Implantable left-ventricular assist devices (LVAD) are successfully used as a bridge to transplant if the patient’s condition is worsening and no donor organ is available. They allow recovery of compromised organ function. However, postoperative bleeding, thromboembolism, and right-heart failure may jeopardize the important improvement of organ function and may even lead to death. We introduce our strategy for implantation of the Novacor LVAD system, which aims at minimal bleeding and maintained right-heart function. The Novacor LVAD was implanted with the heart beating during extracorporeal circulation in 8 patients, 3 of whom had previous cardiac surgery. Postoperatively, no patient developed right heart failure or had to undergo redo thoracotomy.

Key words: Left-ventricular assistance – Implantable assist device – Novacor – Beating heart implantation

Introduction

Currently, cardiac transplantation is considered the therapy of choice for patients with end-stage cardiac failure refractory to medical treatment and not amenable to other surgical therapeutic modalities. The discrepancy between availability of donor organs and the demand is steadily widening due to the increasing number of transplant candidates and the scarcity of suitable donor organs. Thus, the individual patient faces a prolonged waiting period and an increased risk of dying during this time.

In this situation, it seems mandatory to use artificial pump systems to bridge the time until a suitable donor organ is available. Recently, multiple assist devices have been developed and their clinical feasibility thoroughly tested. Systems which are totally implantable except for a percutaneous drive line are most promising (2, 6, 7, 11). The efficacy of these devices with regard to improvement of survival pre- and post-cardiac transplantation have been well documented. Moreover, the continuous miniaturization of the controller and power support has contributed to improvement of patient mobility and quality of life during support (3, 18). However, bleeding complications at implantation, right heart failure, and thromboembolic events still cause a significant morbidity and mortality.

Based on this background, we describe our implantation technique which aims at minimizing the risk of bleeding and preventing periooperative right-heart failure and represents evolving experience during our first 22 patients.

Implantation Technique

All patients undergo monitoring of the arterial pressure (radial artery) and pulmonary hemodynamics by placement of a Swan-Ganz catheter. Prophylactic antibiotic treatment with a second-generation cephalosporine is started preoperatively and continued until removal of the thoracic drains. Aprotinin was used following a ‘high dose’ protocol starting prior to surgery (1).

The patient is placed in supine position. Thorax and abdomen as well as the inguinal region are generously disinfected and covered. The skin incision for the median sternotomy is extended into the upper quadrants of the abdomen close to the umbilicus. After separation of the subcutis, the left rectal sheath was opened and its posterior portion separated from the muscle. The pocket is enlarged down to the linea semicircularis. The transversalis muscle is partially divided at the lateral border of the rectal muscle, and the diaphragm detached from the rib cage to gain enough space for placement of the device. Meticulous control of bleeding is important. Thereafter, the posterior sheath of the rectal muscle is opened close to the median line and the preperitoneal fat layer separated from the back side of the right rectal muscle, and the diaphragm is nicked at the right costal cartilage to allow a straight positioning of the outflow conduit and closure of the abdominal wall without tension. The enism process is resected in most cases.

The median sternotomy is performed in a routine manner. The pericardium was entered via an L-shaped incision pointing toward the left side. The left-sided detachment of the diaphragm up to the level of the ventricular apex results in a good access to the device pocket. Frequently, the left pleural space is opened by accident and subsequently has to be drained. The pericar-
The ascending aorta is dissected up to the truncus where it is prepared for cannulation. Two purse-string sutures are placed at the right-atrial appendage. Prior to systemic heparinization, 100 ml of blood are drawn from the aortic cannulation site for preclotting of the conduits. Clotting of the conduits is accomplished simultaneously to the ongoing surgical procedure. Careful removal of thrombotic material from the lumen of the conduits is essential.

Extracorporeal circulation is instituted using a standard aortic cannula and an atrial two-stage cannula. All patients are perfused at normothermic conditions and are totally unloaded (negative central venous pressure, collapsed atrium). Following luxation of the heart, 12 patch-armed Ethibond sutures (Ethicon, Norderstedt, Germany) (size 1, MH) are placed in a circular manner around the apex to allow the fixation of the attachment ring for the inflow conduit (Fig. 1). Afterwards the myocardial wall within the attachment ring is excised, the inflow conduit inserted into the left ventricle and connected to the attachment ring. The device is filled with heparinized saline solution, the biological valve and the inflow conduit mounted. Sealing is controlled by closure of the outflow tract with consecutive pressure increase in the ventricle-pump chamber system. Additional sutures are placed, if necessary. Prior to insertion of the device into the pocket, the drive line has to traverse the abdominal wall. A long subcutaneous tunnel directed to the right lower abdomen via an additional incision caudal to the umbilicus is designed to prevent infection (Fig. 2).

