CardioWest (Jarvik) Total Artificial Heart: A Single-Center Experience With 42 Patients

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Background. **When implanted in patients with biventricular failure, the CardioWest total artificial heart has asserted itself over time as a reliable bridge-to-transplant device that as yet is used by only a few international teams. The aim of this single-center retrospective study is to assess both the comorbidity and survival of patients awaiting heart transplants while receiving circulatory support with a CardioWest total artificial heart.**

Methods. **From 1990 to December 2006, 42 patients received a CardioWest total artificial heart at our center. Mean age at the time of implantation was 45.7 ± 9.5 years, and 40 patients (95%) were men. Idiopathic or dilated cardiomyopathy was diagnosed in 45.2% (n = 19) of the patients and ischemic cardiomyopathy in 42.8% (n = 18). Average body surface area was 1.9 ± 0.22 m^2.**

Results. **Duration of support was 1 to 292 days (mean, 101 ± 86 days). Twelve patients died (28.5%) while receiving device support, and 30 patients (71.5%) underwent transplantation. Actuarial survival rates for the transplanted patients were 90% (n = 25), 81% (n = 14), and 76% (n = 10) at 1, 5, and 10 years, respectively. Causes of death during device support included multiorgan failure in 6 (50%), sepsis in 2, acute respiratory distress syndrome in 2, alveolar hemorrhage in 1, and other cause in 1. There were no device malfunctions that led to patient death. Adverse events included stroke in 3 patients (7%) and infections in 35 patients (85%) during support.**

Conclusions. **The CardioWest total artificial heart is an excellent bridge-to-transplant device for patients with biventricular failure. Our study demonstrates excellent safety, reliability, and efficiency. Exceptional outcome after transplantation underlines its capacity to aid in end-organ recovery.**

(Ann Thorac Surg 2009;87:124–30)

The CardioWest C-70 (formerly known as the Jarvik-70) is a pneumatically driven, orthotopic total artificial heart (TAH) implanted as a permanent device by DeVries and colleagues [1] in 1982 in a patient who survived 112 days. Three years later, Copeland and associates [2] reported on the use of a Jarvik as the first successful bridge to transplantation. The CardioWest is unique among bridge-to-transplant devices because it replaces all four valves and both ventricles of the native heart. Implanted in patients with biventricular failure, the CardioWest has over time asserted itself as a reliable bridge-to transplant device but as yet is used by only a few international teams [3, 4]. The CardioWest TAH is a mechanical circulatory support device capable of saving very sick patients in severe congestive heart failure [5].

Accepted for publication Sept 23, 2008.

Presented at the Forty-fourth Annual Meeting of The Society of Thoracic Surgeons, Fort Lauderdale, FL, Jan 28–30, 2008.

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The aim of this single-center retrospective study is to assess both the comorbidity and survival of patients awaiting heart transplants while receiving circulatory support with a CardioWest TAH.

Patients and Methods

The Device

The CardioWest C-70 (SynCardia Systems Inc, Tucson, AZ) is a pneumatically driven TAH that totally replaces the failing ventricles. The prosthetic ventricles are made of polyurethane and Medtronic-Hall mechanical valves that provide unidirectional flow. Blood and air are separated by a four-layer polyurethane diaphragm that moves back and forth by air pressure pulses controlled by an external pneumatic driver (CardioWest drive console). The console regulates the rate, systolic duration, and driving pressures for each of the two ventricles. A pneumotachometer provides information about the device output. Thanks to the short filling pathways, the CardioWest can lower filling pressure and improve end-organ perfusion. The TAH can provide flows up to 9.5 L/min, but it is usually used to provide flows at 5 to 7 L/min.

