ANESTHETIC MANAGEMENT FOR THE PLACEMENT OF A FULLY IMPLANTABLE ARTIFICIAL REPLACEMENT HEART: A CASE REPORT

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On July 2, 2001, the first totally implantable artificial replacement heart was placed successfully in a human being at Jewish Hospital, Louisville, Ky. This institution has performed a total of 5 implants to date. The topic of this discussion is the second recipient who underwent surgery in September 2001.

Implantation of an artificial replacement heart is a complex case that provides a series of challenges and unique situations for the anesthesia provider. The anesthetist must stabilize the hemodynamics of a critically ill patient with end-stage heart disease by using multiple high-dose inotropic drugs, antiarrhythmic agents, and, possibly, an intra-aortic balloon pump (IABP), a ventricular assist device, or both before cardiopulmonary bypass (CPB). The postbypass period creates a unique situation in which the only control the anesthesia provider has on the hemodynamics is management of the systemic vascular resistance. This article describes the anesthetic management of the recipient of the Abiocor artificial heart with the longest survival time.

Key words: Abiocor, end-stage cardiomyopathy, hemodynamics, replacement heart.

Of the patients with end-stage cardiomyopathy on a heart transplant list, 95% do not receive a donor heart. Due to this severe shortage of donor organs, an artificial replacement heart has been pursued for several decades. To date, 10 patients have received an Abiocor artificial replacement heart (Abiomed, Inc, Danvers, Mass), the latest artificial heart device available.

Anesthetic management often is complicated by the preoperative multisystem organ failure arising from the patient's advanced cardiomyopathy. Hemodynamic stabilization before cardiopulmonary bypass is extremely challenging, and the postbypass period creates a unique situation in which the only control the anesthesia provider has on the hemodynamics is management of the systemic vascular resistance. This article describes the anesthetic management of the recipient of the Abiocor artificial heart with the longest survival time.

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Implantation of an artificial replacement heart is a complex case that provides a series of challenges and unique situations for the anesthesia provider. The anesthetist must stabilize the hemodynamics of a critically ill patient with end-stage heart disease by using multiple high-dose inotropic drugs, antiarrhythmic agents, and, possibly, an intra-aortic balloon pump (IABP), a ventricular assist device, or both before cardiopulmonary bypass (CPB). The postbypass period creates a unique situation in which the only control the anesthesia provider has on the hemodynamics is management of the systemic vascular resistance with vasoactive infusions.

The concept of a permanent replacement heart dates to 1957, when Kolff and Akutsu performed the first implantation of an artificial replacement heart in an animal, which survived for 6 hours. Cooley performed the first artificial replacement heart in a human in 1969 and again in 1981. The replacement heart in these cases served as an interim measure until orthotopic cardiac transplantation could be accomplished. Throughout the 1980s, the artificial heart became highly publicized when the Jarvik-7-1000 was placed in several patients by Devries. Initially, these implants seemed to be successful, but the 3 long-term survivors eventually died of thromboembolic events and infection. These earlier devices all contained percutaneous wires and tubes that limited mobility and led to infection.

The pursuit of a permanent replacement heart perseveres as the incidence of congestive heart failure continues to rise in the face of a severe shortage of donor hearts for transplantation. It has been estimated that approximately 60,000 people in the United States could benefit from cardiac transplantation. Only 2,300 (approximately 4%) of these people per year are likely to receive a heart transplant due to the small supply of donor hearts and significant medical and financial restrictions.

The Abiocor device (Abiomed, Inc, Danvers, Mass) has been developed as a potential alternative to transplantation. The engineers who designed the Abiocor have attempted to address the complications noted with other replacement heart devices such as infection and thromboembolic events. The Abiocor is the only replacement heart that has been designed to fit totally inside the body. There are no percutaneous wires or tubes, and the surface of the device is smooth and seamless, which, in theory, decreases the chance of blood cell damage and clots.