Outflow conduit and outflow valve are connected. The outflow conduit is temporarily occluded for anastomosis with the ascending aorta using an alligator clamp. The ascending aorta is partially side-clamped as proximal as one can with the clamp being directed towards the non-coronary sinus, if possible. The ascending aorta is longitudinally incised and the outflow conduit anastomosed end-to-side using 4–0 prolene (Fig. 3). After meticulous de-airing, the clamp is released and blood allowed to flow into the system. In parallel to the anastomosis, the drive line is connected with the controller system and the latter started in a single-contraction mode for further de-airing. Thereafter, it is switched to the fill-rate-trigger mode and the patient’s central venous pressure raised via the extracorporeal circulation. Catecholamine and vasodilator therapy is adjusted to the pulmonary vascular resistance, which has been assessed preoperatively, to the right-ventricular filling and contractility, and to the increase of pump flow. After checking for bleeding, the extracorporeal circulation is terminated and coagulation normalized by application of protamine and by substitution of fresh frozen plasma and packed platelets. Temporary pacing wires are attached to the right atrium and ventricle. Thoracic drains are inserted into the thorax and the device pocket. The abdominal wall is readapted with full-thickness bites, and the sternum closed in routine manner (Fig. 4).

Anticoagulation with i.v. heparin is initiated immediately after surgery, aiming at partial prothrombin time of 60–80 sec. After removal of the thoracic drains coumarin treatment is started. All patients are extubated as early as possible. Hemodynamic
land marks are pump volume > 5 L/min, mean arterial pressure > 80 mmHg, and central venous pressure < 20 mmHg.

Results

Eight patients (7 male, 1 female) underwent a Novacor N100 LVAD implantation by the technique described above between April '94 and April '95. It should be mentioned that we used a different technique, mainly with regard to the preclotting of the conduits, in our early experience. This has been published elsewhere (18). Mean age of this patient cohort was 40 ± 14 years (mean ± SD) Mean body surface (BSA) was 1.99 ± 0.3 m². The cause of end-stage heart failure was dilative cardiomyopathy in five and ischemic heart disease in two patients. One patient presented with biventricular dilatation following correction of Fallot’s tetralogy during childhood. Apart from this patient, the two patients with ischemic heart disease had a history of cardiac surgery. Cardiac output as measured by the thermodilution technique was calculated to 3.3 ± 0.9 L/min. An elevated pulmonary vascular resistance was noted in 3 patients. Another 3 patients suffered from renal failure which necessitated continuous veno-venous hemofiltration prior to LVAD implantation.

Intraoperatively no complication occurred. Mean surgical time (extracorporeal circulation) was 199 ± 25 (82 ± 17) min. In none of the cases was the aorta cross-clamped or the heart arrested by cardioplegia. The inotropic and vasodilator medica-

Table 1 Patient data

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (years)</th>
<th>BSA (m²)</th>
<th>Previous cardiac surgery</th>
<th>CO (L/min)</th>
<th>PVR</th>
<th>CVHV</th>
<th>Preoperative catecholamine requirement</th>
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BSA: Body surface area; CO: Cardiac output; PVR: Pulmonary vascular resistance; CVHV: Continuous veno-venous hemofiltration

Table 2 Intraoperative data

<table>
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<tr>
<th>Case</th>
<th>Implantation time (min)</th>
<th>ECC time (min)</th>
<th>PRBC (Units)</th>
<th>FFP (Units)</th>
<th>PP (Units)</th>
<th>Dopamine μg/kg/min</th>
<th>Dobutamine μg/kg/min</th>
<th>Epinephrine μg/kg/min</th>
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<tr>
<td>X±SD</td>
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</table>

ECC time: duration of extracorporeal circulation; PRBC: packed red blood cells; FFP: fresh frozen plasma; PP: packed platelets
tion required for weaning from cardiopulmonary bypass is listed in Table 2. Following antagonization of heparin 5.8 ± 1.9 U of fresh frozen plasma and 1.1 ± 0.8 packs of platelets were administered.

The patients were extubated after a mean period of 18 ± 13 hours. No patient required rethoracotomy. The drainage loss varied between 1930 and 14,300 ml. Most of the drainage fluid was asanguinous secretion pouring out of the device pocket. The transfusion requirements after implantation are listed in Table 3. Four patients underwent heart transplantation after a support interval of 19,35,136, and 335 days. All patients are alive and were discharged home. The remaining 4 patients are still under support, partly on an outpatient basis, and are awaiting transplantation.

