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Relationship between psychosocial variables and compliance in patients with heart failure

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Hear failure (HF) is the leading indication for hospitalization in older adults.¹⁻³ Moreover, HF is the primary cause of death in more than 43,000 patients each year and a contributory cause in an additional 220,000 patients.⁴ The increasing incidence and prevalence of HF are associated with high medical resource consumption that have major socioeconomic implications for our society.⁵ For these reasons, the last 2 decades have witnessed a remarkable explosion in HF research, and many new therapeutic options are available.⁶

Although it is necessary to develop new medical therapy for HF that will improve clinical outcomes in a cost-effective manner,⁷ a more critical issue is helping patients benefit from existing efficacious treatments. Treatment effectiveness is largely dependent on a patient's ability to follow the regimen. Poor compliance with medical recommendations remains a substantial problem among patients with HF who must follow a multicomponent treatment regimen that includes medications, dietary restrictions, exercise recommendations, and symptom management.⁸

A wide range of factors is assumed to affect compliance with treatment regimens, including the nature of the regimen,⁹ the patient's characteristics,¹⁰⁻¹³ and social support.^{14,15} Although several sociodemographic, psychosocial, and social support variables have been identified, none are con-

sistently associated with high levels of compliance.¹⁶ Furthermore, to date, researchers have not examined compliance with treatment regimens in relation to sociodemographic, psychosocial, and social support variables in patients with HF.⁸

The purpose of this study was to describe the sociodemographic, psychosocial, and social support variables that predict compliance with the treatment regimens in patients with HF. The study addressed the following questions: (1) What are the overall and individual compliance rates for lifestyle behaviors (follow-up appointments, medications, diet, exercise, and smoking and alcohol cessation) among patients with HF? (2) What is the relationship between compliance and sociodemographic, psychosocial, and social support variables? and (3) What are the predictors of compliance in patients with HF?

The overall goal of this study was to provide health care workers with information to facilitate prompt identification of precipitating factors of non-compliance, so that practical strategies to improve compliance in patients with HF can be rigorously pursued. Improving patient compliance with new and more established therapeutic options may be the key to improving clinical outcomes among patients with HF. Furthermore, enhancing compliance in this population will decrease episodes of HF decompensation, which lead to increased health care expenditures.

METHODS

Study subjects and data source

The appropriate Institutional Review Board reviewed and approved the study. The convenience sample included 82 persons who were older than 18 years, had a primary diagnosis of HF, and were receiving care at an outpatient HF clinic in Los Angeles. Such patients were included in the

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study if they were alert and oriented and able to understand English.

Ninety-one patients expressed an interest in participating in the study and met the selection criteria, signed informed consent, and completed the semistructured interview between August and December of 1999. A total of 82 subjects, with a mean age of 54.14 years (SD, 12.91; range, 22-90 years), completed and returned the survey questionnaires, a response rate of 90%. The demographic characteristics of the sample are presented in Table I. The majority of the subjects were male, white, married, had a high-school or higher education, and were retired (because they had reached the legal age for retirement or had early retirement because of medical disability).

Of the 9 who did not complete the study, 3 had recurrent bouts of HF exacerbation requiring hospitalization, 5 stated that they did not have the time to complete the questionnaires within the 2-week window, and 1 was lost to follow-up. Sociodemographic data and compliance rates among the 9 patients were comparable with those of the 82 subjects who completed and returned the survey questionnaires.

The 82 study subjects who completed all study procedures had been diagnosed with HF for a mean of 5.72 years (SD, 5.99; range, 0-28 years). The largest percentage (45%) had experienced HF between 1 and 5 years. The mean left ventricular ejection fraction of the sample was 27.6% (SD, 11.55; range 10%-60%). A majority of the subjects were New York Heart Association class II (42.7%) or III (35.4%). Sixteen percent were New York Heart Association class I and 6% were class IV. The etiology of HF was idiopathic for 34.1%, ischemic for 32.9%, dilated for 23.2%, and gestational, alcoholic, or congenital for 9.8%. Seventy-three percent presented with systolic dysfunction and 27% presented with diastolic dysfunction.

