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Heart Transplantation in Patients with End-Stage Heart failure and Cardiac Ascites

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ABSTRACT

Objective: Donor shortage and improved medical treatment of heart failure increase the prevalence of patients with end-stage heart failure and cardiac ascites to heart transplantation. The clinical outcome of heart transplantation in these patients has not been reported. Here, we sought to evaluate the clinical outcome of heart transplantation in patients with end-stage heart failure and ascites.

Methods: Data were collected by retrospective chart review.

Results: Between 1989 and 2005, 45 patients with end-stage heart failure and moderate to severe ascites underwent orthotopic heart transplantation. There were 33 men and 12 women with median age of 44 years (range 10-63 years). The causes of heart failure were congenital heart disease in 4 patients (9%), dilated cardiomyopathy in 21 patients (47%), rheumatic heart disease in 7 patients (16%), coronary artery disease in 10 patients (22%), and restrictive cardiomyopathy and transplant coronary artery disease each in 1 patient. Twenty of 45 patients (44%) had previous cardiac operation. There were 10 in-hospital deaths (22%): bleeding in 4 patients, sepsis with multiple organ failure in 5 patients and non-diagnostic graft failure in 1 patient. Profuse postoperative bleeding requiring reoperation occurred in 14 patients (31%). The independent risk factors for hospital death were low serum albumin (odds ratio, 0.05; 95% confidence interval, 0.003-0.591; p=0.018) and reoperation for bleeding (odds ratio, 30.11; 95% confidence interval, 2.38-380.26; p=0.009).

Conclusions: Heart transplantation in patients with end-stage heart failure and ascites was associated with high hospital mortality and morbidity. The co-existence of cardiac ascites and hypoalbuminemia implied poor prognosis.

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Ultramini-abstract

Between 1989 and 2005, 45 patients with end-stage heart failure and ascites underwent orthotopic heart transplantation. Heart transplantation in patients with end-stage heart failure and ascites was associated with high hospital mortality and morbidity. The co-existence of cardiac ascites and hypoalbuminemia implied poor prognosis.

Introduction

The continuous improvement in clinical outcome after heart transplantation has established heart transplantation as a standard and efficient therapy for end-stage heart failure [1]. Long-term survival is limited by transplant coronary artery disease and the complications produced by the toxicities of maintenance immunosuppression [1-3]. In recent decades, survival after heart transplantation is gradually improving, and there is increasing patient risk profiles before transplantation [4]. The increasing patient risk profiles include previous cardiac operations, use of mechanical assist devices, diabetes mellitus, critically ill recipients, high pulmonary vascular resistance, prior sensitization, long allograft ischemic time, and use of nonstandard or marginal donors [4]. Both donor shortage and improved medical treatment of end-stage heart failure will increase the prevalence of patients with severe or late-stage heart failure to heart transplantation. Right ventricular failure and cardiac ascites occur as late complications of end-stage heart failure, and its development usually reduces patient survival [5-7]. Cardiac ascites and cirrhosis might develop in patients with a long history of congestive heart failure and systemic venous hypertension [8,9]. The clinical outcome of heart transplantation in these patients has not been reported in series [10]. Here, we sought to evaluate the clinical outcome of heart transplantation in patients with end-stage heart failure and cardiac ascites.

Patients and Methods

Patients. A total of 241 consecutive patients underwent heart transplantation from June 1989 through July 2005 at National Taiwan University Hospital. Patients with moderate to massive ascites before transplantation were included in this study.

Definitions. The diagnosis of cardiac ascites was based on clinical history, physical examination and findings of abdominal sonography. Patients with liver cirrhosis secondary to hepatitis virus infection or alcoholism were excluded from transplant candidates. The diagnosis of liver cirrhosis was based on ultrasonic findings [11-13]. The cause of ascites was considered as cardiac if patients had severe congestive heart failure and no evidence of alcoholic or post-hepatitis liver cirrhosis. None of our patients received liver biopsy to confirm the diagnosis of liver cirrhosis.

Data on age, sex, diagnosis of heart disease, renal and liver function tests, hemodynamics, allograft ischemic time, and clinical outcome were recorded. Data of right atrial pressure, transpulmonary gradient and pulmonary vascular resistance were derived from cardiac catheterization. The severity of liver function impairment was graded according to the Child-Pugh score [14].