Discussion

Currently left-ventricular assist devices are successfully used as a bridge to transplantation, improving life quality and survival. According to published data and the increasing waiting times, a liberalization of the indication for device implantation seems warranted. Consequently, programs for permanent device implantation as an alternative to transplantation have been initiated (4,5). While LVAD systems were initially implanted only in patients with end-stage heart failure who could not be stabilized despite maximal medical therapy, it now appears that patients with NYHA class III–IV symptoms derive a significant benefit. However, low perioperative mortality and morbidity is an essential prerequisite for broadening indications.

The implantation technique presented seems to fulfill this prerequisite and to allow a more rapid accomplishment of the operation than other strategies (9). No patient died perioperatively, and severe complications with impairment of the quality of life did not occur. Moreover, this technique was also suitable for patients with a history of previous cardiac surgery. To solve the well-known problem of thrombus formation at the inflow and outflow valve area despite adequate anticoagulation the manufacturer has changed the valve design. Whether this will result in a lower rate of thromboembolic complications remains to be seen.

Early attempts to position the device subcutaneously in very obese patients were abandoned due to the imminent risk of perforation and infection. Preperitoneal pockets have generally been accepted, meanwhile. To prevent perforation into the abdominal cavity we prefer a placement of the device in front of the posterior sheath of the rectus muscle to strengthen the preperitoneal tissue, as used to be the practice with large defibrillator systems (15). In contrast to others we detach the diaphragm extensively from the left rib cage. This allows anastomosis of the inflow conduit at the apex of the heart in the luxated position and to easily control bleeding in the surgical field. If the connection is accomplished using only a small diaphragmatic window (12,13,14), checking for bleeding is almost impossible. Internal herniation, which may theoretically result from the generous detachment of the diaphragm did not occur so far. This may be due to development of an extensive fibrotic scar around the pocket which we have found at every explantation of the system.

The anastomosis between inflow conduit and apex can be easily accomplished with the heart beating, rendering cardioplegic arrest dispensable. Some authors recommend anastomosing the outflow conduit first in stable patients after sideclamping the ascending aorta but before extracorporeal circulation is instituted (9,10). We do not see any advantage in this technique: the 15–20 min longer perfusion does not harm the patient and the risks associated with increased afterload following reduction of the aortic lumen are totally avoided using extracorporeal circulation throughout. A further advantage of our technique is the simplified length measurement of the conduit. Very long prosthetic tubes may bend, while too short conduits put tension on the anastomoses and may provoke bleeding at the suture sites.

The function of left-ventricular assist devices requires adequate right-heart function. The hypothesis of passive perfusion of the lungs during right-heart failure according to the Fontan principle has proven possible in only few cases. Under these circumstances, excessive central venous pressures were necessary to achieve sufficient blood flow through the lungs.

The perfusion pressure defined as the difference between mean arterial blood pressure and central venous pressure is low in patients with manifest right-heart failure. Treatment with volume loading, pulmonary vasodilatation and systemic vasoconstriction not infrequently leads to a vicious circle of inadequate cardiac and pump output which does not allow recovery of the impaired organ function.
It is rather difficult to differentiate a pericardial tamponade from right-heart failure, as both situations have similar hemodynamic consequences. A local hematoma compromising right-ventricular or right-atrial inflow is often not visible during echocardiography, and this renders decision making for surgical reevaluation in situations with low cardiac output and high central venous pressure rather difficult. It is, therefore, necessary to take every precaution to prevent bleeding. As previously mentioned, the manufacturer has changed the design of the system during the study period. The valve holder and the prosthetic material of the outflow conduit have been improved. While earlier conduits were not sealed and had to be precotted, the new conduits are impermeable for blood. Nevertheless, precotting is still helpful as it makes checking for bleeding easier prior to thoracic closure, although bleeding ceases rapidly with correct anticoagulation.

The measures taken to prevent postoperative right-heart failure after implantation of the left-ventricular assist device and to avoid bleeding complications seems to have been successful. In the present series, weaning from extracorporeal circulation was possible without major problems and central venous pressure remained moderate. No postoperative right-heart failure developed, although at least in the patient with correction of Fallot’s tetralogy (with resection of the pulmonary valve) right-ventricular complications were expected. Moreover, postoperative bleeding complications did not play a significant role. No patient had to undergo a rethoracotomy and all three patients with previous cardiac surgery had only moderate drainage losses and transfusion requirements.

In conclusion, the present series, although small, demonstrates that the implantation technique for the Novacor N100 is simple and associated with a low complication rate. Cardioplectic arrest at implantation is unnecessary, and implantation with the heart beating seems to help prevent right-heart failure.

References


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