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Two-year follow-up of quality of life in patients referred for heart transplant

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BACKGROUND: Assessment of physical and mental health has become one of the ultimate tests of health-related quality of life (HRQOL) for patients with advanced heart failure. Little is known, however, about the comparative effects of surgical or medical treatment on the HRQOL of these chronically ill patients over time.

METHODS: We examined 77 patients (74% of whom were male), aged 56.1 ± 12.7 years who were referred for heart transplant evaluation at a single heart failure center to describe the effects of time and treatment status on changes in HRQOL scores (physical and mental health and depression) using the Short Form-12 and the Beck Depression Inventory at 2 time points during their illness trajectory. The 2 evaluations on average were 2 years apart (mean 24.5 ± 2.8 months). All patients were evaluated at baseline, and 3 groups were identified at the time of the 2-year follow-up: transplant recipients ($n = 17$), transplant candidates ($n = 13$), and medically stable patients considered too well to receive a transplant ($n = 47$). Nonparametric statistics were used to analyze group differences in HRQOL scores. The significance level was set at a P value less than .05.

RESULTS: Demographic and HRQOL scores were not significantly different among the 3 groups at baseline. During follow-up, physical health and depression scores significantly improved over time in all patients, but changes in mental health were minimal. Group comparisons showed that although all patients continued to have low HRQOL scores at the time of follow-up evaluation, medically stable patients had higher mental health scores and less depressive symptoms than their counterparts.

CONCLUSION: Our results support the need for ongoing HRQOL assessment with an emphasis on timely recognition and treatment of psychologic distress throughout the heart failure illness trajectory. Heart transplant recipients and candidates equally need special attention and follow-up because they both seem to have emotional and psychologic repercussions. (Heart Lung® 2005;34:187–93.)

Despite recent improvements in survival related to newer therapies, advanced heart failure (HF) remains a condition with a generally poor prognosis and an annual mortality rate

as high as 30%.¹⁻³ Persons with HF often experience decreased ability to perform activities of daily living, reduced emotional well-being, decreased cognitive and social function, and increased depressive symptoms, all of which contribute to diminished health-related quality of life (HRQOL).⁴ Quality of life or overall satisfaction with life is defined “as a polymorphous collage that embraces a patient’s level of productivity, the ability to function in daily life, the performance of social roles, intellectual capabilities, emotional status, and life satisfaction.”⁴ Because clinicians and health care researchers are most interested in those aspects of life that are more closely related to health status (e.g., physical and mental functioning, and depression), these measurements are increasingly recognized as important outcomes to consider in persons with HF.⁵

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Heart transplantation has been recognized as the definitive therapeutic approach for patients with advanced HF.⁶ However, because of the limited number of available donor hearts, only a minority of patients undergo heart transplantation.⁷ Fortunately, recent advances in medical therapy, including use of angiotensin-converting enzyme inhibitors and beta-blockers, have improved clinical function and decreased both short- and long-term mortality rates.^{8,9} As a result, many patients who achieve hemodynamic optimization remain stable and may not be significantly different from patients who have undergone transplantation.⁷ In contrast, some patients awaiting transplant surgery who experience clinical deterioration may demonstrate worsening HRQOL over time.¹⁰⁻¹³ According to the Wilson and Cleary conceptual model,⁵ HRQOL is influenced by biologic and physiologic variables, symptom status, functional status, general health perceptions, and individual and environmental characteristics. Given the role of biologic and physiologic variables, and symptom and functional status in HRQOL, it was hypothesized that HRQOL would be different among these groups of patients.

Although a myriad of studies exist on the HRQOL of heart transplant candidates and recipients, the majority of investigators focused on either transplant candidates¹⁰⁻¹³ or recipients¹⁴⁻¹⁸ as separate populations. Furthermore, most of the recently published studies examining transplant candidates and recipients used a cross-sectional design; very few investigators have conducted longitudinal investigations of HRQOL of patients referred for heart transplant evaluation.⁹ Therefore, little is known about the effects of time and treatment on the long-term HRQOL of these vulnerable patients.