Heart transplantation. All of the procedures of heart transplantation were performed through a median sternotomy. The techniques of cardiopulmonary bypass were described previously [15]. The operative techniques of heart transplantation in patients with prior cardiac operation were similar to that in patients receiving transplantation as a first cardiac

procedure. In patients with previous cardiac operation, we spent a liberal time for tissue dissection and relief of dense adhesion. Preliminary exposure of femoral vessels was performed in cases with a high risk of severe hemodynamic compromise during re-sternotomy. Femorofemoral cardiopulmonary bypass can be instituted very rapidly if needed.

Immunosuppression

All patients received triple-drug immunosuppressive therapy according to our heart transplantation protocol previously described [16,17]. Since 1995, we started to use rabbit antithymocyte globulins for induction therapy. Azathioprine (4mg/kg) was given one hour before the operation. Solumedrol (1000mg) was infused while release of the aortic cross-clamp. Rabbit antithymocyte globulin (1.5-2.5 mg/kg/day) was given after transplantation for five days. Cyclosporine was started orally within five days after transplantation or after the recovery of renal function. Cyclosporine dose was adjusted according to renal function and serum cyclosporine level, which was maintained at the trough level of 300-500 ng/ml during the first three months after transplantation and 200-300ng/ml one year after transplantation. Azathioprine was given at 1-2 mg/kg/day after transplantation, with the dose adjusted to maintain a white blood cell count 4000-6000/mm3. Prednisone (0.5mg/kg/day) was started on the second postoperative day and tapered to 0.2 mg/kg/day by the first month after transplantation. Tacrolimus (FK-506) and mycophenolate mofetil

(Cellcept) were used for recurrent rejection or severe adverse reactions to cyclosporine and azathioprine. Since 2004, we started to use mycophenolate mofetil for primary immunosuppression instead of azathioprine. To prevent nephrotoxicity, cyclosporine dose was decreased to maintain serum trough level of 250-350 ng/ml during the first three months after transplantation and 150-250 ng/ml one year after transplantation.

All patients were followed monthly at special cardiac transplantation clinic. Standard chest roentgenogram, blood tests, electrocardiogram and physical examinations were routinely performed at regular intervals.

Statistical analysis. The results are expressed as median with a range or as frequencies for the categorical variables. Data analysis was performed using the Chi-square test, Fisher's exact test and Mann-Whitney test. Univariate and multivariate stepwise logistic regression was used to identify independent risk factors for hospital death. The patient and graft survival curve was plotted by the Kaplan-Meier method. Survival was compared by log-rank test between patients with and without ascites. $P \leq 0.05$ was considered statistically significant.

Results

Patient characteristics. From 1989 through 2005, 241 patients with end-stage heart failure underwent heart transplantation. There were 198 men and 43 women, and the median age was 49 years (range 0-71 years). The causes of heart failure were congenital heart disease in 8 patients (3%), dilated cardiomyopathy in 134 patients (56%), coronary artery disease in 69

patients (29%), and others. Eight patients received a re-transplantation and 4 patients received combined heart-kidney transplantation. None of the patients had signs of chronic hepatitis virus B or C infection. Chronic alcohol abuse was denied by all patients.

Forty-five patients with end-stage heart failure had moderate to massive ascites before transplantation. The rate of transplant patients with ascites increased slightly from 14% (14/102) during the 1989 to 1998 to 22% (31/139) during the 1999 to 2005. There were 33 men and 12 women, and the median age was 44 years (range 10-63 years). The causes of heart failure were congenital heart disease in 4 patients (9%), dilated cardiomyopathy in 21 patients (47%), rheumatic heart disease in 7 patients (16%), coronary artery disease in 10 patients (22%), and restrictive cardiomyopathy and transplant coronary artery disease each in 1 patient. Patient demographics and laboratory data before transplantation were listed in Table 1. Twenty of 45 patients (44%) had previous cardiac operation including 2 multiple valve replacements, 1 coronary artery bypass surgery, 1 total cavopulmonary connection, 1 Fontan operation, 1 Rastelli operation, 1 heart transplantation, and 1 Senning operation. The median level of serum total bilirubin was 1.9 mg/dl (range, 0.5 to 9.6); serum albumin, 3.4 g/dl (range, 1.4 to 4.8); serum blood urea nitrogen, 26 mg/dl (range, 9.6 to 109); serum creatinine, 1.3 mg/dl (range, 0.49 to 11); serum asparate aminotransferase, 34 U/L (range, 12 to 223), and serum alanine aminotransferase, 21 U/L (range, 7 to 196). Twenty patients (44%) had the prothrombin time prolongation more than 4 seconds. The findings of preoperative

abdominal sonography were moderate ascites in 23 patients and massive ascites in 22 patients. Two patients had cardiac cirrhosis before transplantation. The median level of Child score was 9 (range, 6 to 12).