Procedures

Patients were recruited during their routine clinical visit and signed an informed consent. Sociodemographic data (eg, age, gender, race, education, marital status, and employment status) and health history specific to HF (eg, New York Heart Association class, number of years since HF diagnosis, type of ventricular dysfunction, left ventricular ejection fraction, treatment assignment) were obtained from patient self-reports and medical records. The primary (principal) investigator conducted a semistructured face-to-face interview with each subject using the Heart Failure Compliance

Table I

Sociodemographic characteristics of patients (N = 82)

Characteristic	Frequency (%)
Age	
≤60 y	52 (63.4)
>60 y	30 (36.6)
Sex	
Male	51 (62.2)
Female	31 (37.8)
Race	
White	56 (68.3)
Black	14 (17.1)
Other	12 (14.7)
Employment Status	
Employed	28 (34.1)
Unemployed	8 (9.2)
Retired	46 (56.1)
Marital status	
Married	55 (67.1)
Widowed, single, or divorced	27 (32.9)
Lives with significant other	72 (92.7)
Education	
≤High school	28 (34.0)
≤College	44 (54.0)
Beyond college	10 (12.0)

Questionnaire. Each interview lasted 25 to 40 minutes. Five additional instruments were used to gather data on patients' psychosocial health status and perceived social support. Patients were asked to take the questionnaires home and mail them back to the investigators within 1 week of the clinic visit. Patients were called after 1 week by the investigators if the questionnaires were not received to follow up on reasons for the delay. Patients who could not complete the questionnaires within a 2-week time frame were withdrawn from the study (n = 9). A patient evaluation form reflected that the average time for completing the questionnaires was 30 minutes.

Instruments

A modified version of the Compliance Questionnaire that was designed to measure compliance behaviors in patients with myocardial infarction¹⁷ was used in the current study. The instrument was revised to address the regimen issues common to patients with HF. Based on the process outlined by Kleinman,¹⁸ 3 semistructured interviews were con-

ducted with patients being treated in an outpatient HF clinic to develop items specific to persons with HF. The process allowed us to identify components for inclusion in the survey instrument. Data from the interviews were then categorized into common themes, and the following 6 health behaviors were identified: follow-up appointments, medications, diet, exercise, smoking cessation, and alcohol cessation. These 6 health behaviors became the 6 subsections for the questionnaire.

Subjects were asked in each subsection to state how important the specific health behavior was for them by using a 5-point scale with 0 indicating not at all important to 4 meaning highly important. This question was designed to measure patients' perception of the importance of complying with the specific health behavior. Patients were also asked to identify whether they had difficulty complying with a specific behavior and the nature of the difficulty. Finally, patients were asked to rate their own estimation of complying with each health behavior on a 5-point scale (0 = none of the time, 1 = very seldom, 2 = about half of the time, 3 = most of the time, 4 = all of the time). Scoring was reversed for the smoking and alcohol use sections because of the negatively worded phrases. All scores were converted to a 0 to 100 scale.

Content validity of the Heart Failure Compliance Questionnaire was established by a panel of 4 clinical nurses who had expertise in the care of patients with HF, 2 behavioral nurse scientists with expertise in psychosocial research, and a sociologist with expertise in survey methods. The experts were asked to review items for clarity and consistency with the compliance literature. Items were modified until 100% agreement by the judge panel was achieved. The first 10 patients who were enrolled in the study were asked to complete an evaluation form that asked them about length, readability, and clarity of contents of the questionnaire. A 100% satisfaction score was obtained.

For purposes of this study, both the overall score (total mean score for all 6 health behaviors) and the individual scores for each health behavior were recorded and analyzed. Patients were categorized as "compliant" if they had an overall score of 75% or greater. For individual health behaviors, patients were categorized as "compliant" if they had a score of 75% or greater, which corresponded to being compliant "most of the time" or "all of the time."

To validate the accuracy of the self-reports, family members who lived with the patients were also asked to rate the patient's compliance with each of

the health behaviors. Patients' and family members' reported compliance rates for all health behaviors measured were significantly correlated as follows ($P \leq .05$): follow-up appointments, $r = 0.272$; medications, $r = 0.464$; diet, $r = 0.336$; exercise, $r = 0.486$, smoking cessation, $r = 0.883$; and alcohol abstinence, $r = 0.270$. Internal consistency for the instrument was tested by using Cronbach α with a result of .68.