The size of the device, which weighs about 2
pounds, affects patient selection. With the model currently available, size clearly limits use in smaller patients, including most females. Difficulty in closing the chest and/or impingement of blood vessels and organs such as the lungs are some of the problems noted with placing the Abiocor device in too small a patient. The thoracic unit should fit in the chest cavity with the lungs fully expanded because the patient should receive an adequate tidal volume (10-14 mL/kg) in the postoperative period when mechanical ventilation will be required to prevent atelectasis and pneumonia. An Abiofit (Abiomed, Inc, Danvers, Mass) analysis, consisting of magnetic resonance imaging and or computed tomography files that are merged with 3-dimensional images of the Abiocor, is done to assist the surgical team in predicting whether the device will fit.6

The patient inclusion and exclusion criteria are listed in Table 1. The subject of this case report had been denied an orthotopic heart transplant due to his advanced age of 70 years. Advanced age is considered a relative contraindication for a heart transplant, and no specific age is identified, although transplants have been performed successfully on patients well into their 60s.

The Abiocor consists of external and internal components that communicate with a transcutaneous energy transfer (TET) system. The internal components consist of the Abiocor thoracic unit, battery, controller, and the TET coil (Figure 1). The thoracic unit consists of an energy converter and 2 artificial blood pumps that function as right and left ventricles. Atrial inflow cuffs and the aortic and pulmonary artery conduits connect to the Abiocor device by twist-lock connectors to the native circulation (Figure 2). The portion of the native atria that remain serves only as an attachment point for the atrial cuffs.

The energy converter located between the ventricles contains a miniature pump that moves hydraulic fluid unidirectionally, shuttling the hydraulic fluid from chamber to chamber. A 2-position switching or porting valve alternates the direction of hydraulic flow between the right and left ventricles. The valve switches the direction of hydraulic fluid to permit left-to-right pulsation and displacement of blood. The system ejects blood alternatively from the left and right pumping chambers in a manner similar to the human

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Table 1. Inclusion and exclusion criteria for Abiocor*

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biventricular failure, maximum medical therapy, and dependent on inotropic agents or unable to tolerate inotropic agents due to severe arrhythmias</td>
<td>Heart failure with significant potential for reversal or candidate for heart transplantation or other conventional therapy</td>
</tr>
<tr>
<td>Older than 18 y</td>
<td>Life expectancy $&gt;30$ d</td>
</tr>
<tr>
<td>High likelihood of dying within 30 days</td>
<td>Serious noncardiac disease (cancer)</td>
</tr>
<tr>
<td>Unresponsive to maximum existing therapy</td>
<td>Irreversible end-organ damage</td>
</tr>
<tr>
<td>Inelgible for orthotopic cardiac transplantation</td>
<td>Psychiatric illness or instability</td>
</tr>
<tr>
<td>Acceptable surgical risk</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Abiofit† analysis</td>
<td>Blood dyscrasias</td>
</tr>
<tr>
<td>Psychologically sound with adequate social support system</td>
<td>Recent stroke or transient ischemic attack due to atherosclerotic disease</td>
</tr>
</tbody>
</table>

* Abiomed, Inc, Danvers, Mass.
† Abiofit is determined by virtual fit analysis with the patient’s magnetic resonance imaging and computed tomography files merged with 3-dimensional images of the Abiocor.
heart in which one chamber fills with blood while the other side empties. The rate of the switching valve determines the rate of the device, which varies between 75 and 150 beats per minute, resulting in cardiac output of 4 to 8 L/min.

An atrial flow balancing chamber, attached to the atrial inflow conduit, is located between the left inflow port and left inflow valve, controlling the left-to-right blood flow balance.4-9 The balancing chamber contains a 10-mL hydraulic fluid reservoir that is in contact with the blood in the inflow chamber via a flexible diaphragm. This reservoir is able to correct flow imbalances in the right and left blood chambers. Without this chamber, the device would always provide equal stroke volumes.

The balancing chamber allows the left chamber to operate in a full fill to full empty mode, while the right chamber operates in a partial fill to partial empty mode. This mechanism permits a variable right ventricular stroke volume. A left-sided pressure higher than the right-sided pressure indicates that the right ventricular output is too high, and more hydraulic fluid will be pumped out of the balance chamber to allow for less right-sided blood pump filling. There will be less blood pumped from the right chamber to reduce the right ventricular stroke volume until the left and right ventricular pressures equilibrate. Conversely, if the right-sided filling pressures are higher than the left, less fluid will be pumped from the balance chamber to allow for more right-sided blood filling.