Before transplantation, 13 patients were in UNOS status IA, 14 patient in UNOS status IB, and 18 patients in UNOS status II. Before transplantation, 9 patients had endotracheal intubation and mechanical ventilation, 4 patients had intra-aortic balloon pump, 5 patients had mechanical support with extracorporeal membrane oxygenation, 1 patient had ventricular assist device, and 4 patients required dialysis treatment because of anuria.

Among donors, there were 33 men and 12 women, and the median age was 27 years (range, 7 to 66). ABO blood types between donors and recipients were identical in 35 cases and compatible in 10 cases. The body weight ratio between donors and recipients ranged from 0.72 to 1.74. The median duration of allograft ischemic time was 160 minutes (range, 40 to 320). All patients underwent orthotopic heart transplantation. One patient who had transplant coronary artery disease and severe renal impairment underwent combined heart and kidney transplantations.

Clinical outcomes. For all patients, there were 30 hospital deaths (12%). For 45 transplant patients with cardiac ascites, there were 10 hospital deaths (22%) occurring between 1 and 152 days after transplantation (Table 1). Patients with cardiac ascites had a higher hospital mortality rate than patients without ascites (22% vs 10%; p=0.042 by Fisher exact test). The

causes of hospital death in patients with cardiac ascites were bleeding in 4 patients, sepsis with multiple organ failure in 5 patients and non-diagnostic graft failure in 1 patient. Profuse postoperative bleeding requiring reoperation occurred in 14 (31%) of 45 patients with cardiac ascites. Autopsy was performed in 4 of 10 patients with hospital death. Pathological examination of the livers in these patients showed pictures of cardiac cirrhosis with centrilobular necrosis and varying degree of fibrosis.

Follow-up was complete in all patients. The mean duration of follow-up was 50.6 ± 43.8 months. For all patients, the 6-month, 1-year, 3-year, 5-year, and 10-year patient and graft survival rates were 86.2 ± 2.2%, 81.8 ± 2.5%, 71.0 ± 3.1%, 62.8 ± 3.5%, and 44.1 ± 5.3%. For 45 patients with cardiac ascites, the 6-month, 1-year, 3-year, 5-year, and 10-year patient and graft survival rates were 75.4 ± 6.4%, 70.1 ± 7.0%, 70.1 ± 7.0%, 61.6 ± 8.4%, and 51.2 ± 9.7% (Figure 1). For 196 patients without ascites, the 6-month, 1-year, 3-year, 5-year, and 10-year patient and graft survival rates were 88.7 ± 2.3%, 84.4 ± 2.6%, 71.4 ± 3.5%, 63.2 ± 3.9%, and 42.7 ± 6.1% (Figure 1). As shown in Figure 1, patients with cardiac ascites had lower 6-month and 1-year patient and graft survival rates than patients without ascites. The survival curves showed no difference since 3 years after transplantation.

Among patients with cardiac ascites, there were 7 late deaths. The causes of late death were sudden death in 3 patients, sepsis with multiple organ failure in 2 patients, non-diagnostic graft failure in 1 patient, and transplant coronary artery disease in 1 patient.

Risks of hospital death. As shown in Table 1, patients with hospital death had more congenital heart disease, low recipient and donor body weight, low serum albumin, massive ascites, low Child score, and high incidence of postoperative reoperation for bleeding. In multivariate logistic regression analysis, the independent risk factors for hospital death were low serum albumin (odds ratio, 0.05; 95% confidence interval, 0.003-0.591; p=0.018) and reoperation for bleeding (odds ratio, 30.11; 95% confidence interval, 2.38-380.26; p=0.009).

