

# Ventricular Assist Devices As a Bridge to Transplantation

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We carried out an analysis of the results obtained in patients (n=23) who received a ventricular assist device before heart transplantation between 1988 and 2005. Their mean age was 52.5 (8.4) years. Reasons for inclusion in the transplantation waiting list were postcardiotomy referral (n=10), myocardial infarction (n=5), primary graft dysfunction (n=7), and dilated cardiomyopathy (n=1). Different types of ventricular assist device were used: the Abiomed 5000 (n=13), the Biomed Comunidad de Madrid (n=9), and the BioMedicus (n=1). The mean transplantation waiting time was 3.0 (2.4) days. In-hospital complications were neurological (n=7), infectious (n=12), renal (n=3), hemorrhagic (n=3), and respiratory (n=2). In-hospital mortality was 39.1% (n=9). Kaplan-Meier analysis gave a 1-year survival rate of 55.2% and a 5-year survival rate of 32.2%. In patients who were discharged home, the 1-year survival rate was 92.3%. Careful patient selection is essential for obtaining good results.

**Key words:** Ventricular assist device. Heart failure. Shock. Heart transplantation.

## Asistencia ventricular mecánica como puente al trasplante

Se analizan los resultados obtenidos en los pacientes con trasplante de corazón tras recibir asistencia ventricular entre 1988 y 2005 (n = 23). La edad media fue de 52,5 ± 8,4 años. Los motivos de inclusión en la lista de trasplante fueron: poscardiotomía (n = 10), infarto de miocardio (n = 5), disfunción primaria del injerto (n = 7) y miocardiopatía dilatada (n = 1). Los modelos de asistencia fueron BioMed Comunidad de Madrid (n = 9), ABIOMED 5000 (n = 13) y BioMedicus (n = 1). El tiempo en alerta cero fue de 3 ± 2,4 días. Las complicaciones intrahospitalarias fueron: neurológicas (n = 7), infecciosas (n = 12), renales (n = 3), hemorrágicas (n = 3) y respiratorias (n = 2). La mortalidad intrahospitalaria fue del 39,1% (n = 9). El análisis de Kaplan-Meier mostró una supervivencia al año del 55,2% y a los 5 años del 32,2%. En los pacientes que recibieron el alta domiciliaria, la supervivencia al año fue del 92,3%. Una adecuada selección de los pacientes es vital para la obtención de buenos resultados.

**Palabras clave:** Asistencia circulatoria. Insuficiencia cardíaca. Shock. Trasplante cardíaco.

## INTRODUCTION

Cardiogenic shock is associated with high mortality.<sup>1</sup> In the majority of studies published, the incidence of post-cardiotomy heart failure is 0.2%-1.2%.<sup>2</sup> When all other therapeutic options have been ineffective, the only remaining course open is transplantation,<sup>3</sup> and until a donor becomes available, hemodynamic stability will need to be maintained mechanically. In this respect, ventricular assist devices are able to efficiently replace heart function,<sup>4-6</sup> and their use as a bridge to transplantation is a good option in patients with refractory

cardiogenic shock.<sup>6,7</sup> Currently, some 300 heart transplants are performed annually in Spain, about 30% of which are urgent — a figure that seems to be progressively increasing.<sup>8</sup> However, in this country there is little experience in the use of ventricular assist devices as a bridge to transplantation. The aim of the present paper is to describe our experience in the use of these devices, and to analyze the post-transplantation survival and prognosis of patients in whom these devices were used.

## METHODS

The study subjects were patients who, between 1988 and 2005, were implanted with a ventricular assist device due to cardiogenic shock, and who later underwent heart transplantation (n=23). The indications for the implantation of a ventricular assist device were those established by the majority of expert groups.<sup>9</sup> In all

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Received November 29, 2005.

Accepted for publication March 15, 2006.

**TABLE 1. Characteristics of the 23 Patients Who Underwent Heart Transplantation After Receiving a Ventricular Assist Device\***

Clinical Characteristics	n (%)
Diagnosis	
Post-cardiotomy	10 (43.5%)
Primary graft failure	7 (30.4%)
Acute myocardial infarction	5 (21.7%)
Dilated cardiomyopathy	1 (4.3%)
Diabetes mellitus	7 (30.4%)
Smokers	10 (43.5%)
High blood pressure	5 (21.7%)
Dyslipidemia	4 (17.4%)
Peripheral vascular disease	2 (8.7%)
COPD	–
Abnormal hepatic enzymes†	17 (73.9%)
High bilirubin level (>1 mg/dL)	8 (36.4%)
Pre-transplantation dialysis	1 (4.3%)
Hyperuricemia	1 (4.3%)

\*COPD indicates chronic obstructive pulmonary disease

†GOT/GPT higher than normal levels.

patients the ejection fraction was <20%; all were in critical clinical condition.

The mean age of the patients (12 men, 9 women) was 52.5 (8.4) years. Table 1 shows the basic clinical characteristics of each patient and the reason for implanting the ventricular assist device. The models implanted were: BioMedicus (n=1; left ventricle), Biomed Comunidad de Madrid (BCM) (n=9; 8 left ventricle, 1 biventricular) and ABIOMED BVS (n=13; 3 left ventricle, 1 right, and 9 biventricular). The BCM system was developed by Spanish scientists and provides excellent results.<sup>10</sup> The ABIOMED BVS 5000 has been used since 1995 in patients in whom a recovery of the myocardium is expected, and in those awaiting transplantation.<sup>11</sup>

Kaplan-Meier curves were used to predict survival. The logarithmic rank test was employed to compare the stratification of groups according to the etiology of heart dysfunction. Significance was set at  $P<.05$ .