Published by Elsevier Inc

0003-4975/09/$36.00
doi:10.1016/j.athoracsur.2008.09.048

Selection Criteria

This study was reviewed and approved by the Institutional Review Board of the University of Nantes Health System, and a waiver of consent was granted. Inclusion criteria for CardioWest implantation were body surface area between 1.7 and 2.5 m^2, evidence of hemodynamic decompensation including cardiac index less than 2.0 $L \cdot min^{-1} \cdot m^{-2}$, central venous pressure greater than 18 mm Hg, high dose of inotropic agents (minimum of two) or difficulty weaning from cardiopulmonary bypass or extracorporeal membrane oxygenation support, or severe and repetitive ventricular arrhythmia. In addition, indication for CardioWest support was extended to patients with massive myocardial infarction in whom a left ventricular or biventricular device cannot be implanted for technical reasons or patients with intracardiac shunt or left ventricular thrombi. All patients included in this study were found to not be candidates for left ventricle assistance device therapy before consideration for TAH implantation. We documented adverse events based on previously published definitions [6].

Patients

Between October 1988 and December 2006, 42 patients (40 men, 2 women; mean age, 45.7 ± 9.5 years; range, 24 to 62 years) of a total of 82 patients (28 of them with Thoratec and 12 with Novacor) underwent mechanical circulatory support with a CardioWest TAH in our center. Patients' weight ranged from 50 to 115 kg (mean, 75.5 ± 14.5 kg), height from 160 to 198 cm (mean, 175 ± 7 cm). Body surface area was 1.5 to 2.51 m^2 (mean, 1.90 ± 0.21 m^2). The cause of heart failure was ischemic cardiomyopathy in 18 patients (43%), dilated cardiomyopathy in 19 (45%), postcardiotomy heart failure in 2 patients (4.8%), fulminant myocarditis in 2 patients (4.8%), and primary graft failure-rejection in 1 patient (2.4%).

Table 1. Preimplant Hemodynamic Variables and Treatment

Preimplantation Characteristics	Results
Left ventricular ejection fraction	0.22 ± 0.08 (0.10–0.30)
Cardiac index ($L \cdot min^{-1} \cdot m^{-2}$)	1.8 ± 0.5
Systolic pulmonary artery pressure (mm Hg)	50 ± 12 (26–70)
Central venous pressure (mm Hg)	20 ± 11 (4–33)
Pulmonary capillary wedge pressure (mm Hg)	28 (11–40)
Receiving dobutamine	62%
Receiving dopamine	31%
Receiving adrenaline	10%
Receiving Perfan	45%
Receiving noradrenaline	12%
Preimplant cardiac arrest	14% (n = 6)
Preimplant intraaortic balloon pump	33% (n = 14)
Preimplant ECMO/ECLS or Bio-Medicus	9.5% (n = 4)

ECLS = extracorporeal life support; ECMO = extracorporeal membrane oxygenation.

Table 2. Preimplant Biologic Variables

Preimplant Laboratory Data	Mean ± SD	Range
Serum urea (mmol/L)	15 ± 11	3–50
Serum creatinine (μmol/L)	175 ± 94	85–489
Creatinine clearance (mL/h)	57 ± 25	16–117
Serum total bilirubin (μmol/L)	46 ± 44	4–235
Serum conjugated bilirubin (μmol/L)	19 ± 17	3–71
Alanine aminotransferase (IU)	191 ± 425	7–1831
Aspartate aminotransferase (IU)	246 ± 490	5–2209
GGT (IU)	126 ± 97	30–291
Prothrombin time (%)	61	25–100
Blood lactate level (mmol/L)	3.8 ± 3	1–13
Factor V	65 ± 31	43–87
Platelet count (per mm^3)	175,900 ± 150,900	68,000–578,000

GGT = γ-glutamyltransferase.

Preimplantation Hemodynamic and Biologic Characteristics

Before being assisted by a CardioWest TAH, all patients were in cardiogenic shock despite maximum inotropic support (Table 1). Fourteen patients (33%) were receiving intraaortic balloon pumping, 6 patients (14%) were receiving mechanical ventilation, and 6 patients (14%) had undergone cardiopulmonary resuscitation within the previous 24 hours. Four patients (9.5%) were receiving mechanical support with extracorporeal membrane oxygenation (ECMO/ECLS) or Bio-Medicus. Thirty-eight percent of the patients (n = 16) had concomitant ventricular arrhythmia. Preoperative laboratory data are summarized in Table 2.