Discussion

Heart transplantation. The clinical outcome of heart transplantation is improving. The 30-day survival rate improved from 84% during the early 1980 to 91% during the late 1990 [1]. The overall 1-year, 5-year and 10-year survival rates for heart transplantation were 80%, 70% and 50% [1]. However, the long-term survival remains unchanged in spite of the ongoing stepwise improvement in early transplant survival. The survival rate for the entire patient cohort of the worldwide registry showed that, after the steep fall in survival during the first 6 months, the survival decreases at a linear rate of 3.4% per year [18]. We had a similar result with the hospital survival rate of 88% and the 1-year patient and graft survival rate of 81.8%.

In view of increasing donor shortage, it is imperative to allocate organs to patients with the greatest need and the greatest chance to derive the maximum benefit [19]. But, the quest for reducing the early mortality rate should not be at the expense of needy patients by being

over-selective in transplant candidates [20]. The risk factors for early mortality included old donor age, old recipient age, having congenital heart disease or coronary artery disease as the indication for heart transplantation, requiring mechanical circulatory support (temporary or pulsatile ventricular assist device), mechanical ventilation, or dialysis at the time of transplant, hospitalized at transplant, prolonged allograft ischemic time, and renal or hepatic dysfunction at the time of transplant [18]. However, the impact of cardiac ascites on the survival of heart transplantation has not been evaluated. In this study, we first demonstrated that the presence of moderate to massive cardiac ascites at the time of transplant was a significant risk factor for hospital death and early mortality after heart transplantation. The significant reduction of patient and graft survival was sustained till 3 years after transplantation.

Ascites. Cardiac ascites and cirrhosis usually develop in patients with a long history of congestive heart failure [5-9]. The occurrence of signs and symptoms of right ventricular failure with ascites and high right atrial pressure is a well-known poor prognostic sign in patients with end-stage heart failure. In a previous study, patients with a right atrial pressure > 12 mmHg had a 47% 1-year survival rate as compared with the 68% survival rate for those with a right atrial pressure < 12 mmHg [21]. Elevated right atrial pressure resulting from right ventricular failure was also associated with a significantly increased risk of early death after heart transplantation [22]. In addition, liver insufficiency with prolonged prothrombin time or elevated serum levels of liver enzymes before transplantation was an independent

predictor of early death after heart transplantation [23]. Prolonged right ventricular failure and systemic venous hypertension will lead to cardiac cirrhosis. Severe bleeding and infection were usually the terminal events. Cardiac cirrhosis was found at autopsy in 75% of the early deaths of heart-lung transplant recipients with right ventricular failure and hyperbilirubinemia [24]. In our study, 31% of patients with cardiac ascites required reoperation for profuse postoperative bleeding. Bleeding and sepsis accounted for 9 of 10 hospital death in patients with cardiac ascites. Although preoperative abdominal sonography in 43 of 45 patients with cardiac ascites showed no liver cirrhosis, congestive liver fibrosis (cardiac cirrhosis) was confirmed in 4 patients on postmortem pathological examination. Cardiac cirrhosis is a clinically silent disorder characterized by a spectrum of morphologic alterations in the liver ranging from mild deposition of sinusoidal collagen to emergence of broad fibrous septa [25,26]. Occurrence of cardiac ascites is the hallmark of cardiac cirrhosis [9]. Laboratory tests have a little role in the diagnosis of cardiac cirrhosis. In the majority of patients with cardiac cirrhosis, serum levels of liver enzymes, bilirubin, and albumin are within the normal range [9]. Ascites is also a manifestation of congestive heart failure and reflects longstanding systemic venous hypertension. The clinical pictures of cardiac cirrhosis usually are masked by symptoms and signs of right ventricular failure. A liver needle biopsy may be required to evaluate the presence and severity of cardiac cirrhosis in patients with cardiac ascites.

Hypoalbuminemia. Child-Pugh score is significantly associated with hepatic decompensation and mortality after cardiac surgery in patients with cirrhosis. Patients with a Child-Pugh score $\geqq$ 8 have a high mortality rate of 67% [27]. In this study, Child-Pugh score was associated with a high hospital mortality rate (Figure 1).

