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Does A Pre–Left Ventricular Assist Device Screening Score Predict Long-Term Transplantation Success? A 2-Center Analysis

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ABSTRACT

Background. A risk factor summation score was previously validated to successfully predict survival after insertion of a left ventricular assist device (LVAD). We investigated whether this scoring system also predicts clinical outcomes after eventual heart transplantation in LVAD recipients.

Methods. A retrospective review was performed on 153 consecutive patients who received an LVAD as a bridge to transplantation at 2 large-volume centers from 1996 to 2003. The scoring system was used to designate low- and high-scoring groups.

Results. Thirty-day mortality and 5-year survival after transplantation were equivalent between groups (4.46% versus 7.32% and 76% versus 70%, respectively). No difference was seen in length of posttransplantation ventilator dependence (2.83 ± 0.49 versus 3.3 ± 0.72 days) or intensive care unit monitoring (6.38 ± 0.77 versus 6.97 ± 1.1 days). However, low-scoring patients had a significantly decreased duration of inotrope support (5.57 ± 0.45 versus 7.74 ± 1.0 days, $P = .035$).

Conclusion. A risk factor summation score may predict which LVAD patients will require prolonged inotropic support following heart transplantation. However, survival in high-risk (elevated score) LVAD patients following heart transplantation is comparable to low-risk groups, favoring the continued practice of LVAD implantation as a bridge to transplantation even in high-risk patients.

INTRODUCTION

Left ventricular assist devices (LVADs) have become a standard therapeutic strategy to bridge patients with end-stage heart failure to transplantation [Peterze 2002; Kherani 2004]. Despite an increasingly critically ill population in which they are used, the majority of patients undergoing LVAD implantation survive to eventual heart transplantation, and long-term survival may be superior to that of medically managed recipients [Aaronson 2002]. However, controversy remains regarding the optimal timing and patient population in which to perform transplantation after LVAD placement [Gammie 2004].

In 1995, Oz et al developed a scoring system for LVAD recipients to facilitate patient selection and better predict those who would benefit from this intervention [Oz 1995]. As LVAD technology became more advanced and their use was expanded to sicker patients, the scoring system was revised in 2002 to more accurately reflect these changes [Rao 2003]. This scoring system has demonstrated the ability to accurately predict mortality following LVAD implantation. What remains to be seen, however, is whether sicker patients (with higher scores) have comparable survival and morbidity to those with lower scores after undergoing eventual heart transplantation. Addressing this question is the goal of this study.

METHODS

One hundred fifty-three LVAD recipients who underwent cardiac transplantation at 2 institutions, New York Presbyterian Hospital and Columbia University (September 1996-May 2002) and Duke University Medical Center (May 1996-May 2003), were included in this study. The length of follow-up ranged from 456 to 2987 days, with a mean of 1405 days.

The LVAD scoring system currently is based on a scale of 10 points, with an inverse relationship between score and clinical stability [Rao 2003]. At the time of LVAD implantation, 4 points are assigned if the patient is ventilated, 2 points if the implantation is performed in the setting of post-cardiotomy shock, 2 points if the patient already has an extracorporeal LVAD in place, 1 point if the central venous pressure is greater than 16 mmHg, and 1 point if the prothrombin time exceeds 16 seconds. Each patient in this study was assigned to one of 2 groups. The highly scored group (group H) comprised patients with pre-LVAD scores in the range of 6 to 10. The lower-scored group (group L) included patients with scores of 0 to 5.

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Table 1. Patient Characteristics*

	All LVAD Recipients	Group L (Low Score, 1-5)	Group H (High Score, 6-10)	*P*, Group L versus Group H
Age, y†	49.2 ± 1.1	49 ± 1.18	48.9 ± 2.4	.88‡
Sex, n (%)				
Male	127 (83)	99 (88)	28 (68)	.0066§
Female	26 (17)	13 (12)	13 (32)	
Race, n (%)				
White	110 (72)	76 (68)	34 (83)	.0714§
African-American	34 (22)	28 (25)	6 (15)	.1950§
Other	9 (6)	8 (7)	1 (2)	.4458§
Etiology of heart failure, n (%)				
CAD	74 (48)	44 (39)	30 (73)	<.0001§
ICM	76 (50)	66 (59)	10 (24)	.004§
Acute cardiomyopathy (acute MI, presumed myocarditis, post-partum)	19 (12)	14 (12)	5 (12)	.56§
Postcardiotomy shock	23 (25)	1 (1)	22 (54)	<.0001§
LVAD score	3.1 ± 0.12	1.63 ± 0.14	7.2 ± 0.22	n/a
Duration of LVAD support, d	74.7 ± 5	76 ± 5.8	70.3 ± 10	.6‡