Antibiotic and Anticoagulation Protocols

Prophylactic antibiotic therapy with a second-generation cephalosporin was administered before surgery and until chest tubes were removed. In case of allergy, cephalosporin was replaced by vancomycin. Other antibiotic therapy was administered only for culture-positive infections. Antimycotic prophylaxis was not performed. Heparin, fluindione (a vitamin K antagonist), and aspirin were used consistently for the 42 patients. Dipyridamole was used until 1999. After bleeding was controlled, anticoagulation with heparin was started 6 hours after surgery. The activated partial thromboplastin time (aPTT) was used to monitor unfractionated heparin. Target levels of aPTT were 60 to 70 seconds. Other tests were prothrombin time (PT), fibrinogen, and anti-thrombin III. Fibrinolysis was antagonized with high doses of aprotinin during and after cardiopulmonary bypass and also during the first few days. We did not monitor platelet aggregation. Aspirin was started at day 1 to 3 at a mean dose of 160 mg/day. When patients were stabilized, heparin was replaced by fluindione. Target levels of international normalized ratio were 2.5 to 3.5.

Table 3. Causes of Death During Device Support

Causes of Death	% (n)
Multiple organ failure	50 (6)
Sepsis	17 (2)
ARDS	17 (2)
Alveolar hemorrhage	8 (1)
Other	8 (1)
Total	100 (12)

ARDS = acute respiratory distress syndrome.

Statistical Analysis

Continuous data were expressed as mean ± standard deviation, and categorical variables were expressed by percentage. For univariate analysis, continuous variables were analyzed using a Mann-Whitney *U* test, and the χ^2 or Fisher's exact test were used for categorical variables as appropriate. Probability less than 0.05 was considered significant. Univariate analysis of preimplant risk factors affecting survival during device support included various demographic, hemodynamic, biologic preimplant variables, and adverse events during circulatory support. We also tried to identify risk factors leading to multiorgan failure while receiving mechanical support.

Results

Patient Data

Mean implant times included aortic cross-clamp time of 108 ± 17 minutes (range, 64 to 155 minutes) and cardiopulmonary bypass time of 137 ± 41 minutes (range, 80 to 280 minutes). For 2 patients chest closure was delayed to postoperative days 2 and 5. There was no death during implantation, but 1 patient died a few hours after surgery of acute massive pulmonary edema. Two other patients required a venovenous ECMO after CardioWest implantation for severe hypoxemia related to acute pulmonary edema or acute respiratory distress syndrome.

Hemodynamics returned to near normal immediately after TAH implantation. Mean cardiac output of the device at the end of the first postoperative week was 5.5 ± 0.7 L/min for the right ventricle and 5.3 ± 0.8 L/min for the left ventricle. Inotropic support was weaned rapidly after TAH implantation in all patients except in cases of sepsis or multiple organ failure (n = 6). Vacuum and percent systole settings were 8 mm Hg and 54%, respectively. Patients were extubated within 20.4 ± 31 days and were discharged from the intensive care unit within 49 ± 46 days.

All patients with a CardioWest TAH stayed in the hospital. All patients walked once or twice a day and exercised using stationary bicycles. Mean time on CardioWest TAH support was 101 ± 86 days (range, 1 to 292 days). Total days and years of support were 4,226 and 11.7, respectively. Twelve patients (28.5%) died while receiving support. Multiorgan failure was the main cause of death (n = 6), followed by infection (n = 2) and acute respiratory distress syndrome (n = 2; Table 3). One patient died of alveolar hemorrhage on postoperative day 37. One patient had a pulmonary cancer diagnosis 1 month after TAH implantation. He died of pulmonary cancer-related complication on postoperative day 55. Another patient with a preimplant cardiac arrest had an irreversible neurologic lesion assessed on computer tomographic scan during the first postoperative days. He had tetraplegia with a state of akinetic mutism and died of infection 5 months after TAH implantation. Mean time on CardioWest support for deceased patients was 44 ± 60 days (range, 1 to 200 days). Thirty patients (71.5%) survived to transplantation, and 27 (64.3% of the total, 88.8% of those undergoing transplantation) lived until discharge from the hospital. After transplantation, 3 patients died during the first postoperative month. Causes of death were sepsis (n = 1), graft failure (n = 1), and multiple organ failure (n = 1). Actuarial survival rates were 90% (n = 25), 81% (n = 14), and 76% (n = 10) at 1, 5, and 10 years, respectively, for the transplanted patients (Fig 1). Actuarial survival rates for the entire cohort (n = 42) were 64% at 1 year, 58% at 5 years, and 54% at 10 years. Univariate analysis did not reveal any preimplant risk factors of mortality while receiving device support or of developing multiorgan failure.