The pump’s surface is coated with Angioflex (Abiomed, Inc). Angioflex is a flexible, durable, and non-toxic plastic material that coats the Abiocor thoracic unit and, in vitro, does not damage blood cells that contact the surface of the device. Cell damage also is decreased by the limited number of moving parts (switching valve and pump motor propeller).

The internal lithium battery can power the thoracic unit for brief periods (up to 20 minutes). The internal battery is recharged continually by the external console or from a patient-carried external battery through the TET coil. The life of the internal battery is about 6 months on the current Abiocor model. A battery with a longer life span is being developed by Abiomed.

Case summary
A 70-year-old man arrived for surgery with end-stage heart failure that resulted from ischemic cardiomyopathy and was refractory to all medical therapy, including multiple inotropic drugs and the use of an IABP. Other medical problems included chronic obstructive pulmonary disease and renal insufficiency as evidenced by a creatinine level of 1.9 mg/dL. His weight at the time of surgery was 86 kg.

His initial ejection fraction was less than 10%. An IABP was already in place, and he required several high-dose inotropic and chronotropic agents to maintain hemodynamic stability. Despite these aggressive treatments, at admission to surgery, he had a cardiac output of 3.6 L/min. Table 2 shows the infusions the patient required before and after CPB. Hemodynamic values before and after CPB are given in Table 3.

The monitors applied included standard electrocardiographic monitoring and arterial blood pressure monitoring, obtained from a left femoral arterial line already in place, through which the IABP had been introduced before arrival to the operating room. The patient had a right subclavian pulmonary artery catheter in place that provided measurement of pulmonary artery pressure (PAP) and central venous pressure. An arterial line was placed with a 20-gauge catheter in the right radial artery. This arterial line was placed in addition to the left femoral arterial line and IABP because the IABP arterial pressure was featured on a monitor separate from the one used for other hemodynamic values. The surgeons preferred that all values be displayed
on a single monitor, so the second arterial line was placed for convenience.

Anesthesia was induced with etomidate, 20 mg; fentanyl, 150 µg; and pancuronium, 10 mg. Induction and intubation were uneventful and without complication. Isoflurane was used at concentrations of 0.5% to 1.0% after induction to maintain anesthesia.

A right internal jugular double lumen introducer was placed with an oximetric pulmonary artery catheter floated to 45 cm. The original right subclavian pulmonary artery catheter was removed for the following reasons: (1) The introducer was a single-lumen catheter, and the double-lumen introducer was preferred for extra venous access. (2) An oximetric pulmonary artery catheter was used that provided valuable information regarding mixed venous oxygen saturation, which evaluates oxygen supply and demand.

A 12F triple-lumen Shiley catheter was placed in the right femoral vein, after several failed attempts at placing it in the left internal jugular vein, to provide volume access and monitoring of the inferior vena cava pressure. Since the Shiley would be the largest volume line, the subclavian veins were avoided due to possible mechanical obstruction from the sternal retractors that can occur during cardiac procedures.

In addition, the surgeons requested a femoral venous catheter so that inferior venous pressure could be monitored after implantation. An indwelling urinary catheter was inserted by the operating room staff. Additional monitoring included pulse oximetry and end-tidal carbon dioxide.

Fenoldopam mesylate, a dopamine-1 agonist was started at 0.05 µg/kg per minute and 1 mg of bumetanide, a loop diuretic, was administered to promote diuresis and improve renal blood flow. All of the cardioactive infusions were adjusted as needed to maintain an SBP of 100-120 mm Hg. Drugs were not all used simultaneously.

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After the patient was steriley prepped and draped, a midline sternal incision was made. A skin incision was made over the right infraclavicular area for placement of the TET coil. A pocket was made in the left side of the chest for the device controller. A second surgical team exposed the right femoral vein and artery. Due to significant disease of the femoral artery, the decision was made to cannulate the distal ascending aorta.