Preoperative serum albumin was used to quantify nutritional status and underlying disease. An albumin level of less than 2.5 g/dL was independently associated with increased risk of reoperation for bleeding, postoperative renal failure, and prolonged ventilatory support, intensive care unit stay, and total length of stay after cardiac surgery [28]. Hypoalbuminemia was a powerful risk factor for perioperative complications in elderly patients and children undergoing cardiac surgery [29,30]. Dichtl et al [31] reported no perioperative mortality after heart transplantation in patients with cardiac hepatopathy and normal plasma protein levels. In our study, hypoalbuminemia was the most powerful risk factor for hospital death after heart transplantation. Nine of 25 patients (36%) with cardiac ascites and serum albumin < 3.5 g/dl had hospital death, and only 1 of 20 patients (5%) with ascites and serum albumin > 3.5 g/dl had hospital death. The co-existence of cardiac ascites and hypoalbuminemia was associated with poor hospital outcome.

Study limitation. This study was limited by small case number and retrospective study. In addition, the duration of right ventricular failure was unknown and the diagnosis of cardiac cirrhosis was not confirmed by liver biopsy. Liver biopsy was associated with high rate of

complications in patients with advanced liver dysfunction [32]. Although our results were preliminary, this was the first study of heart transplantation in patients with end-stage heart failure and cardiac ascites. Patients should be carefully selected for heart transplantation, especially in patients with cardiac ascites and serum albumin < 3.5 g/dl. Because the hospital mortality rate was not low in patients with cardiac ascites and normal serum albumin, we recommended that an invasive liver biopsy may be indicated only in patients with cardiac ascites and hypoalbuminemia before transplantation.

Conclusions. Heart transplantation in patients with end-stage heart failure and ascites was associated with high hospital mortality and morbidity. The co-existence of cardiac ascites and hypoalbuminemia implied poor prognosis.

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Table 1. Patient characteristics in 45 patients with cardiac ascites: comparison between patients with and without hospital death by Fisher exact test and Mann-Whitney U test.

Variables	Died (n=10)	Alive (n=35)	P-value
Male	5 (50%)	28 (80%)	0.101
Median age in years (range)	40 (17-60)	45 (10-63)	0.4443
Diagnosis of heart disease			
Dilated cardiomyopathy	2 (20%)	19 (54%)	0.078
Coronary artery disease	2 (20%)	8 (23%)	0.999
Rheumatic heart disease	3 (30%)	4 (11%)	0.172
Congenital heart disease	3 (30%)	1 (3%)	0.03
Others	0	3	
Body weight in kilograms	48.95 (32-65)	59.8 (23-100)	0.026
Blood type-identical	8 (80%)	27 (77%)	0.999
Previous cardiac operation	7 (70%)	13 (37%)	0.083
Diabetes mellitus	3 (30%)	6 (17%)	0.393
Donor-age in years	25.5 (12-66)	27 (7-58)	0.6324
Donor-male	7 (70%)	26 (74%)	0.999
Donor-body weight in kilograms	55 (45-70)	65 (20-85)	0.0105
Recipient/donor body weight ratio	1.1 (0.78-1.5)	1.08 (0.72-1.74)	0.5755
Serum albumin (g/dl)	2.8 (1.4-3.73)	3.7 (2.2-4.8)	0.0005
Serum total bilirubin (mg/dl)	1.1 (0.5-6.27)	2.1 (0.5-9.6)	0.6522
Serum asparate aminotransferase (U/L)	37.5 (16-96)	34 (12-223)	0.7431
Serum alanine aminotransferase (U/L)	21.5 (9-72)	21 (7-196)	0.6036
Serum blood urea nitrogen (mg/dl)	29 (13.7-85)	24.3 (9.6-109)	0.6039
Serum creatinine (mg/dl)	1.25 (0.6-3.19)	1.3 (0.49-11)	0.8695
Prothrombin time prolongation > 4 seconds	3 (30%)	17 (49%)	0.473
Ascites-massive	8 (80%)	14 (40%)	0.035
Child-Pugh score	9.5 (7-12)	8 (6-12)	0.0286
UNOS status IA or IB	7 (70%)	20 (57%)	0.606
Right atrial pressure	19 (8-26)	20 (6-36)	0.902
Transpulmonary gradient	9 (4-20)	8 (0-28)	0.6614
Allograft ischemic time	205.5 (40-279)	143 (57-320)	0.6328
Reoperation for bleeding	8 (80%)	6 (17%)	<0.001

Figure legends

Figure 1. Patient and graft survival curves plotted by Kaplan-Meier method in patients with and without cardiac ascites.