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Linda Pham
(California Heart Center
Foundation and UCLA, Los
Angeles, CA), The Impact of
Psychosocial Care on At-
Risk Patients Following
Heart Transplantation: A
Single-Center Experience

ABSTRACT

This quantitative retrospective study examines the correlation between post surgical psychosocial interventions and outcome in heart transplant patients who were identified as at-risk preoperatively and able to receive a heart transplant, where outcomes included survival and number of non-standardized hospitalization. Data was collected from the University of California at Los Angeles Medical Center heart transplant database. Data was analyzed by using two-tailed *t*-tests and chi-square tests to assess the variation between groups. The Wilcoxon log-rank statistic was used to compare Kaplan-Meier survival curves. 46 patients were identified as at-risk during their pre-transplant psychosocial assessment. Results indicated that at-risk patients who received psychosocial care demonstrated a significantly higher 5-year actuarial survival compared to patients that did not receive post transplant psychosocial care (68% vs. 38%, $p=0.038$). Similarly, patients in the post transplant psychosocial care group exhibited a significantly higher 1-year freedom from any hospitalization compared to the patients without psychosocial care following transplantation (66% vs. 33%, $p=0.019$), while patients with post transplant psychosocial care only demonstrated a trend toward lower 5-year actuarial freedom from any hospitalization compared to the group without post transplant psychosocial care (36% vs. 24%, $p=0.09$). This study revealed that psychosocial

intervention post heart transplant appears to yield better survival and decreased number of non-standardized hospitalizations. Further study is warranted in order to assess the impact of psychosocial care for patients following heart transplantation.

THE IMPACT OF PSYCHOSOCIAL CARE ON AT-RISK PATIENTS FOLLOWING
HEART TRANPLANTATION: A SINGLE-CENTER EXPERIENCE

A project based on data collected at the University of California, Los Angeles in conjunction with the California Heart Center Foundation, submitted in partial fulfillment of the requirements for the degree of Master of Social Work.

Linda Pham

Smith College School for Social Work
Northampton, Massachusetts 01063

2010

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CHAPTER 1

INTRODUCTION

In the field of heart transplantation, patients go through a process where they are referred for transplantation upon being diagnosed with end-stage heart failure, meaning that when medical treatment and less drastic surgery have failed, a patient is recommended to receive a heart transplant. Due to the short supply of organ donors, patients must traverse a careful selection process before receiving their donor heart. This selection process involves navigating through an intensive evaluation to determine if the patient is biologically and psychosocially viable for a donor heart. If the patient represents a suitable candidate after the evaluation, they are then placed on a waiting list for the next available heart (National Heart Lung and Blood Institute, June 28, 2009).

There have been numerous studies (Miller, 1998; Levenson and Olbrisch, 1993; Evangelista et al, 2005; Owen et al., 2006; Owen, Bonds & Wellisch, 2006) regarding the effects of evaluations or assessments on heart transplant candidates in predicting post heart transplant outcomes, including the number of hospitalizations, rejection episodes, and survival. These exploratory findings ultimately suggest that risk factors such as employment, drug and alcohol use, history of substance abuse, mood disorders, past suicide attempts, and adherence to medical regimen presented during the pre-transplant assessments predicted survival rates (Owen, Bonds & Wellisch, 2006). In their discussion, these studies state that it is important to utilize this type of information with

caution and discretion due to an insufficient amount of research and data, as it may lead to life-altering consequences (Owen, Bonds & Wellisch, 2006).

There is an assumption that the recovery for the average transplant patient does not solely lie with the medical and biological issues, but also extends to the realm of psychosocial issues in the areas of support, pre-disposed stressors (mood disorders), employment, suicidal attempts, and so forth. In essence, these are risk factors, which may ultimately affect patient recovery. These assessments of risk factors are employed in order to filter out the high-risk patients that are, at the time of high-risk diagnosis, inadequate candidates for transplantation. However, little research has been performed to effectively demonstrate how patients fared after their pre-transplant psychosocial assessment and heart transplant surgery.