Adverse Events

FIT COMPLICATION. Two patients had fit problems, and chest closure was only possible on postoperative days 2 and 5 after treatment of acute pulmonary edema. One patient required reoperation on postoperative day 3 for repositioning.

DEVICE MALFUNCTION. There was no device malfunction leading to patient death, but some severe events occurred in 4 patients (9.5%). An air leak caused by a tear at the driveline to the right ventricle junction was discovered during repeat surgery for hemodynamic collapse. This tear was a weakness point further to the driveline traction onto the left rib when repositioning the right ventricle. It was closed manually by banding the driveline with a silicone tube. A valve dysfunction attributable to mitral valve thrombosis was detected in 1 patient on postoperative day 69 and was treated on three occasions with fibrinolytic therapy resulting in an incomplete success but without bleeding or neurologic adverse

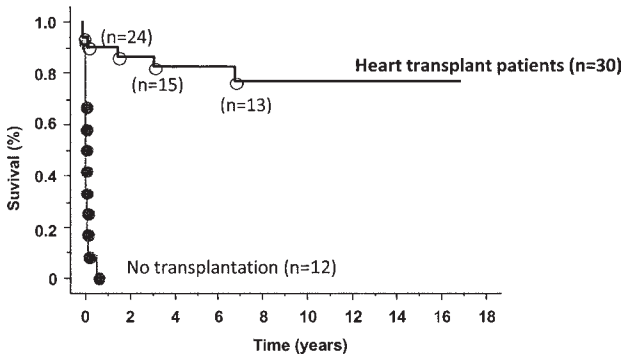

Fig 1. Actuarial survival of the patients who reached transplantation and patients who died during device support.

event. Fortunately, a suitable donor organ made immediate cardiac transplantation possible on postoperative day 72. He is currently doing well 12 years after transplantation. One malfunction of the control system (alarm and computer monitoring system) has necessitated a console change. The fourth patient had a central venous line blocking the CardioWest right ventricle tricuspid valve causing hemodynamic collapse. Fortunately, this malfunction was diagnosed in time and dealt with before venous line rupture and prosthetic valve fatal entrapment could occur.

INFECTIONS. Thirty-five patients (83%) had documented infection while receiving support. Mean infection per patient was 2.1. Two infections were lethal. Bacterial pneumonias were the most frequent infections during support with an incidence of 45% (n = 19). We recorded 11 (26%) positive blood cultures and 14 (33%) catheter infections. There were six (14%) driveline infections and two (4%) superficial sternal infections. Two cases of mediastinitis occurred; 1 patient required repeat surgery for drainage and irrigation on postoperative day 48. He underwent heart transplantation on postoperative day 159 with no major infection problem and is still alive at 7 years of follow-up. For the second patient, mediastinitis was discovered at transplantation on postoperative day 216, and this patient died of sepsis 14 days after heart transplantation. One patient exhibited ascites infection on postoperative day 33. He benefited from heart transplantation on day 141 and is still alive.

NEUROLOGIC EVENTS. During support, 3 patients (8%) had a stroke with neurologic sequelae. Among them, 1 patient had cardiac arrest and was transferred to our department for implantation. It was performed as an emergency with no previous neurologic function assessment. After TAH implantation, he had tetraplegia with a state of akinetic mutism. The second patient experienced a stroke during device implantation with symptoms immediately noted after surgery. For the third patient, the stroke happened on postoperative day 102. One transient ischemic attack (2%) occurred on postoperative day 265.