The patient was heparinized with 34,000 U (400 U/kg) of heparin. The surgical team proceeded with aortic and venous cannulation, and CPB was initiated. The aorta was cross-clamped, and the pulmonary artery catheter was pulled back to 15 cm in the superior vena cava (SVC) to remove it from the surgical

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**Table 2. Cardioactive infusions before and after CPB**

<table>
<thead>
<tr>
<th>Before CPB</th>
<th>After CPB</th>
</tr>
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<tbody>
<tr>
<td>Dopamine, 7 µg/kg per minute</td>
<td>Vasopressin, 5-15 U/h</td>
</tr>
<tr>
<td>Dobutamine, 5 µg/kg per minute</td>
<td>Norepinephrine, 0.02-0.1 µg/kg per minute</td>
</tr>
<tr>
<td>Milrinone, 0.75 µg/kg per minute</td>
<td>Nitroprusside, 0.25-1 µg/kg per minute</td>
</tr>
<tr>
<td>Amiodarone, 33 mL/h (900 mg in 500 mL of dextrose 5% in water)</td>
<td></td>
</tr>
<tr>
<td>Epinephrine, 0.15-0.3 µg/kg per minute, adjusted as needed to maintain an SBP of 100-120 mm Hg</td>
<td></td>
</tr>
<tr>
<td>Norepinephrine, 0.02-0.05 µg/kg per minute, adjusted as needed to maintain the SBP as above</td>
<td></td>
</tr>
</tbody>
</table>

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**Table 3. Hemodynamic values before and after CPB**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Before CPB (with IABP)</th>
<th>After CPB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure, mm Hg</td>
<td>118/63</td>
<td>110-130/70-80</td>
</tr>
<tr>
<td>Pulmonary artery pressure, mm Hg</td>
<td>46/24</td>
<td>NA</td>
</tr>
<tr>
<td>IVC pressure, mm Hg†</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>SVC pressure, mm Hg†</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>SvO₂, %</td>
<td>58</td>
<td>83</td>
</tr>
<tr>
<td>Cardiac output, L/min</td>
<td>3.6</td>
<td>4-8</td>
</tr>
</tbody>
</table>

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* CPB, cardiopulmonary bypass; SBP, systolic blood pressure.
† Dopamine, dobutamine, milrinone, amiodarone, and epinephrine were discontinued on CPB initiation. Rates on all of these drugs were adjusted as needed to maintain an SBP of 90-110 mm Hg. Drugs were not all used simultaneously.

* IVC and SVC pressures are a reflection of the central venous pressure.
field. The native ventricles were excised. Right and left inflow atrial cuffs were trimmed (Figure 3) and sewn to the corresponding atria. The outflow grafts then were sewn to the aorta and pulmonary artery. The Abiocor device was connected to the atrial cuffs and the outflow pulmonary and aortic grafts (see Figure 2).

Once the device was connected properly, the process of de-airing was begun by lung inflation, placing the patient in Trendelenburg position, and agitating the device. When transesophageal echocardiography (TEE) demonstrated the absence of intra-atrial air, the aortic cross-clamp was released. The Abiocor device was started at a rate of 60 beats per minute and adjusted to keep the cardiac output between 4 and 8 L/min.

After CPB was terminated, the initial systolic blood pressure was 90 to 100 mm Hg, with diastolic pressures of 50 to 60 mm Hg. Systemic vascular resistance was controlled with norepinephrine at 0.04 µg/kg per minute and a vasopressin infusion at 5 U/h. Both infusions were titrated as needed to maintain the appropriate parameters.

After the TEE demonstrated that a large amount of air had resurfaced in the left atrium, the aorta was reclamped and CPB was re instituted for about a minute to further de-air the device. Late intra-atrial air often occurs during or after CPB weaning as the blood flow to the lungs increases and forces air from the pulmonary veins. Hidden pockets of air can pool in the anterior spaces of the arches of the great vessels and surface after appropriate de-airing measures are taken. Another factor that possibly contributed to the late resurfacing of air was the ability of mechanical devices such as the Abiocor to create negative pressure and entrain air through loose or even well-secured suture lines. Separation from CPB again was achieved without difficulty.

The blood pressure began to rise, with systolic pressures of 130 mm Hg. At this time, the norepinephrine and vasopressin infusions were discontinued. The blood pressure continued to stay elevated at a higher level than the surgeon preferred; therefore, a nitroprusside infusion was started at 0.5 µg/kg per minute for a relatively short time.