This present study is designed to explore the effects of post heart transplant psychosocial interventions on patients determined to be at-risk prior to transplantation. If research studies have found that psychosocial assessments are helpful in predicting outcome for post heart transplant patients, then one would assume that a post heart transplant biological and psychosocial assessment with continued aftercare based upon that assessment would also be beneficial to the patient and his or her outcome. Thus, I will be examining the correlation between psychosocial intervention following transplantation and the frequency of non-standard of care hospital visits in patients deemed to be at risk pre-heart transplantation and their survival rates 5-years post heart transplant. Research such as this would indicate the importance of continual patient psychosocial evaluation and treatment following cardiac transplantation, thereby

allowing patients to receive proper care and interventions as needed that would ultimately assist in their recovery and prolonging their life expectancy.

CHAPTER 2

LITERATURE REVIEW

There have been many discussions around the issues that pertain to the success rates and morbidity rates surrounding heart transplantation. Psychosocial evaluations prior to transplantation have consistently been an important area of study in determining the success rates in patient recovery. These psychosocial evaluations look at a patient's psychological history and social life factors. A consensus report put out by the American Society of Transplant Physicians stated that positive results of post heart transplant outcomes were defined as the absence of personality disorder, suicidal behavior, substance abuse, active psychosis and the presence of good adherence to medical regimens, adequate social support and financial resources, and good cognitive functioning (Miller, 1998).

Levenson and Olbrisch (1993) performed a process survey that looked at medical institutions that utilized psychosocial evaluations as a part of their screening process for patients viable for transplantation. The survey examined four factors: whether the respondent had a formal or informal psychosocial criteria, who conducted the evaluations and the process used, whether the potential psychosocial criteria for selection of candidates was listed, and the number of patients turned down for transplantation due to medical, financial, and psychosocial reasons. A total of 64% of cardiac programs responded to the survey. It was found that most of the evaluations required a psychiatrist, psychologist, or social worker in order to determine the candidate's suitability for the

transplant. Cardiac programs were more likely to consider the following psychosocial items as a contraindication to transplantation: schizophrenia with active psychotic symptoms, current suicidal ideation, history of multiple suicide attempts, dementia, severe mental retardation, current heavy drinking, and current use of addictive drugs. Thus, for heart transplantations, it was twice as likely (5.6%, range = 0% - 37%), when compared to liver (2.8%, range = 0% - 20%) or kidney (3.0%, range = 0% - 33%) transplantations, to refuse patients for transplantation based upon psychosocial assessments. Overall, a majority of the responding programs required a pre-transplant psychosocial assessment, however the evaluation process was not uniform in regards to types of questions asked or consistency of assessors, and usually second opinions were not sought (Levenson and Olbrisch, 1993).

With the non-uniform measures which are used to screen out certain patients and the lack of research done on post transplant care, which is not likely to be uniform either, it begs the question of what would happen if assessments were uniform and care during pre-transplant was followed through during post transplant. Evangelista and colleagues (2005) concluded that patients waiting for the transplant and those who had the transplant require the same degree of care, since they share similar emotional and psychological reactions.

One study, the first of its kind, was an evidence based study looking at pre-transplant psychosocial screening. With the growing awareness that psychosocial and behavioral factors contribute to the quality of post transplant outcomes and that guidelines in many psychosocial assessments were neither clear nor thorough in their assessments, Dobbels et al. (2009) designed a prospective study, which followed patients

from pre-transplant until one year post transplant in heart, liver and lung transplant candidates at the University of Leuven (Belgium).