REPEAT SURGERIES. Mediastinal repeat surgeries for atrial tamponade or bleeding were performed in 22 patients (52%) and for mediastinitis in 1 patient. One patient required reoperation for device malfunction (closure of air leak). Device repositioning was necessary in 1 patient on day 3. One patient had an abdominal surgery for spontaneous splenic rupture on day 14. The cause of this rupture was not determined. The patient survived and underwent heart transplantation on postoperative day 140 and was eventually discharged home.

BLEEDING. Twenty-two patients (52%) returned to undergo a total of 28 repeat surgeries subsequent to bleeding or tamponade. Six cases of extramediastinal bleeding occurred in 6 patients (14%): hematemesis owing to pectic ulcer (n = 3), hemoperitoneum owing to splenic rupture (n = 1), hemoptysis owing to alveolar hemorrhage (n = 1), and epistaxis (n = 1).

RENAL DYSFUNCTION. Twenty-seven patients (64%) with a mean pretransplant creatinine concentration of 190 ± 103 μmol/L required temporary dialysis or continuous hemofiltration during support.

RESPIRATORY DYSFUNCTION. Three cases of acute respiratory distress syndrome occurred immediately after TAH implantation, 2 of them requiring venovenous ECMO. The femoral vein and right auricular appendage vein were cannulated. One short femoral cannula was used for blood draining from the lower body, and an atrial cannula was used for blood return. An ECMO flow of 2 to 3 L/min was enough to reverse hypoxemia. One patient died a few hours after weaning from ECMO, and the second one survived to transplantation and was discharged home from the hospital.

Tracheotomy was necessary in 8 patients (19%) for prolonged mechanical ventilation. Pulmonary infection incidence was 45%.

HEMOLYSIS. Severe hemolytic events were identified in 3 patients (7.1%). All of them survived to transplantation and were discharged home after 74, 130, and 168 days of CardioWest support.

GASTROINTESTINAL TRACT PROBLEMS. Three cases of pectic ulcer were diagnosed in a context of gastrointestinal bleeding. One case of pancreatitis occurred on postoperative day 2. Two patients had ascites during support.

Comment

The CardioWest is currently the only TAH to have obtained both European and American approval. Its leadership position is well justified by the results published for several years by Copeland and associates [6–8] with more than 80% of implant patients alive at transplantation. These excellent results, also obtained in our experience with 71% of transplanted patients receiving CardioWest support, are validated in the long term inasmuch as in our series transplanted patients' survival rate, subsequent to support, reaches 76% at 10 years.

The exceptional hemodynamic performances of the CardioWest allow optimal pulsatile cardiac output, restoring tissue perfusion that is adapted to vital functions. All our patients have been rapidly weaned from their inotropic support, thus avoiding any deleterious vasoconstrictor effect, using high pump outputs without excessive vacuum so as to reduce hemolytic events. Even though in our series multiple organ failure is the main mortality cause (50%; n = 6) during CardioWest, its incidence is relatively low for patients with severe heart failure. Other causes of death include infections (17%; n = 2) and acute respiratory distress syndrome (17%; n = 2) despite a venovenous ECMO in 1 patient. Pulmonary infection associated with pulmonary edema appears to be the factor favoring this pulmonary complication in our series, but polytransfusion, an ARDS risk factor after heart surgery according to Milot and coworkers [9] had also probably increased its incidence.