*LVAD indicates left ventricular assist device; CAD, coronary artery disease; ICM, idiopathic cardiomyopathy; MI, myocardial infarction.

†Age is given as mean ± standard error.

‡Independent samples *t* test.

§Fisher exact test.

Pertinent clinical demographics and duration of support time were compared between groups. Outcomes measured included 30-day mortality and long-term survival, duration of ventilatory support, duration of inotropic support, and length of stay in the intensive care unit posttransplantation.

Approval for device implantation was obtained from the institutional review board at both institutions, and informed consent was obtained from each patient. The procedures followed were in accordance with institutional guidelines. Categorical data are expressed as absolute or percentage frequency values and were compared with χ^2 or Fisher exact tests where appropriate. Continuous variables are expressed as the mean ± standard deviation (SD) or standard error mean (SEM) and were compared using independent sample *t* tests. For all analyses, $P < .05$ was considered statistically significant. Kaplan-Meier analysis was used to calculate survival along with a log-rank *P* value when comparing groups. Actuarial survival at 1, 3, and 5 years posttransplantation was calculated by constructing life tables. All data were analyzed using GraphPad Prism software (GraphPad Software, San Diego, CA, USA).

RESULTS

A total of 153 patients were included in this study. After scoring analysis, there were 112 patients in group L and 41 in group H. Mean age for group L and group H was 49 ± 1.18 and 48.9 ± 2.4 years, respectively (Table 1). There was a significantly higher percentage of women in group H (32% versus 12%, $P = .007$). There were no significant gender differences among groups. Coronary artery disease leading to ischemic cardiomyopathy was the most common etiology of heart failure in group H (73%), while patients in group L were more likely to present with an idiopathic cardiomyopathy (59%). Postcardiotomy shock was common in group H (54%), but extremely rare in group L (1%). Mean duration of LVAD support was comparable between the 2 groups (76.25 ± 5.9 versus 70.3 ± 10 days, $P = .60$)

The overall 30-day posttransplantation mortality was 5.2%, and was not significantly different between groups (4.46% for group L versus 7.32% for group H, $P = .445$) (Table 2). Posttransplantation actuarial survival for all LVAD recipients at 1, 3, and 5 years was 88%, 83%, and 75%, respectively (Figure 1). The survival rate was similar between groups: 87%, 86%, and 76%, at 1, 3, and 5 years, respectively, for group L, as compared to 90%, 83%, and 70% for

Table 2. Operative Data*

	No.	Mean	Standard Deviation	Standard Error of Mean	*P*
30-day mortality					
Low	112	4.46			.445†
High	41	7.32			
Ventilation duration, d					
Low	101	2.83	4.92	0.489	.58‡
High	38	3.35	4.54	0.75	
Intensive care unit duration, d					
Low	97	6.38	7.56	0.767	.62‡
High	36	7.11	6.81	1.15	
Inotrope duration, d					
Low	94	5.75	4.39	0.453	.035†
High	35	7.85	5.98	1.04	

*Low indicates LVAD score 1-5; High indicates LVAD score 6-10

†Fisher exact test.

‡Independent sample *t* test.

