Implantation technique for the Novacor left ventricular assist system

The Novacor left ventricular assist system (Baxter Healthcare Corp., Novacor Div., Oakland, Calif.) is currently undergoing clinical investigation as a bridge to cardiac transplantation. The original animal and clinical protocols recommended placement of the pump/energy converter within the peritoneal space. During preclinical cadaver fitting trials, we determined that it might be difficult to place this device in the peritoneal cavity of tall, slender patients, patients having a small muscular abdomen, and many women. We were also concerned that peritoneal placement would increase the risk and severity of infection and that abdominal organs might be injured by direct contact with the pump. In studies in cadavers, we therefore developed a technique using preperitoneal placement of the pump/energy converter. This technique has now been used successfully in more than 200 patients. A detailed description of this insertion technique is presented to facilitate its current use for the implantation of temporary devices and to plan for the implantation of permanent systems. (*J THORAC CARDIOVASC SURG* 1994;108:604-8)

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Design, bench testing, laboratory animal research, and clinical trials of the Novacor left ventricular assist system (LVAS) (Baxter Healthcare Corp., Novacor Div., Oakland, Calif.) in a temporary configuration have been ongoing for more than 20 years.^{1,2} The projected end point of this effort is a totally implantable, nonvented system that would complement cardiac transplantation as a modality of treatment for patients with end-stage heart failure. The original concept was to place the pump/energy converter within the peritoneal space.¹ Pump inflow would be via the left ventricular apex and the pump outflow graft would be sutured to the abdominal aorta. This

anatomic location was selected because of the limited space within the thorax. As part of our preclinical training, we evaluated the abdominal wall of many subjects and implanted the Novacor LVAS in six cadavers. We soon recognized that intraperitoneal placement of the pump/energy converter in tall, slender individuals and individuals who have a small muscular abdomen would be difficult because of the size and weight of the device. We feared that anastomosis of the pump outflow graft to the abdominal aorta would be technically difficult and limit access for replacement of pump parts in cases of component failure. Because long Dacron grafts had been used successfully in aortic surgery, we believed that the LVAS outflow graft could safely be placed on the ascending aorta. Because of these concerns, we developed the following implantation technique.

Implantation procedure

The patient is placed in a supine position. Peripheral intravenous, radial arterial line, and pulmonary artery catheters are placed under local anesthesia. After induction of general anes-

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thetia, the patient is intubated, and a urinary catheter and nasogastric tube are placed. The patient is prepared from the neck to the knees. After the surgical field is draped, a longitudinal skin incision is made from the suprasternal notch to 2 cm below the umbilicus (Fig. 1). The linea alba is identified, and the left and right anterior rectus fascia is exposed. The left anterior rectus fascia is incised several millimeters from the linea alba, so that the rectus abdominis muscle is exposed. It is important not to incise the linea alba to preserve the integrity of the abdominal wall and prevent hernia formation (Fig. 2, A). A plane is developed posterior to the rectus abdominis muscle to create a pocket for the LVAS pump/energy converter (Fig. 2, B). The pocket extends superiorly to the costal margin and inferiorly to the iliac crest. Laterally, it extends beyond the linea semilunaris beneath the external oblique muscle. In patients who have a small abdomen, the right rectus sheath may be incised and a similar pocket developed beneath the rectus abdominis lateral to the linea semilunaris. Hemostasis is achieved with electrocautery and suture ligation. The pump/energy converter is inserted in the pocket to ascertain size and position.

The sternum is divided with an oscillating saw and the pericardial sac is incised. The aortic graft is preclotted by soaking it in 70 ml of normal saline solution containing 1 U of cryoprecipitate and then adding 20,000 U of topical thrombin. This procedure is performed three times, with fresh cryoprecipitate and thrombin being used each time. The cryoprecipitate and thrombin are massaged into the graft and fibrin clumps are removed from the lumen. The aortic graft is tailored so that it will reach from the pump to the ascending aorta after being blindly tunneled through the diaphragm with the aid of blunt dissection and cautery. A partial occlusion vascular clamp is placed on the ascending aorta, and a 2 cm incision is made. The aortic graft is anastomosed end to side with 4-0 polypropylene suture. The graft is clamped close to the anastomosis, the aortic vascular clamp is removed, and the anastomosis is examined for hemostasis. Additional 4-0 polypropylene buttressed sutures are used as needed to achieve hemostasis. The left ventricular cannula is tunneled through the diaphragm. The blood-contacting surfaces of the pump/energy converter are primed with 5% albumin, the inflow and outflow valves are properly positioned, and the pump/energy converter is placed to the left of the midline in the previously prepared pocket. With the aid of a large trocar, the vented power cable from the pump/energy converter is tunneled subcutaneously across the abdomen and exits from the right upper abdominal quadrant. The apical and aortic conduits are connected to the pump/energy converter.