Anesthesia was maintained with pancuronium, fentanyl, and isoflurane. The patient received a total of 15 mg of pancuronium and 1,000 µg of fentanyl. Isoflurane was administered at a concentration of 0.5% to 1.2% as needed to maintain blood pressure at acceptable levels, along with the vasoactive agents.

Protamine was administered to reverse the heparin. A significant coagulopathy ensued after the heparin was reversed. Platelets and other clotting factors often are destroyed during CPB. Also, complement activation results when the blood cells come in contact with the foreign tubing of the bypass circuit, resulting in fibrinolysis. Post-CBP coagulopathy usually is proportional to bypass time. The bypass time for this case was 128 minutes. The following laboratory values were obtained: prothrombin time, 18.4 seconds; partial thromboplastin time, 44.5 seconds; platelet count, 88.0 ¥ 10^3/µL; fibrinogen level, 369 mg/dL; hemoglobin, 7.5 g/dL; hematocrit, 22%. Blood products administered included 8 units of fresh frozen plasma, 4 units of platelets, and 4 units of packed red blood cells.

Volume was administered as needed, primarily in the form of the aforementioned blood products. The rate of administration was dictated by blood pressure and the right and left atrial pressures. Desired parameters were a systolic blood pressure of 90 to 110 mm Hg and atrial pressures of 10 to 15 mm Hg. Frequent fluid shifts often are noted during the postoperative period because the Abiocor device is very volume-dependent. Once appropriate hemostasis was achieved, the chest was closed and the operation was completed.

The patient’s condition remained stable during transport to the open heart recovery room. In the recov-
ery room, he required low-dose vasopressin (2 U/h) to maintain the blood pressure at 105/60 mm Hg. Left and right atrial pressures were maintained by porting valve adjustments from a team of Abiocor engineers. These adjustments allowed hydraulic fluid to be released or held from the balancing chamber as needed to equalize right- and left-sided cardiac outputs.

Upon arrival to the recovery room, the left atrial pressure was 12 mm Hg, and the right atrial pressure was 14 mm Hg. The right atrial venous saturation was 90%. The patient remained intubated and was placed on mechanical ventilation with the following settings: FIO$_2$, 100%; tidal volume, 900 mL; respiratory rate, 10 breaths per minute; and positive end-expiratory pressure, 5.

**Discussion**

The Abiocor replacement heart was designed to physiologically mimic the function of the human heart. The device is currently in clinical trials. US Food and Drug Administration (FDA) approval for 5 implants was announced in early 2001. After the implantation of the 5 initial Abiocor devices, the FDA issued approval for a total of 15 implants. After completion of the 15 implants, the FDA will reevaluate the device to determine whether it can be placed on the market. Abiomed’s goal in the preliminary clinical trial of the Abiocor device is a survival time of 6 months along with satisfactory quality of life.9

• **Anesthetic management.** The patient with end-stage cardiomyopathy is critically ill. Other organ systems most likely will be affected, possibly to the extent of failure. This multisystem organ failure is the result of decreased cardiac output and compromised perfusion to the other organs. Hemodynamic support is required before surgery and during the operative period before CPB, due to the patient’s advanced cardiomyopathy. Supportive therapy includes catecholamine (dopamine, dobutamine, epinephrine, and norepinephrine) and noncatecholamine (phosphodiesterase inhibitors such as milrinone) infusions. The patient also might receive antiarrhythmic therapy such as with an amiodarone infusion. An IABP, a ventricular assist device, or both may be needed in addition to the inotropic support. Despite these aggressive measures, patients are not expected to survive for more than 30 days. Diuretic therapy, such as with bumetanide or furosemide, is likely to be a part of the patient’s preoperative regimen and may need to be continued during the operative period. If renal insufficiency is a concern, fenoldopam, a dopamine-1 receptor agonist, may be used to increase renal perfusion. Fenoldopam has been shown to increase renal blood flow and glomerular filtration rate in a dose-dependent manner without significantly changing heart rate or blood pressure.12 During the pre-CPB period, fluid should be administered with caution, because a failing heart does not tolerate volume well.