Standardized measures of physical and mental health were obtained using the Medical Outcomes Study Short Form-36 (MOS SF-36) General Health Survey.¹⁹ Physical health was operationalized in the study as a measure of the extent to which the patient was limited in performing certain tasks. The physical health scores were obtained by combining scores on the following 4 subscales of the MOS SF-36: the physical functioning subscale (10 items), the role physical subscale (4 items), the bodily pain subscale (2 items) and the general health perception subscale (5 items). Mental health was defined in the study as a measure of the patient's well-being, anxiety, and depression. The mental health scores were also based on 4 subscales of the MOS SF-36, as follows: the vitality subscale (4 items), the social functioning subscale (2 items), the role emotional subscale (3 items) and the mental health subscale (5 items). Scores were obtained by reversing the negatively worded items on each of the subscales, transforming the scores to a 0 to 100 scale, taking the total mean score for each subscale, standardizing each subscale total, and computing the total aggregate scores for physical and mental health following the computational formula provided by the Medical Outcomes Study Trust Foundation.²⁰ Reliability and validity of the MOS SF-36 have been established in patients with HF.²⁰ In the present study, the internal consistency reliabilities of the physical and mental health aggregates were 0.84 and 0.83, respectively.

Patients were also asked to rate their overall health satisfaction, operationalized as each patient's 10-step rating of his or her own health at the present time. The scale is similar to the instrument used to measure valuation of health for the European Quality of Life Scale.²¹ Subjects were asked to place an "x" on the scale to indicate how they rated their own health satisfaction during the last 24 hours. Possible scores on the scale ranged from 0 to 10, with 0 indicating worst health satisfaction and 10 indicating best health satisfaction as perceived by the patients. The reliability of the European Quality of Life scale in previous studies with chronically ill patients was 0.86.²¹ The total

Table II

Scores for compliance, social support, and psychosocial variables (N = 82)

Variable	Minimum	Maximum	Mean	SD
Compliance				
Overall	38	96	84.86	10.25
Follow-up appointments	50	100	98.17	7.64
Medication	75	100	96.34	8.89
Diet	0	100	71.04	18.62
Exercise	0	100	53.35	30.87
Smoking cessation	0	100	96.65	16.56
Alcohol cessation	0	100	93.6	19.17
Social support				
Total, network	1	10	5.02	3.23
Total (Perceived Social Support Scale)	13	84	71.85	13.05
Significant other	4	28	24.74	4.96
Family	4	28	24.3	5.02
Peer	5	28	22.8	4.86
Psychosocial				
Physical health*	-10.17	101.72	39.54	30
Mental health*	8.02	87.26	55.6	21.16
Health satisfaction	1	9	5.57	2.18
Neuroticism	0	9	3.28	2.55

*Scores recorded have been standardized to allow for comparison with the general US population.

internal consistency for the scale in the current study was 0.89.

Additional measures of psychosocial adjustment to illness in the study included the use of the Neuroticism Scale from the Eysenck Personality Questionnaire.²² The Neuroticism Scale measures intensity of neuroticism, with neuroticism defined as a tendency to worry and be anxious, irrational, and shy.²² It has been previously used in patients with HF²³ and consists of 9 items scored as 0 if not present or 1 if present. Item scores are added to get the total neuroticism score with the highest score, 9, indicating highest degree of neuroticism. The total internal consistency for the Neuroticism Scale in the current study was 0.80.

Social support was defined as the number of social networks available to the patient and the level of support available from the patient's point of view. To measure the number of social networks, patients were asked to list the initials of people who provided them with support during their diagnosis with HF. The total number of persons listed was recorded. Perceived social support was measured by using the Perceived Social Support Scale which consists of 3 subscales, each comprised of 4 items to measure significant other support, family support, and peer support. Patients responded to

each items using a 7-point Likert scale ranging from 1 (very strongly disagree) to 7 (very strongly agree). The minimum score of 4 indicated low social support, and a maximum score of 28 indicated high social support for each of the 3 subscales. The test-retest reliability for the total and the 3 subscales in previous studies was 0.85, 0.72, 0.85, and 0.75, respectively.²⁴ For the current study internal consistency for the total and 3 subscales was 0.94, 0.91, 0.95, and 0.89, respectively.

Statistical analysis

Descriptive statistics were used to characterize the study population, calculate compliance rates and mean scores on psychosocial and social support measures, and obtain information related to the presence of factors that make following prescribed activities difficult. Pearson product moment correlations were calculated to identify the variables that significantly correlated with overall and individual compliance scores. Variables significant at $\leq .10$ were included in a stepwise multivariate linear regression model in which overall compliance was the dependent variable. Multivariate analysis was also conducted, individually examining compliance with follow-up appointments, medications, diet, exercise, and smoking.

Table III

Factors correlated with overall and individual compliance rates (N = 82)

	Compliance						
	Overall	Follow-up visit	Medication	Diet	Exercise	Smoking cessation	Alcohol cessation
Sociodemographics							
Age			0.442†				
Race			0.223*				
Education	0.242*	0.257*	0.271*				
Marital status		0.264*				-0.324†	
Psychosocial variables							
Mental health	0.317†	0.248*		0.262*	0.468†		
Physical health	0.393†			0.284*	0.507†		
Health satisfaction	0.255*				0.435†		
Neuroticism	-0.308†	-0.306†	-0.321†		-0.317†		

* $P < .05$.† $P < .001$.