The current study was conducted to describe the effects of time and treatment status on changes in HRQOL scores during 2 years in the illness trajectory of patients with advanced HF who were referred for heart transplant evaluation. The overall goal of the study was to examine whether patients who had received a heart transplant since their baseline evaluation differed in physical and mental health and depressive symptoms compared with patients who were still awaiting heart transplantation and patients who were stabilized on medical therapy.

METHODS

Procedures

This quasi-experimental investigation was a sub-study of a larger descriptive study examining the HRQOL of patients with advanced HF. After obtain-

ing institutional review board approval to conduct follow-up HRQOL evaluations, a letter was sent to patients ($n = 55$) who participated in the larger study between June and December 1999. Six months later, a second letter was sent to patients ($n = 47$) who participated in the larger study between January and May 2000. To be included in the study, patients had to have baseline HRQOL evaluations at the time of their initial heart transplant referral that were completed in the preceding 2 years (mean 24.5 ± 2.8 months). A total of 77 patients responded to the mail surveys, giving an overall response rate of 75%.

Sociodemographic data (e.g., gender, age, race, education, marital status, and employment status) and health history (e.g., cause of HF and New York Heart Association class) were obtained from patient self-report at the time of baseline evaluation. Data pertaining to treatment status were obtained from patient medical records at the time of the 2-year follow-up evaluation.

Quality of life assessment

Because the purpose of the current study was to evaluate HRQOL, we included a comprehensive measure of HRQOL, the Short Form-12 health survey, which was completed by all participants at the baseline evaluation and 2 years thereafter. The SF-12 measured two distinct components of HRQOL, the physical and mental health domains, similar to that obtained from the 36-item Short-Form (SF-36) health survey.¹⁹ The SF-12 was used by our colleagues in an earlier study to reflect the physical and mental health of patients with HF.²⁰ The physical health score includes items on physical function, role limitations caused by physical health problems, body pain, and general health. The mental health score reflects vitality, social functioning, role limitations caused by emotional problems, and mental health.¹⁹ Martensson and colleagues²⁰ reported average physical and mental health scores of 34.8 ± 6.8 and 47.3 ± 7.1 , respectively, in their sample. In the U.S. general population, the SF-12 items explained more than 90% of the variance in the SF-36 physical and mental health summary measures.²¹ For the current study, Cronbach's alpha was .88 for the physical health score and .84 for the mental health score.

To comprehensively examine the psychologic domain of HRQOL that was not captured in the SF-12, we included a specific measure for depression, the Beck Depression Inventory (BDI), a well-validated tool used in chronically ill populations.²² The BDI is

Table I
Baseline demographic characteristics

Characteristic	Transplant recipients (n = 17)	Transplant candidates (n = 13)	Medically stable (n = 47)	P value
Age, years				
Median (25th, 75th percentile)	63 (47, 67)	58 (51, 66)	53 (48, 65)	.243
Gender, N (%)				.213
Male	11 (64.7%)	12 (92.3%)	34 (72.3%)	
Female	6 (35.3%)	1 (7.7%)	13 (27.7%)	
Race, N (%)				.536
White	13 (81.3%)	8 (61.5%)	35 (77.8%)	
Black	0 (0%)	2 (15.4%)	2 (4.4%)	
Other	2 (12.5%)	3 (23.1%)	8 (17.7%)	
Marital status, married N (%)	11 (68.8%)	11 (84.6%)	29 (64.4%)	.678
Education, N (%)				.440
≤High school	4 (26.7%)	6 (13.3%)	5 (41.7%)	
Vocational or junior college	5 (33.3%)	16 (35.5%)	3 (25.0%)	
≥College	6 (40.0%)	23 (33.3%)	4 (33.3%)	
Employment status, Yes N (%)	2 (12.5%)	2 (15.4%)	15 (33.3%)	.089