Our series has been characterized by a total absence of device dysfunction-related death. The classic blocking of the central venous line into the tricuspid valve prosthesis as described in several publications [3, 5] causing a fatal

Table 4. Preimplantation Characteristics of Various CardioWest Published Series

Characteristic	El-Banayosy et al [5]	Copeland et al [6]	Present Study
Intraaortic balloon pumping	67%	17%	33%
Mechanical ventilation	74%	30%	14%
Venovenous hemofiltration	52%	NA	7%
Previous cardiac surgery	50%	32%	7%
Cardiopulmonary resuscitation (24 h before implantation)	45%	27%	14%
Mechanical circulatory support (before implantation)	35%	8%	9.5%
Creatinine level (μmol/L)	184 ± 167	150 ± 56	175 ± 94

pump output drop could be avoided in one of our patients thanks to a prompt diagnosis and immediate explantation of the venous line. Our series has not yet been published, and therefore we here report the first case of a CardioWest severe dysfunction secondary to an air leak at the artificial right ventricle junction, which was manually repaired by circling the driveline with a silicone tube. This was not a manufacturing defect but a weak point caused by the right ventricle traction owing to a thread used to reposition the artificial heart. Lastly, mitral valvular dysfunction caused by thrombosis and partially treated through fibrinolysis proved it was possible to normalize fibrin status of patients during CardioWest TAH providing they were 1 month away from surgery.

According to our statistical analysis, there is no preoperative factor related to a potential increase of the mortality risk during CardioWest TAH. Our small cohort of patients probably explains these results, but we were surprised, noticing that patients with severe modifications of their biologic checkup (hepatic or renal) before implantation did not have a statistically worse prognosis than other patients. Thus, patients who died of multiorgan failure while receiving CardioWest did not have a preoperative biologic condition more deleterious than others. This tends to show that multiorgan failure recovery, especially hepatic injuries, is possible with the CardioWest and makes it difficult to select patients for circulatory support solely on biologic criteria. This probably explains the difficulty in identifying mortality risk factors in studies with the CardioWest TAH. Nevertheless, Leprince and colleagues [4] have found a significantly higher preimplantation bilirubin level in patients with multiorgan failure during support.

Our mortality rate during circulatory support (28.5%) compares with published results [3, 5, 10] with, however, some noticeable differences according to the centers. Thus, the 4% mortality reported by Copeland and colleagues [7] during a national trial could not be reproduced by El-Banayosy and associates [5], whose mortality rate reaches 50% during support. Although all studies on circulatory support underline that their cohort is made up of patients with severe heart failure, the various mortality rates are probably related to a different severity level according to the series. Thus, the Bad Oeynhausen cohort [5] showed higher preimplantation incidences of mechanical ventilation, intraaortic balloon counterpulsation, cardiocirculatory arrest, and first circulatory support than patients from the Arizona team [6] (Table 4). The use of a severity scoring could be applied not necessarily to predict mortality during support but to allow comparison among series of supported patients as well as to analyze each series' morbidity and mortality.

In our series, adverse events during support have been frequent, but none of them led to a significant mortality increase. This analysis of complications shows that the incidence of repeat surgeries for bleeding or tamponade as well as the incidence of temporary dialysis were twice to three times higher in our series than in the series by Copeland and colleagues [6] and El-Banayosi and associates [5] (Table 5). Several factors led us to believe that our anticoagulation protocol was probably too aggressive and worsened these bleeding complications. In fact, heparin was started on postoperative hour 6 and aspirin 1 or 2 days later. This prescription appears to be too early because for the past few years we have been initiating heparin from postoperative hour 24 and aspirin after the first week of circulatory support if postoperative bleeding was important. Our fear of thromboembolic risk, which had motivated this early anticoagulation, showed itself as being unjustified because of the low thromboembolic complications with the CardioWest. Of second importance is monitoring of anticoagulation variables. Contrary to some teams with a sophisticated monitoring protocol of anticoagulation [6, 11], we do not have any reliable means to assess platelet activation with functional tests, and using thromboelastography was not possible in our department. Therefore, unfractionated heparin monitoring was essentially measured with the aPTT. However, this test reliability has been questioned in recent years because it is poorly standardized in the laboratory and can be affected by many factors other than heparin concentration [12]. Consequently, each laboratory should determine its own therapeutic aPTT range and regularly verify it. Furthermore, aPTT undergoes circadian variations up to 50% of its value between nighttime and morning during continuous heparin perfusion [13], and its measurement is falsely lowered in