Criteria for entry and removal of variables were based on the likelihood ratio test with enter and remove limits set at $P \leq .05$ and $P \geq .100$. The ratio of cases to independent variables for each of the models (8:1) was acceptable for multiple regression. The adequacy of each model was examined, and all assumptions of multiple regression (normality, linearity, and equality of variance) were met. Histograms of standardized residuals for overall compliance and compliance with all 6 behaviors examined in the study were normally distributed. Standardized partial regression scatterplots between the dependent variables and the variables that entered the model demonstrated weak linearity, which supports equality of variance. There were no influential outliers identified. Likewise, multicollinearity was not detected among the independent variables.

RESULTS

The compliance rate for the overall HF regimen was 85.13% (SD, 10.01%). Higher levels of compliance (>90%) were noted for follow-up appointments, taking prescribed medications, and smoking and alcohol cessation. Poor compliance (<75%) was observed with dietary and exercise recommendations (Table II).

The mean scores on social support and psychosocial variables are also provided in Table II. On average, patients in the sample had a network of 5 persons who provided them with support. Perceived social support was relatively high for all 3 subscales (ie, means of 23 to 25 on a scale with a

maximum of 28). The mean physical health score (39.54) and mental health score (55.60) for the current sample are slightly higher than the mean physical health and mental health aggregate scores for persons with HF in the general US population (31.02 and 45.65, respectively).²⁰

In a univariate analysis, overall compliance was correlated with higher education, higher mental health and physical health, higher health satisfaction, and lower neuroticism (Table III). Variables significantly correlated with individual compliance behaviors of interest are also summarized in Table III. None of the sociodemographic or psychosocial variables of interest were correlated with alcohol abstinence. Furthermore, clinical and social support variables were not significantly correlated with overall or individual compliance rates and were not included in the multivariate model.

When sociodemographic variables (age, race, marital status, and years of education) and psychosocial variables (mental health, physical health, health satisfaction and neuroticism) were included in a step-wise multivariate linear regression, 24% of the variance in overall compliance was explained by the model. Variables that independently contributed to the overall compliance were higher education, higher mental and physical health, and lower neuroticism (Table IV). Predictors of patient compliance with follow-up appointments were being married and lower neuroticism. Medication compliance was higher for older patients and patients with lower neuroticism scores, whereas dietary compliance was higher in

patients with higher mental health scores. Predictors of exercise compliance included higher physical and mental health scores and lower neuroticism scores. The only characteristic related to compliance with smoking restrictions was marital status; patients who were married had higher compliance scores.

A secondary analysis of the data was completed to determine the percentage of patients who had difficulty following prescribed activities and factors that made following treatment regimens difficult. A higher number of patients reported difficulty following dietary and exercise recommendations (39% and 61%, respectively), as compared with other prescribed behaviors (medication, 30%; smoking cessation, 11%; keeping medical appointments, 8.5%; and alcohol cessation, 4.9%). Lack of self-motivation and inability to control the urge to drink more fluids and/or eat restricted foods were the 2 most common factors that made following dietary recommendations difficult. On the other hand, lack of self-motivation, lack of energy, and presence of physical symptoms made following exercise recommendations more difficult. Difficulty with taking medications was mainly related to side effects of treatment.

DISCUSSION

The overall compliance rate documented in this study was high. In general, patients were compliant with follow-up appointments, taking prescribed medications, and smoking and alcohol cessation. These scores are higher than the ones reported in the literature for the general population as compiled by Haynes,²⁵ which were as follows: follow-up appointments, 16% to 84%; medications, 31% to 58%; and smoking cessation 71% to 96%. However, compliance rates with dietary and exercise recommendations fall within the currently reported rates of 13% to 76% and 40% to 50%, respectively.²⁵

Education contributed minimally to overall compliance, although it was excluded from each of the models for individual health behaviors. In general, the research on education and compliance has been mixed, with little or minimal support for higher education leading to increased compliance.

Mental health generally has not been studied as a predictor of compliance among patients with HF. In this sample, higher mental health was the second variable that entered the model and predicted overall compliance. In a large clinical trial, patients who reported less depression and anxiety demonstrated better medication compliance.¹⁶ The link between mental health and compliance behaviors needs further study.