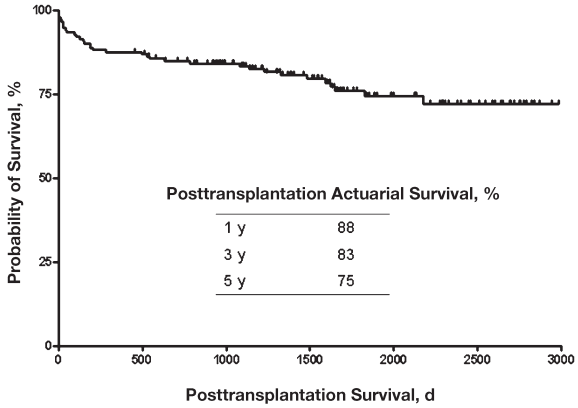

Figure 1. Kaplan-Meier actuarial survival curves for all patients receiving a transplant after left ventricular assist device support. Day 0 is defined as the day of heart transplantation. Survival is defined in terms of actuarial life or death.

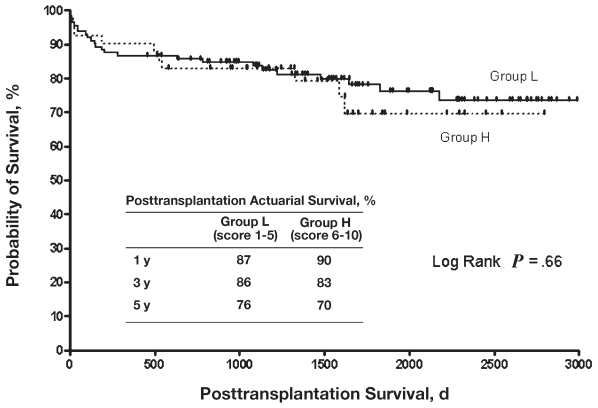

Figure 2. Kaplan-Meier actuarial survival curves comparing left ventricular assist device recipients with low screening scores (group L, score 1-5, solid line) to high screening scores (group H, score 6-10, dashed line). Day 0 is defined as the day of heart transplantation. Survival is defined in terms of actuarial life or death.

group H (Figure 2). The overall 8-year posttransplantation actuarial survival for all patients was 72.3% (Figure 1). Analysis of 8-year actuarial survival yielded a log-rank *P* of .66 in a comparison between groups (Figure 2).

No difference between the 2 groups was seen with regard to number of posttransplantation days requiring mechanical ventilation (2.83 ± 0.49 group L versus 3.3 ± 0.72 group H, *P* = .59) or intensive care unit monitoring (6.38 ± 0.77 versus 6.97 ± 1.13, *P* = .68) (Table 2). However, group L had a significantly decreased duration of inotrope support (5.57 ± 0.45 versus 7.74 ± 1.0 days). Thirty-day mortality was 4.5% (5/112) in group L and 7.3% (3/41) in group H (*P* = .44, Fischer exact test).

DISCUSSION

LVADs represent the standard of care in treating end-stage heart failure, conferring significant advantages in terms of mortality and quality of life over medical therapy alone [Rose 2001]. It has also been demonstrated that status 1 heart transplantation candidates receiving an LVAD versus inotrope therapy alone have improved clinical and metabolic function, leading to a survival advantage 6 months following transplantation [Bank 2000]. Using a scoring system as a measure of preimplantation medical stability, it has been demonstrated that LVAD recipients scoring less favorably (higher score) fare worse after implantation than patients with lower scores [Oz 1995; Rao 2003].

In contrast, this study demonstrates that if patients who are at high risk to undergo LVAD implantation (high score) are able to survive to eventual transplantation, their postoperative morbidity and survival are comparable to a lower-risk group. These data suggest that it is worthwhile proceeding to transplantation in high-risk LVAD recipients, as there is a high likelihood of long-term success.

This study has a number of limitations, including those related to any retrospective analysis. The decision to divide LVAD recipients into high- and low-scoring groups was arbitrary and may have introduced unintended bias. The effect of an increased percentage of women in group H remains unclear. As might be expected, the critically ill patients (group H) were more likely to suffer from postcardiotomy shock and coronary artery disease, yet they had comparable outcomes to the healthier recipient group. Importantly, only those patients in both groups who were deemed stable enough after LVAD implantation to receive heart transplantation were included in this study, and their clinical success emphasizes the importance of surgeon judgment and patient selection in heart transplantation. Finally, data from 2 different medical centers were combined to enhance the statistical power of this study and to limit institutional bias. However, this multi-institutional approach may mask important differences in program-specific practice patterns or outcomes.

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