The patient is given intravenous heparin, 300 U/kg body weight, to produce an activated clotting time of approximately 500 seconds. An aortic cannula appropriate for the surface area of the patient is inserted in the ascending aorta near the origin of the innominate artery. Venous cannulas are positioned in the superior and the inferior venae cavae. The atrial septum is palpated to rule out an atrial septal defect or patent foramen ovale. Cardiopulmonary bypass is instituted. The patient's core temperature is maintained at 37° C. The heart is retracted anteriorly, exposing the apex. Buttressed sutures (2-0 Ethibond, Ethicon, Inc., Somerville, N.J.) are placed circumferentially around the apical dimple and passed through the apical sewing ring (Fig. 3, A). The sutures are tied, securing the apical ring to the heart. The patient is placed in the Trendelenburg position and a stab incision is made in the center of the ring (Fig. 3, B). A Foley catheter with a 30 ml balloon, which has been passed

Fig. 1. The skin incision extends longitudinally from the suprasternal notch to 2 cm below the umbilicus.

through the lumen of a cylindrical knife (cork borer), is introduced into the left ventricle (Fig. 3, C). The Foley balloon is inflated and a core of myocardial tissue inside the ring is excised. The cork borer and Foley catheter are removed simultaneously, bringing the myocardial core with them (Fig. 3, D). After the tissue core is free, the Foley balloon is deflated and removed. Care is taken to maintain the blood level above the mitral valve to prevent air from entering the left atrium. The left ventricular cavity is carefully inspected. Thrombus and/or exuberant trabeculations that may obstruct the apical cannula are debrided. The apical cannula is inserted into the ventricle, and the pursestring suture of the apical ring is tied. The skirt of the apical cannula is sutured to the apical ring circumferentially. A 4-0 polypropylene buttressed suture is placed in the aortic graft. A 2 mm opening is made in the center of the pursestring suture. This section of the graft is elevated above the pump/energy converter, as well as the ascending aorta. With the patient in the Trendelenburg position and with the aortic graft occluded near its anastomosis with the aorta, the device is activated, and air is vented through the opening in the graft. A pressure-monitoring line is inserted into the left atrium via the right superior pulmonary vein. After all the air is removed from the LVAS, the pursestring suture is tied. The LVAS is set at a fixed rate of approximately 20 beats/min, while at the same time cardiopulmonary bypass flow is reduced by

Fig. 2. A, The left and right anterior rectus fascia have been longitudinally incised lateral to the linea alba. A plane is developed posterior to the rectus abdominis muscles. B, The rectus abdominis muscle has been retracted and a pocket developed along the posterior rectus sheath.

Fig. 3. A, Buttressed 2-0 Ethibond sutures are placed circumferentially around ventricular apex. B, The apical ring has been secured and a stab incision made in the ventricular apex. C, A Foley catheter, which has been passed through a cork borer, is inserted into the ventricle. D, A core of myocardial tissue has been excised.

Fig. 4. The Novacor pump has been inserted in the pocket. The right and left anterior rectus fascia have been closed anterior to the pump.

20%. The aortic graft of the LVAS is unclamped, and adequate filling of the LVAS is verified. The LVAS is then placed in the fill rate trigger mode and cardiopulmonary bypass is slowly discontinued (2 to 3 minutes) while the LVAS rate and output increases.