a self-report inventory designed to measure severity of depressive symptoms. The 21-item tool consists of a Likert-type format from 0 (absence of symptom) to 3 (severe or persistent presence of the symptom). Eight of the BDI items pertain to somatic symptoms of depression (e.g., loss of appetite and sleep disturbance), and 13 of the items reflect cognitive-affective symptoms of depression (e.g., hopelessness and social withdrawal). Scores on the BDI range from 0 to 63: scores 0 to 9 indicate no symptoms of depression, scores 10 to 16 indicate mild depression, scores 17 to 29 indicate moderate depression, and scores 30 to 63 indicate severe depression.²³ In the current study, Cronbach's alpha for the BDI was .81.

Statistical analysis

The sample was described using nonparametric analysis given the disparate size of the three patient groups and the nature of the data. Data are presented as medians (25th and 75th percentiles) or frequencies and percentages. We first examined changes across time in HRQOL scores in the entire sample by using Wilcoxon signed-rank tests. In the entire sample, to determine whether there were relationships in HRQOL scores based on demographic factors (i.e., age and gender), Spearman rho correlations or the Mann-Whitney *U* test was used depending on the level of measurement of the de-

mographic factor. In patients who underwent transplantation, the relationships between time since surgery and HRQOL scores were examined with Spearman rho correlation coefficients. Finally, differences among the three groups at the two evaluation points were compared using Kruskal-Wallis statistics. Results were considered significant at a *P* value less than .05. All statistical calculations were performed with SPSS for Windows (version 10.0, SPSS Inc., Chicago, IL).²⁴

RESULTS

Patient characteristics

Seventy-seven patients (57 men and 20 women), aged 56.1 ± 12.7 years (range 20-80 years) and seen at a single HF center, were included in the study. Baseline demographic characteristics were similar among participants in the sample (Table I). All patients were in New York Heart Association class III (64%) or IV (36%) and had an average ejection fraction of 26.8 ± 6.4 at baseline. Furthermore, 27 patients (35%) presented with ischemic cardiomyopathy, 30 patients (39%) presented with dilated cardiomyopathy, and 20 patients (26%) presented with idiopathic cardiomyopathy. At the 2-year follow-up, 17 patients (22%) had received their heart transplant within the 2 years preceding the baseline evaluation (mean years since transplant, $1.7 \pm .7$),

Table II

Comparison of median quality of life scores of participants at baseline and two-year follow-up

		Recipients (N = 17)	Candidates (N = 13)	Medically stable (N = 47)	χ^2*	P
Physical health (SF-12)	Baseline, median (25th, 75th percentile)	30.3 (20.1, 35.8)	33.0 (27.4, 42.2)	35.1 (28.0, 46.5)	6.059	.056
	Two-year F/U, median (25th, 75th percentile)	35.2 (32.4, 44.6)	40.4 (26.9, 54.0)	46.9 (37.7, 56.7)	7.803	.019*
Mental health (SF-12)	Baseline, median (25th, 75th percentile)	47.6 (36.7, 58.8)	56.7 (48.3, 60.2)	51.4 (40.4, 58.2)	1.682	.431
	Two-year F/U, median (25th, 75th percentile)	41.9 (38.8, 51.2)	42.4 (38.6, 53.0)	49.2 (49.2, 57.8)	7.604	.022*
Depression (BDI)	Baseline, median (25th, 75th percentile)	12.0 (8.5, 18.5)	10.0 (3.5, 14.0)	9.0 (5.5, 14.0)	4.393	.111
	Two-year F/U, median (25th, 75th percentile)	13.0 (7.0, 15.5)	10.0 (4.0, 12.0)	6.7 (1.0, 9.0)	9.227	.010*

F/U, Follow-up; BDI, Beck Depression Inventory; SF, Short Form.

* χ^2 derived from Kruskal Wallis; $P \leq .05$.