During the post-CPB period, the patient with an artificial heart is no longer subjected to arrhythmias and cardiac depression.13 All inotropic, chronotropic, and antiarrhythmic agents can be discontinued when bypass is instituted, as these agents are incapable of affecting the replacement device. The only hemodynamic parameters in the control of the anesthetist after CPB are preload (the Abiocor device is volume-dependent) and afterload.

Nitroprusside and isoproterenol are used for the treatment of hypertension. Isoproterenol is an excellent peripheral vasodilator due to its β$_2$ effects on the vascular system. The chronotropic β$_1$ effects on heart rate are not a concern with a replacement heart.14,15 Nitroprusside is a familiar efficacious vasodilator and is rapidly titratable.

The drugs of choice for hypotension following implantation of an artificial heart are arginine vasopressin (AVP) and norepinephrine. Endogenous arginine vasopressin secretion is a baroceptor-mediated response. Endogenous preparations of arginine vasopressin (anti-diuretic hormone) have been shown to act as a powerful vasopressor in patients with catecholamine-resistant hypotension and severe multisystem organ dysfunction, as often seen in septic states or following cardiac surgery.16 Catecholamine-resistant hypotension is defined as a failure of increased norepinephrine doses (up to 0.2 µg/kg per minute) to maintain a mean arterial blood pressure of 70 mm Hg or greater.

The administration of AVP has been shown to cause a pronounced decrease in norepinephrine requirements just minutes after starting the AVP infusion.17 Levels of AVP have been demonstrated to be decreased during shock and vasodilatory states, probably as a result of the central nervous system exhaustion of AVP stores.18,19 Arginine vasopressin also is effective at offsetting the vasodilation caused by long-term administration of amiodarone and angiotensin-converting enzyme inhibitors.20

The administration of AVP in normotensive patients produces no effect on blood pressure.21 When treating catecholamine-resistant hypotension, AVP seems to act synergistically with the catecholamine agents, resulting in an increase in blood pressure.17,22 Arginine vasopressin primarily has been studied in conjunction with catecholamines, particularly norepinephrine. There are few data to show the drug is effective when used as the sole vasoconstrictor in
postcardiotomy shock states; however, in this particular case, vasopressin was used alone and the blood pressure increased accordingly. Vasopressin has been shown to have fewer compromising effects on perfusion of the viscera, heart, and lung compared with norepinephrine and has been shown to aid in the recovery of renal function.1

This patient population likely will have factors that will contribute to post-CPB coagulopathy, such as previous chest surgery in which scar tissue has formed, poor tissue quality, and preoperative coagulation abnormalities, such as uremic platelet dysfunction. Aprotinin or other synthetic antifibrinolytics, such as aminocaproic acid, can be used to prevent fibrinolysis, platelet dysfunction, the inflammatory response, and complement activation.1,23,24

There is an increased risk of central nervous system insult from emboli or low cerebral perfusion during replacement heart surgery. Sodium channel blockers, such as phenytoin and fosphenytoin, reduce ischemia-induced glutamate release and seem to be effective for neuroprotection during periods of cerebral ischemia.1,10,11,25

• Monitoring the patient with an artificial replacement heart. It should be noted that no electrocardiographic tracing will appear once the replacement heart is activated. The arterial blood pressure demonstrates a pulsatile wave form, resembling native heart pulsations. The SVC was monitored from the pulmonary artery catheter that was pulled back to about 15 cm when CPB was initiated.

The PAP was not monitored after CPB due to the mechanical difficulties of floating a pulmonary artery catheter into an artificial heart, and, also, the PAP loses some significance since the right side of the implantable replacement heart can respond to increased PAPs without the risk of right-sided heart failure as seen in the human heart. After CPB, mixed venous saturation was obtained from an oximetric pulmonary artery catheter after advancing the catheter into the native right atrium with surgically assisted manipulation and TEE guidance. Due to the artificial heart’s constant cardiac output and the lack of coronary sinus venous return, an accurate SVO₂ can be obtained from the SVC as long as there is no SVC or inferior vena cava obstruction.

A left atrial line was placed by the surgical team via the right superior pulmonary vein. The left atrial pressure was maintained from 10 to 15 mm Hg by adjustments to the porting valve from the external controller device by a team of engineers and perfusionists.