When the patient is in hemodynamically stable condition, the venous cannulas are removed. After the pump prime is returned to the patient, the aortic cannula is removed. All cannulation sites are oversewn. Heparin is reversed with an appropriate dose of protamine. All operative sites are copiously irrigated with an antibiotic solution consisting of 1 gm of vancomycin in 1 L of saline solution. Two No. 36 chest tubes are placed along the anterior surface of the heart. Jackson Pratt drains are placed in the pump/energy converter pocket. The sternum is approximated with six 5-0 sternal wires. The anterior rectus sheath is closed with interrupted 0-0 polyglactin sutures, the subcutaneous tissue is closed with continuous 2-0 polyglactin, the skin with 3-0 polyglactin subcuticular sutures, and Steri-Strip bandages (3M Health Care, St. Paul, Minn.) are applied to the wound (Figs. 4 and 5).

Discussion

We have used this technique to implant the Novacor LVAS in 13 patients. Three of these 13 patients had pump pocket complications. The first patient had a history of extensive radiation therapy of the chest wall and abdomen for lymphoma. After the operation, the wound healed poorly with the tissue becoming taut; therefore, the abdominal portion of the incision was opened to relieve the tension. Despite the LVAS being exposed, the wound never became infected. This patient died 28 days after LVAS insertion of fungal sepsis that apparently was not related to the LVAS.

The second patient's abdominal wound incision partially separated at 21 days as the result of a *Staphylococcus aureus* infection. The LVAS pocket was opened, drained, and irrigated in the operating room. The wound was left open and managed with dressing changes and vancomycin irrigations every 6 hours. Eventually, wound cultures became negative. The patient successfully received a transplant on day 53 after the LVAS operation.

Fig. 5. The Novacor LVAS in place. The power cable exits in the right upper quadrant.

After transplantation, the wound healed well with no evidence of infection. A skin graft to the pump site was performed 6 months after transplantation to stabilize the wound.

The third patient had multiple complications after receiving the LVAS, including right heart failure, renal failure, thromboembolism, and infection of the LVAS pocket and mediastinum. This man died 87 days after LVAS insertion.

The incidence of device-related wound complications in our Novacor LVAS series was 23% (15% infection). Although this percentage is significant, it is similar to the 25% device-related infection rate reported for the

Thermocardiosystems Heartmate³ device (Thermocardiosystem, Inc., Woburn, Mass.). This is not surprising considering the similarity of devices, patients, and implant procedures. It is hoped that all device-related complications will become less prevalent with experience.

Several variations of this technique have been used clinically. The most noteworthy is the use of hypothermic ischemic arrest, especially during apical cannulation. The risk of air embolization may be reduced in a non-beating heart, and some believe cardioplegic arrest facilitates the removal of ventricular thrombus. However, we have had no instances of air embolization and no difficulty removing the thrombi. Furthermore, we believe it most critical to preserve right ventricular function in these patients. Therefore, we do not believe it advantageous or necessary to arrest the heart during LVAS insertion.

Preperitoneal LVAS placement has proven and theoretical advantages. Because the peritoneal cavity is not violated, the risk of intraabdominal organ injury is reduced. In the first patient to receive a Novacor device, the LVAS was inserted intraperitoneally and the patient had a perforated colon 14 days after transplantation.⁴ Whether the risk of infection is greater with the intraperitoneal or extraperitoneal position is not entirely clear. The development of an intraperitoneal infection would seem to carry greater risk, but the omentum has the capacity to wall off or localize infection. Many patients have had the Thermocardiosystems left ventricular assist device inserted intraperitoneally.³

Placement of the pump/energy converter in a more

peripheral location will help dissipate heat. Also, depending on the patient's anatomy, the pump/energy converter pocket can be enlarged to fit the anatomy of the abdominal wall. This technique has also been used by other Novacor investigators in more than 200 patients ranging in size from 49 kg to 142 kg with body surface areas ranging from 1.54 m² to 2.78 m². This technique simplifies the implant procedure and allows the heaviest component of the system (pump/energy converter) to be supported by the abdominal wall (see Fig. 5). This technique has worked well in allowing a considerable percentage of patients to be ambulatory and able to exercise freely. Finally, there is the potential advantage of this extraperitoneal site to make the device more accessible for component part replacement, particularly when the device becomes a totally implantable system. This information suggests that this technique would be appropriate for permanently implanted devices.

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