13 patients (17%) were still awaiting heart transplantation, and 47 patients (61%) were stabilized on their current medical therapy.

Relationships in entire sample

In the entire sample, older age was associated with increased depression ($\gamma = .286$, $P = .009$). Women had lower (worse) physical ($P < .001$) and mental health scores ($P = .035$) and higher depression scores ($P < .001$) than men (Mann-Whitney U). Time since transplant among transplant recipients was not related to any of the HRQOL variables. We also observed a strong relationship between depression and physical and mental health. ($\gamma = -.442$, $P < .001$ and $\gamma = -.617$, $P < .001$, respectively). Depression was related to lower physical health, and those with greater depression also had worse mental health.

During follow-up we found that physical health and depression of the overall sample significantly improved over time ($Z = -3.642$, $P = .000$; $Z = -2.584$, $P = .010$, respectively). Although the median mental health scores worsened for participants, the decrease in mental health scores was not statistically significant.

Group differences

The median HRQOL scores of recipients, candidates, and medically stable patients with HF at base-

line and 2-year follow-up are displayed in Table II. Quality of life scores were similar across the three groups at baseline. Group differences in physical and mental health and depression scores were noted during the 2-year follow-up. Our findings showed that transplant recipients and candidates had lower physical and mental health scores at the time of the 2-year follow-up when compared with patients who were stabilized on medical therapy. Our data also revealed that although depression scores of transplant recipients and candidates did not significantly worsen over time, improvements in depression scores among medically stable patients accounted for the group differences in depression.

DISCUSSION

The present study was conducted to describe the effects of time and treatment status on changes in HRQOL scores of patients with advanced heart disease during a 2-year follow-up period. A comparison was made between three groups of patients who had received a heart transplant, were still awaiting a transplant, or were medically stable. Our results showed that changes in physical health and depression scores of the overall sample improved over time. Presumably, patients found ways to cope with their condition and had adjusted to the initial impact of knowing they needed heart transplant surgery regardless of their treatment group.

Our data revealed that perceived physical health improved across all three groups, but improvements in this domain of HRQOL were most notable among medically stable patients. Although research has shown that heart transplantation achieves as good a functional recovery as a procedure such as coronary artery bypass grafting, which permits a full recovery of cardiac function,²⁵ decreased exercise tolerance remains an ongoing problem even beyond the immediate posttransplant period.²⁶ In fact, data show that exercise capacity remains markedly reduced in heart transplant recipients relative to individuals with intact hearts of similar age, and that for reasons that are not completely understood, heart transplantation only partially restores exercise capacity to normal.²⁷ Exercise intolerance also accounts for impaired functional capacity and consequently lower physical health in heart transplant candidates.²⁸ On the contrary, higher physical health scores in medically stable patients reflect the potential benefits associated with maximum pharmacologic therapy in this group of patients with HF. These findings are similar to those from our group reported more than a decade ago.⁷

Consequently, impaired functional capacity may negatively impact mental health or emotional well-being. Our data concur with this speculation. Both transplant recipients and candidates reported decreased mental health scores. On the other hand, medically stable patients reported no change in their mental health scores at the two evaluation times. More important, we found that medically stable patients were less depressed than patients who had undergone heart transplant surgery or who were awaiting heart transplantation.

Although changes in mental health scores were not statistically significant, our data demonstrate the vulnerability that exists among transplant recipients and candidates who continue to experience depressive symptoms.^{29,30} Investigators have reported that psychologic distress postsurgery is mediated by continued dysfunction and concern with physical symptoms, such as fatigue, headaches, and palpitations, and that anxiety and depression improve during the first year after surgery.³¹ However, our data indicate that psychologic impairment remains even beyond the first 2 years of surgery. In fact, abnormal scores among female transplant recipients were observed in a similar study beyond 5 years posttransplant surgery.³²