Table IV

Predictors of overall and individual compliance rates (N = 82)

Variable	Adjusted R ²	F	P
Overall compliance			
Education	0.038	4.121	.046
Mental health	0.120	8.360	.005
Physical health	0.172	5.968	.017
Neuroticism	0.240	7.823	.007
Follow-up appointments			
Marital status	0.076	7.553	.007
Neuroticism	0.176	10.659	.002
Medication			
Age	0.185	19.189	.000
Neuroticism	0.252	8.000	.006
Diet			
Mental health	0.057	5.805	.018
Exercise			
Mental health	0.209	22.135	.000
Physical health	0.240	4.269	.042
Neuroticism	0.272	4.409	.039
Smoking cessation			
Marital status	0.204	21.448	.000

In this study, the third predictor of overall compliance was higher physical health. Physical health also correlated with exercise compliance and dietary compliance. The former is intuitive; patients who feel better are more likely to follow exercise recommendations. The relationship between physical health and dietary compliance is less clear and requires further study.

Finally, lower neuroticism predicted higher overall regimen compliance and compliance with specific health behaviors such as follow-up appointments, medications, and exercise. According to Lazarus and Folkman,²⁶ persons who face ambiguous situations experience stress and anxiety from their uncertainty about what to expect; this uncertainty underscores their inability to help themselves, and their perceived helplessness contributes to further stress and anxiety. This theory may explain the inverse correlation between neuroticism and compliance in the study.

Although the investigators expected social support to emerge as a multivariate predictor of compliance, this was not confirmed. The lack of correlation between social support and compliance in the study may be related to the homogeneous nature of the sample; patients in the current sample all had a strong social support system. This assump-

tion has been made considering that more than 90% of the sample lived with a significant other, and it is also based on significantly high perceived social support scores reported by the patients.

Data related to presence of factors that made following prescribed activities difficult was obtained after initial analysis of the data to provide more meaningful information related to compliance behaviors of patients with HF. The findings show that more patients had difficulty with dietary and exercise recommendations than any of the other prescribed activities measured in the study. Grady et al²⁷ explored the extent of difficulty in following prescribed activities in post-heart transplant patients and concluded that patients had most difficulty with diet and exercise activities. These investigators also found that the extent of difficulty in following prescribed activities highly correlated with compliance with the treatment regimen. Hence, the presence of factors that made following dietary and exercise regimens difficult may explain the low compliance observed for both of these behaviors in the current study. Although some of the factors are disease-related (ie, lack of energy, presence of physical symptoms), a few were associated with psychologic well-being of the patients. This included the lack of self-motivation to do what was right and inability to prevent oneself from doing what was restricted. Providing psychologic support and counseling to patients with HF that address dietary and exercise regimens may alleviate feelings of difficulty patients may have in following medical recommendations with these activities. This may ultimately improve patient compliance behaviors.

The findings of this study are limited by the homogeneous nature of the sample. A majority of the patients were highly educated and had consistently strong social support systems. These patient characteristics are not necessarily typical of the average person with HF. Future research with a less homogeneous group of patients having less social support in the evaluation of a multivariate model may be needed to elucidate the relationship between compliance and social support variables. Furthermore, other factors need to be examined when considering the complex associations found between psychosocial variables and compliance with medical regimens.

The use of self-report as the only measure of compliance behaviors in the current study is another limitation. Noncompliance with treatment regimens tends to be under-reported and compliance tends to be over-reported in interview reports⁹; thus, actu-

al patient compliance as reported by the patients may have been overestimated in our study. The use of objective measures like pill counts and serum bioassays in conjunction with self-reports should be explored in future studies describing compliance behaviors of patients with HF. A combination of self-report and objective measures may yield a higher incidence of truthfulness concerning compliance behaviors in this patient population.

CONCLUSION

In this study, we found that patients with HF had poor compliance with dietary and exercise regimens. Since following a dietary and exercise regimen has been demonstrated to reduce morbidity in this population, strategies to increase compliance with diet and exercise recommendations should be rigorously pursued. Helping patients understand their treatment regimen may improve their compliance. In addition, interventions to promote self-management and increase perceptions of mental and physical health should also be implemented as a means to improving general health perceptions and consequently compliance with treatment regimens. Addressing factors that make following prescribed activities difficult for patients may be key to improving compliance with treatment regimens. While the study underscored the importance of identifying precipitating factors of poor compliance, additional studies that examine a less homogeneous sample need to be undertaken to explicate the relationship between psychosocial variables and compliance with treatment regimens among patients with HF.

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