Table 5. Adverse Events of Different Series of CardioWest

Adverse Event	Copeland et al [6]	El-Banayosy et al [5]	Present Study
Repeat surgery for bleeding	19.6%	18%	54.7%
Infections	77%	NA	83%
Dialysis	19%	15%	62%
Mean time TAH support (days)	92 ± 91	86 ± 89	101 ± 86

NA = not available; TAH = total artificial heart.

case of hyperfibrinogenemia [14]. Several clinical studies have thus shown the difficulty in obtaining reliable aPTT values in patients receiving heparin [15] compared with an anticoagulation measurement of an antifactor Xa activity. According to Baker and coworkers [16], 68% of aPTT measurements below the therapeutic range have in fact an effective anti-Xa activity. Thus, the anti-Xa activity has become our reference test since 2000, and the therapeutic range applied to our patients during TAH is situated between 0.2 and 0.3 IU/mL. Finally, as both these modifications have been made to the anticoagulation protocol, the rate of repeat surgery has decreased from 58% to 38% ($p = 0.16$).

Hemodynamic instability during repeat surgeries for hemorrhage and increased hemodialysis risk [17] subsequent to the use of aprotinin have irreparably damaged a renal function already altered by the cardiac insufficiency. Indeed, the mean preimplantation level of creatinine among patients who underwent dialysis during CardioWest support was 190 ± 103 μmol/L.

Although 80% of patients presented with septic problems, infectious complications associated with the assistance device were low (14% drive infection and 4.7% mediastinitis) despite repeat surgeries for hemorrhage and a mean support duration of 101 ± 86 days. The high incidence of pulmonary infections reflects the long intubation period of these patients who stayed in the intensive care unit for a mean duration of 49 days. Concerning the 3 patients with neurologic events, only 1 patient presented a true neurologic deficiency at postimplantation day 102. The other two cases were related to a preimplantation cardiocirculatory arrest or to a perioperative event with no direct connection to the assistance. Nevertheless, for transparency of the results, we related them to the artificial heart. No brain hemorrhage was diagnosed during follow-up. Although anecdotal, the spontaneous spleen rupture complicated by a hemoperitoneum could be operated on emergently, and the patient underwent transplantation 3 months after abdominal surgery in satisfactory conditions. He is currently asymptomatic with a 2-year-follow-up. This clinical case proves that even severe digestive hemorrhage with hemoperitoneum can be correctly dealt with during CardioWest circulatory support.

Despite all these adverse events while receiving support, greater than 70% of patients have reached heart transplantation in good conditions, and posttransplantation hospital mortality was 10%. At late follow-up, results were exceptional with a survival rate of 90%, 81%, and 76% at 1, 5, and 10 years, respectively, for these patients. Concerning survival, these results confirm the fact that circulatory support as a bridge-to-transplant does not represent a mortality risk factor after heart transplantation as shown by Baron and associates [18] in a series of 404 patients. Despite the high proportion of hemodialysis during CardioWest support in our study, renal function recovery was almost complete after transplantation as only 1 patient was still undergoing dialysis 1 year after heart transplantation (data not shown).

In conclusion, we believe CardioWest TAH is an excellent device for decompensating patients with biventricular failure. It restores optimal hemodynamic function and promotes end-organ recovery. Our experience documents its safety, reliability, and efficacy even in cases of serious adverse events like bleeding or renal insufficiency. With a rate of survival to transplantation of 71.5% and a long-term survival after transplantation of 76% at 10 years, the CardioWest confirms its excellent position in the field of bridge-to-transplantation device for patients with irreversible biventricular failure.

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DISCUSSION

DR MARC MOON (St. Louis, MO): Oftentimes when we are going to put an assist device into a patient as a bridge to transplant, we will put an LVAD (left ventricular assist device) in first, and if the right ventricle then fails, we will put in an RVAD (right ventricular assist device). It is not necessarily determined ahead of time what we are going to do. Obviously in these patients it has to be determined ahead of time. What kind of criteria do you use to determine a patient who is going to need this device as opposed to an LVAD or LVAD/RVAD?