The right atrial pressure was reflected by measurements of the SVC and inferior vena cava pressures. Superior and inferior vena cava pressures were monitored because there is risk of obstruction to either vessel during implantation of the replacement heart as a result of the device’s size.1

Preoperatively, TEE was used to rule out a patent foramen ovale. The presence of a patent foramen ovale can result in postimplantation arterial desaturation and should be corrected surgically.26 The TEE procedure also permitted assessment of air in the Abiocor device, aiding in the de-airing process before weaning from CPB. After separation from bypass, TEE was used to assess flow across the polyurethane atrioventricular valves and flow in the pulmonary artery and the ascending and descending thoracic aorta.1

The surgical team determined that TEE is an invaluable tool during sternal closure since use helped ensure that there was no compression of the left pulmonary veins. Decreased pulmonary vein flow will increase PAP and may necessitate repositioning of the thoracic unit before closing the chest.27

There is an increased risk of embolic events from thrombus, air, or both during implantation of a replacement heart. The use of neurological monitoring in cardiac surgery is controversial but may be useful when implanting a replacement heart.1 Electroencephalography, transcranial Doppler, bispectral index monitoring, and cerebral oximetry were the modalities used during this case for monitoring anesthetic depth and cerebral perfusion and to aid in detection of cerebral emboli. Following the case, it was determined by the neurological monitoring team that no significant embolic or ischemic events had occurred during the procedure.

• Ethical considerations. Implanting a replacement heart in a human being generates many concerns, including the ethical considerations surrounding the procedure. The Abiocor differs from other artificial heart devices in that it has always been considered destination therapy, meaning it does not serve as a bridge to a human heart transplant, but as a permanent replacement device. The implications of such a procedure raise many bioethical concerns.28

One of the more profound questions is whether it is ever appropriate to perform research on dying patients. Any patient considered for an Abiocor must have a predicted survival time of less than 30 days. There are individuals who oppose research involving terminally ill patients because they believe the patients are so desperate and vulnerable that they cannot give reasonable informed consent. Also, the opponents believe that a dying patient should be spared the burdensome and painful side effects of experimental procedures during their final days.28,29
The Abiomed Corporation used a new approach to protect the welfare and decisional autonomy of the potential research participants by establishing the Independent Patient Advocacy Council. An individual patient advocate is available for every patient who enters or considers entering the Abiocor clinical trial. The role of the advocate is to help the patient and families understand the potential risks and benefits of this procedure. The advocate remains with the patient and family during the postoperative period to assist with making other important medical decisions. All advocates have a background in clinical medicine, and all function completely independent of the sponsoring company and the medical teams.

The ethical implications of implanting a replacement heart will continue to be studied during the clinical trial phase. As with all medical research, there will be an ongoing debate between those who want to see technologic advances ultimately benefit the majority of human beings and others who question whether the rights of the early research subjects are being violated.

Conclusion
This unique and interesting case was challenging for the anesthesia providers. The review of the hemodynamic and pharmacologic management of this case provides an excellent review of the principles of cardiac anesthesia. One must understand the concepts of standard cardiac surgery and anesthesia to fully appreciate the differences offered by this particular case.

The implantation of the Abiocor replacement heart is still in clinical trials. The long-term implications of such a procedure are yet to be determined. Currently, there is hope that eventually the Abiocor can provide an alternative to orthotopic cardiac transplantation for the thousands of people with end-stage cardiac failure. As the clinical trial proceeds, the device will continue to be refined as new problems are noted. The ethical questions that arise will be addressed as new patients assist in pioneering this procedure.

To date, 10 Abiocor devices have been implanted. The subject of the present article survived longer than any of the other patients, living 17 months with the replacement heart. The postoperative course was complicated by pulmonary dysfunction, which required long-term ventilatory support, and high fevers. The patient was discharged to home on postoperative day 215, where he remained for about 9 months. He died when the membrane that separates the blood from the hydraulic fluid began to wear out and stretch, resulting in a decrease in cardiac output.

The patient was reported to have an improved quality of life with the Abiocor implant. During this time, he celebrated birthdays, his wedding anniversary, and the birth of his first great grandchild. There was often television footage of him at his favorite café with his friends after he went home with the replacement heart.

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