## RESULTS

Between August 1988 and July 2005, 23 patients implanted with ventricular assist devices underwent a heart transplantation (6.8% of all the heart transplants at our center). The mean number of days that patients were maintained on these devices was 4.7 (4.2). The mean length of time for a donated organ to become available once patients were included on the waiting list was 3 (2.4) days.

Table 2 shows the complications experienced and the postoperative mortality figures. The in-hospital mortality

**TABLE 2. Postoperative Complications and Cause of Death in Patients Who Underwent Heart Transplantation After Receiving a Ventricular Assist Device**

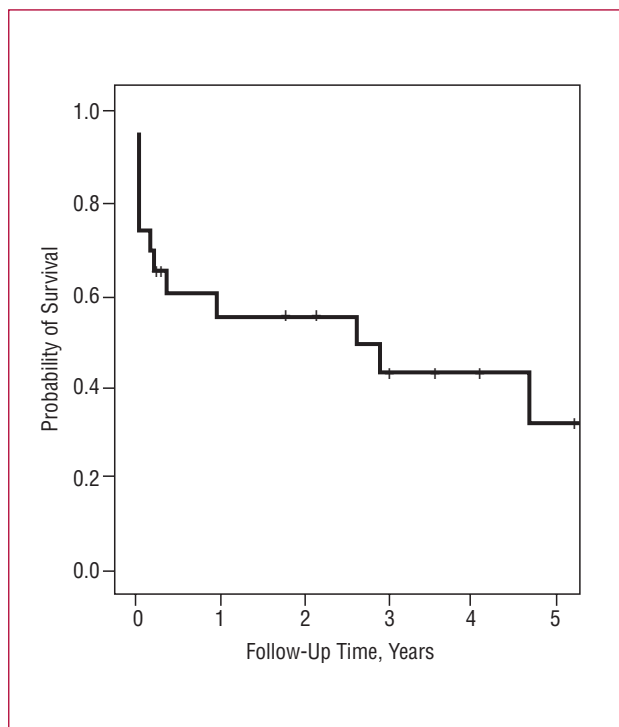
Complications	n (%)
Complications	
Neurological	7 (30.4%)
Pneumonias	12 (52.2%)
Need for a tracheotomy	2 (8.7%)
Kidney failure	3 (13%)
Re-intervention for bleeding	3 (13%)
Cause of death	
Primary graft failure	3 (13%)
Neurological	3 (13%)
Multi-organ failure	2 (8.7%)
Septic shock	3 (13%)

rate was 39.13% (n=9). Two patients (8.7%) died in the first 24 h following transplant. No in-hospital deaths were recorded from the year 2000.

Overall one year survival was 55.2%; overall five year survival was 32.2% (Figure). When only the patients who were eventually discharged are taken into account (n=14), one year survival reaches 92.3%. No significant differences were seen in survival with respect to the reason for being included on the waiting list (primary graft failure compared to all other causes; logarithmic rank test 0.4;  $P=.52$ ). Better survival rates were seen in patients treated after 1995 (n=13;  $P<.05$ ).

## DISCUSSION

The scientific community has designed a number of mechanical devices that can be used to take over the function of the heart. The ABIOMED BVS 5000 has been used in our patients since 1995; this device is designed to assist the heart for a short period and has the advantages of being easy to use and relatively inexpensive.<sup>11-14</sup> When choosing a device, its functional characteristics should be appropriate for the length of the waiting list in the country where transplantation is to be performed.<sup>8</sup> In Germany, El-Banayosy et al<sup>18</sup> report they use the ABIOMED system only when a short period of ventricular assistance is envisaged. Spain is one of the countries with the highest number of donors.<sup>15</sup> This means that the waiting period until a heart becomes available is shorter than in other nations. This is particularly true for emergency patients, who are awarded national priority (the mean waiting time was 3 days in the present study). If, as in other countries, waiting times are longer, the use of longer-duration assist devices may be required.



**Figure 1.** Five year survival curve for patients who underwent a heart transplant after implantation with a ventricular assist device (n=23). Survival at 1 and 5 years was 55.2% and 32.2%, respectively.

Fifty three ventricular assist devices have been implanted in patients at our center since 1988; 23 of these patients (43.4%) later went on to receive a new heart. In our opinion, and in agreement with other authors,<sup>16</sup> good results are achieved when technological improvements are accompanied by medical staff gaining continued experience. In the present study, only 2 patients who underwent a transplant since 1999 (n=8) died in hospital. In agreement with that proposed by many authors, the proper selection of patients is also vital if good results are to be obtained.<sup>16</sup> Given the possibility that the number of donors may become smaller over the next few years,<sup>8</sup> patient selection may become especially important.

Some authors have described the survival rates achieved after the use of ventricular assist devices as a bridge to transplantation in more heterogeneous patients.<sup>4,13,17</sup> Navia et al<sup>4</sup> report a post-transplantation one year survival of 69%.<sup>4</sup> Samuels et al<sup>12</sup> described their experience with 45 patients assisted with the ABIOMED BVS 5000 system, 31% of whom were eventually discharged. In the present work, 1 year survival was 55.2%, and 5 year survival 32.2%; early mortality was 39.1%. The 1 year survival of the patients who were eventually discharged was 92.3%. Few would have likely survived if they had not received circulatory assistance as a bridge to transplantation.

The data actually appear to indicate that survival is better among patients transplanted due to primary graft failure, but this difference is not significant. It should also be noted that the groups compared were small.

In conclusion, in patients with refractory cardiogenic shock, the implantation of a ventricular assist device as a bridge to transplantation can be an effective course of action. The present patients showed 1 and 5 year survival rates of 54% and 31%, and among those who were discharged, the 1 year survival rate was 92.3%. The proper selection of patients and the type of device to be implanted is essential if good results are to be obtained.

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