DR ROUSSEL: First of all, according to our policy, we think the CardioWest total artificial heart is the device of choice in an acute situation. Because we had such good results with the CardioWest, our team was feeling more confident with this device. It wasn't our policy to try to assist the patient with an LVAD and then bridge to a BVAD (biventricular assist device).

DR EVGENIJ POTAPOV (Berlin, Germany): I have a question about the size of the Jarvik, because in Berlin we sometimes have a problem with shrinking of the pericardium after long-term CardioWest assistance and some problems in implanting a donor heart into this shrinking pericardium. Do you have this problem and how do you solve this problem?

DR ROUSSEL: Absolutely, it is often the case. Unfortunately we lost 1 patient a few months ago. After a few months of device support, the pericardial cavity was shrinking. He was a big man with a large body surface area, and it was really difficult to put in the graft, and I think we had cardiogenic shock after the heart transplantation due to the compression of the graft. But it is a true problem.

DR POTAPOV: And do you know the solution for this?

DR ROUSSEL: We try to open as much as possible the pleural cavity.

DR POTAPOV: We tried putting some breast implants into the pericardial cavity at the time of CardioWest implantation to keep the cavity, to preserve it from shrinking, but we have no such large experience. That may be one of the solutions.

DR ROUSSEL: It is a clever solution.

DR POTAPOV: Thanks. It is not mine. It is Professor Hetzer's.

DR PEI H. TSAU (Tucson, AZ): Just a comment on the shrunken pericardial space. What we have done with that is we actually open up the left pericardium, just take the whole thing down, down to the phrenic nerve. That way we allow a space for the donor heart to basically go in. If that is not enough, we will take down the right side pericardial space to allow the donor heart.

DR MOON: You mean when you are doing the transplant?

DR TSAU: When we are doing the transplant, yes.

Now, as far as the comment about selecting whether or not the CardioWest versus BVAD versus just uni-VAD preoperatively, we actually have this algorithm at the University of Arizona that we go through that looks at, whether or not just by echo[cardiography], Mvo_2 (mixed venous oxygen), and MUGA (multiple gated acquisition) scan, any evidence of right ventricular failure. If the patient has evidence of right ventricular failure with right-sided but very dilated high CVP (central venous pressure), we will go ahead and be more aggressive about just going in and preferably putting in a BVAD instead of just an LVAD.

DR MOON: Do you have data on that published?

DR TSAU: Yes.

DR MOON: Are you one of the coauthors?

DR TSAU: Yes.

DR MOON: Okay.

DR O. H. FRAZIER (Houston, TX): This pump is, and always has been, a great technology for just what you described. Except for the group in Utah, the total artificial heart program was abandoned in the US in 1969. We believed that an electrically powered, untethered, implantable left ventricular assist device would allow patients to receive enough support for hospital discharge even to be considered. It simply did not seem feasible or practical that the tethered TAH would allow patients to return to productive, outpatient lives. Doctors Kolff, Jarvik, DeVries, and many others did a great job in keeping this research going. This important work to develop a TAH has continued with Dr Copeland's and your groups.

Clearly, for the mortally ill patient with a heart that has been destroyed by disease it is best to remove the native heart and capture both right and left ventricular function simultaneously, especially since RVAD/LVAD combinations have historically been associated with a poor prognosis.

One approach to the problem of pump size when the heart is replaced by a large pulsatile pump is to separate the atria. Have you tried this approach? You can sew the pumps on after separating the atria, which makes a little more room by allowing for greater flexibility for displacing the pumps into the right and left chest. The foramen ovale is the only tissue the two atria have in common and must be allocated to the right or left side. I prefer to leave it on the left side.

Have you discharged any of these patients? Discharge remains the greatest barrier to use of the technology in the US, although the barrier is artificial. Because we can't discharge these patients, we have problems with excessive costs that must be borne by the hospital.

DR ROUSSEL: For your first question, we didn't try to separate both atria, mainly because we didn't know this technique.

And for your second question, unfortunately it was impossible to discharge patients on support because we didn't have the console to allow them to go back home, but in the next future I hope we will have this console.