33 (40–140)</td>
<td>8.9 ± 0.3</td>
<td>4.1 ± 0.7</td>
<td>2</td>
</tr>
<tr>
<td>No. 7</td>
<td>44 ± 16</td>
<td>94 ± 14 (20–170)</td>
<td>8.9 ± 0.3</td>
<td>3.5 ± 0.9</td>
<td>13</td>
</tr>
<tr>
<td>No. 8</td>
<td>58 ± 18</td>
<td>62 ± 38 (18–124)</td>
<td>9.1 ± 0.5</td>
<td>4.1 ± 1.2</td>
<td>3</td>
</tr>
<tr>
<td>No. 9</td>
<td>32 ± 15</td>
<td>31 ± 9 (18–97)</td>
<td>9.2 ± 0.8</td>
<td>4.3 ± 0.8</td>
<td>4</td>
</tr>
</tbody>
</table>
min per m$^2$, with a central pressure of 18–22 mmHg and a double-drug inotropic support, in the absence of high pulmonary vascular resistance [14]. In one patient (no. 4) we performed as a last resort and without success hybrid assistance. We added to the DeBakey, a right para-corporeal pneumatic ventricular assist device (MEDOS HIA-VAD). The patient died 2 days after right device implantation.

3.6. Device infection or dysfunction

No infection over the device was observed among these patients.

No device dysfunction was observed in these patients.

3.7. Effect of continuous flow on organ function

DeBakey VAD provided a decrease of both cardiogenic shock and organ failure in all patients but one (patient no. 5). The later was a female patient who had very severe cardiogenic shock pre-operatively. Despite a device mean output flow of 4.3 ± 0.7 l/min, the flow assistance provided neither clinical improvement, nor decrease in cardiogenic shock and organ failure she was preoperatively suffering from. Concerning mid term effect of continuous flow on organ function: in patients for whom assist duration exceeded 3 months, renal and hepatic function were summarized in Figs. 3 and 4. In patients nos. 3, 6 and 7, who were supported 124, 224 and 109 days, respectively, we observed a normalization of the renal (blood creatinine) and hepatic (bilirubinemia and amino leucine aspartate transferase (ALAT)) functions. This normalization lasted during the whole period of support.

3.8. Pulsed flow recovery

Pulsed flow recovery was observed in five patients (nos.
1, 3, 6, 7 and 9) who were assisted for 45, 124, 224, 109 and 47 days, respectively, we observed a true pulsed flow recovery in patients nos. 3, 6 and 7 and an intermittent one in patient nos. 1 and 9. This pulsed flow recovery was detected either clinically or with arterial Doppler (Fig. 5) as well as with aortic sigmoid reopening during TTE.

4. Discussion

Compared to other left ventricular assist devices which have already proved their efficacy as bridge to transplantation, the interests relevant to the DeBakey VAD are its small size, low weight, ease of use and original concept.

The DeBakey VAD miniaturization permits small surgical incision together with a strictly intrathoracic implantation of the pump. By avoiding the making of an abdominal parietal pocket, this device provides a better comfort to the patient and reduces device infectious complications. Titanium inflow cannula rigidity and length led us to perform implantations with a beating heart, thus maintaining at best myocardial function especially that of the right ventricle. Complications observed in patient no. 7 encouraged us to expand cross-clamping implantation indication not only in the presence of apical thrombi but also in all patients with left intracavitary thrombi. In patient no. 6, external left appendage ligation with beating heart technique prior to device implantation, did not allow us to ensure a safe total exclusion of the clotted left appendage. This patient experienced thrombi migration from the incompletely excluded left appendage into the pump. The inducer/impeller is the only movable part of the tube flow. The flow straightener as well as the diffuser are not movable. Thrombi migration could hindered in the flow straightener, which is the first non-mobile component and may result in dramatical cardiac output collapse with a maintained pump speed and an increase in power consumption. Such a thrombus migration into a pulsatile device would have most likely ended up with a peripheral migration since the flow straightener in our case acted as a filter.

Bleeding, thromboembolism and hemolysis are classical cascading post-operative hemorrhagic complications encountered with mechanical device. Intermittent events of thrombus formation may cause hemolysis. Figs. 1 and 2 show an increase of power consumption prior to or simultaneous with such hemolytic events, that were not only related to the pump rotation speed. Hemorrhage, post-operative transfusion, and coagulation imbalance have previously been correlated to the rate of right ventricular dysfunction. Right ventricular dysfunction is still one of major concern with left ventricular assist device.

As previously mentioned, the anticoagulation level we have used for patients with a DeBakey VAD was less than usually used for patient with a pulsed flow assist device. Nevertheless other anticoagulation protocol have been now recommended for DeBakey VAD according to the Pitie hospital to prevent, minimize and manage postoperative bleeding [15,16].

Questions raised by this new assist device mainly concerned the efficacy of a non-pulsatile flow on the recovery of cardiogenic shock visceral damages and on the mean and long-term results of continuous flow [17,18]. Despite experimental works reporting pulsatile flow superiority compare to continuous flow [19], the DeBakey VAD has provided satisfactory results. We have noted no difference in pump index between patients who survived and those who died from multi-organ failure (Table 3). Similarly, mid-term results on renal and hepatic functions were satisfactory, allowing normalization of biological markers during more than 7 months for patient no. 6. In fact, on mean- and long-term follow-up, patients had recovered an arterial pulsatility under assistance so that one cannot unconditionally oppose pulsatile flow to continuous flow. After a while, the assisted left ventricle recovers some efficient contractility. This period depends on patient’s haemodynamics, as well as the test used to explore this pulsatility resumption. Consequently, arterial Echo-Doppler appears to be an efficient way to detect such pulsatility. In patient no. 7, arterial Echo-Doppler brought out a pulsed flow recovery in the axillary artery as well as in the outflow graft whilst TTE.
did not detect any opening or flow through the aortic valve. Besides, the detection of an anterograde pulsed flow in the outflow graft ruled out concerns about flow competition between pump-generated continuous flow and ventricle-generated pulsed flow. In fact, ventricular systole can be transmitted to the outflow graft through the pump.

The advantages of miniaturization and ease of implantation provided by this new device support are encouraging so far.

References


Fig. 5. Vascular Echo-Doppler benefit: recovery of a pulsed flow in the outflow graft.