Transplant recipients attributed their psychologic distress to knowledge of their continuing vulnerability to major health problems including graft rejection, infection, neoplasm, and death.³³ It follows

that, although cardiac transplantation relieves the dysfunction associated with HF, transplant surgery does not free patients from the influence that somatic concern exerts on dysfunction.²⁵ As a result, many never completely resume their previous roles and continue to experience significant life stresses including unemployment, financial strain, and hospitalizations. On the other hand, patients who have been stabilized on medical therapy may experience less anxiety and improved mental health because of decreased somatic complaints (e.g., shortness of breath and fatigue), which is often associated with newer and more advanced treatment regimens.^{8,9} The resultant decrease in symptomatology, minus the impending threat of major health problems associated with transplant surgery, may have led to decreased levels of mental health in our medically stable patients. Most likely, patients who have been stabilized on medications also have decreased levels of uncertainty, unpredictability, and feelings of lack of control compared with cardiac transplant recipients. Likewise, the impact of waiting for a heart transplant on patients and the associated symptoms and dysfunctions of transplant candidates is well documented in the HF literature.^{4,10}

We also found that older age and female gender were associated with lower levels of physical and mental health and higher levels of depression. These findings related to age were not unusual and have been reported throughout the HF¹ and heart transplant literature.³⁴ However, agreement concerning HRQOL outcomes in men and women is less consistent. Gender differences in outcomes between men and women in our study could not be accounted for by age or severity of cardiac disease. A possible explanation could be that women perceived less relief from signs and symptoms of HF or decreased ability to perform activities of daily living, two factors that were ranked as highly important predictors of stress among patients with HF,³⁵ transplant candidates,¹⁰ and transplant recipients.¹⁵ Women who underwent coronary bypass surgery reported receiving less support than men.³⁶ Perhaps this factor accounts for the gender differences we observed in our sample.

The study was limited by the small sample size, the relative homogeneity of the patients, and the fact that it was a convenience sample. Patients volunteered to participate in the study and may actually have had better HRQOL scores than patients who did not volunteer. The three groups were naturally occurring and may reflect an inherent bias in the study sample. However, given the ethical issues involved in randomizing patients to surgical versus

medical treatment for advanced HF, it is unlikely that a randomized trial will ever be conducted. Thus, this study provides important data for clinicians and patients who are considering the benefit and cost of being listed for heart transplant.

Our study was also limited by choice of instruments used to assess mental health. There are data to support that although the SF-12 is sensitive to changes in physical health dimensions, it may not be responsive enough to detect changes in mental health.¹⁹ Perhaps the lack of responsiveness in the instrument may have accounted for the minimal changes we observed in mental health scores across time in the three groups. The use of a more disease-specific instrument to measure mental health may have been more appropriate than the SF-12, which was designed for a wide variety of patients and conditions and therefore was not specific for patients with HF. Nevertheless, the data from the study provide important information to advance our understanding of HRQOL and consequent changes that patients face throughout the HF trajectory.

Our findings underscore the need for intensified supportive psychotherapeutic treatment that includes patients and their primary caregiver as a means of reducing stress during both the recovery and waiting process. However, limited studies have shown the benefits of interventions that address both the psychosocial and emotional needs of transplant recipients and candidates and their caregivers. This is therefore an area in transplantation and HRQOL research that warrants further study.

CONCLUSION

This article supports the usefulness of following patients who present for possible heart transplantation to assess HRQOL. Of patients who are initially referred to an HF center, those patients who are listed but who do not undergo transplantation at 2 years are more depressed, have worse physical health, and report poorer mental health than patients who undergo transplantation or who are judged to be medically stable and therefore too well to receive a heart transplant. Patients referred for transplantation but who can be medically stabilized have HRQOL status at 2 years that rivals or exceeds patients after heart transplantation. Timely recognition and treatment of psychologic distress and limitations in physical health may be key to improved outcomes for heart transplant recipients, candidates, and patients stabilized on current medical therapy.

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