The study followed 141 patients (28 heart, 61 liver, and 52 lungs), and focused on multiple variables consisting of demographic characteristics, anxiety, depression, personality traits, received social support, self report adherence with the treatment regimen, and pre-transplant clinical characteristics and comorbidity for the pre-transplant assessment to see the predictions of poor post transplant outcome. It was found that pre-transplant non-adherence to medication, higher education level, low social support, and low scores on personality traits were independent predictors of post transplant non-compliance to immunosuppressant regimen within the first year after transplant. Also, a lack of a stable partnership was a significant predictor of late graft loss between the first 6 to 12 months of post-transplant (Dobbles et al., 2009). A study by Bunzel and Wollenek (1994) had already indicated that heart transplant patients with an empathic and supportive partner had better surgical and post transplant outcomes compared with patients without such an active relationship involvement.

In looking at the study presented, it is rather apparent that much emphasis is placed on the pre-transplant psychosocial assessments and the importance and value of such evidence is as pertinent in predicting success following transplant while providing adequate care for patients. There have been many studies looking at the correlation of pre-transplant psychosocial assessments and its relation to recovery and morbidity rates (Miller, 1998; Levenson and Olbrisch, 1993; Evangelista et al., 2005; Owen et al., 2006; Owen, Bonds & Wellisch, 2006).

A study done by Owen et al. (2006) looked at heart transplant patients who received pre-transplant evaluations between January 1, 1997 and December 31, 2000. The evaluations examine basic demographic characteristics of each patient, which included age, gender, ethnicity, educational attainment, brief psychiatric history, history of alcohol, tobacco, substance abuse, social history, and medical history. Mental status examination and psychiatric interviews were also conducted during the pre-transplant assessment. Each patient had a level of understanding of their medical condition and understanding of the risk factors and benefits that were associated with heart transplantation, which was then rated by clinicians using a 3-point Likert scale anchored by “poor,” “good,” and “excellent.” A chi-square analysis was also completed to test the relationship between each of the categorized-coded psychiatric risk variable in association with one of the three risk group categories (Good, Acceptable [moderate], vs. High-Risk).

The study indicated that individual risk factors set forth by the pre-transplant assessment significantly predicted survival. Substance abuse, past suicide attempt, and poor adherence to recommended medical regimens were variables that were significantly predictive of survival time. Observations were also made after the study showing that shortly after transplantation, the high-risk group was already experiencing greater mortality rates compared to the other groups (Owen, Bonds & Wellisch, 2006). This study put forth data and information that supported the idea that different levels of risk groups differ in results.

Olbrisch et al. (2002) suggested that it was imperative to identify psychosocial risk factors in poor transplant outcomes so that appropriate treatment could be matched

with at-risk patients before transplantation. A retrospective study looking at 567 patients transplanted between 1994 and 2008 was performed at UCLA that evaluated the correlation between pre-transplant social work and psychiatric assessments and post heart transplant patient outcome. The study evaluated patients who were deemed high-risk (having any of the following: history of mood disorder, substance abuse, non-adherence to medical therapy, and concerns regarding level of support). This meant that there were some patients that were deemed high-risk during their pre-transplant evaluation, but were ultimately able to receive heart transplants despite these predisposed high-risk life factors as they were receiving pre-transplant intervention allowing patients to be viable for the transplant. It was found that these high-risk patients exhibited worse post transplant outcomes, including significantly worse long-term survival, compared to a control group, which consisted of patients that were not declared high-risk during their pre-transplant evaluation (Moreno, et. al, 2009).

These studies investigated the significance of pre-transplant psychosocial evaluations/assessments and their predicting factors on post heart transplant recovery and morbidity rates. In effect, these studies evaluating pre-transplant assessments raise questions about the relationship between post transplant care and recovery and morbidity rates and show reason for the need of the current study. Ultimately, with this positive correlation between high-risk pre-transplant assessments and poor post transplant outcome, it begs the question of what care could be given to address these risk factors in order to augment post transplant outcome in these types of patients. In addressing what care could be given to these patients, one can also see the impact that the care has on the patient's recovery, mortality, and morbidity rates.

Dew et al. (2005) looked at the profiles and predictors of the course of psychological distress across four years after heart transplantation. This study consisted of 156 heart transplant patients who were assessed at 2, 7, 12, 36, and 42 months post transplant. There were five groups that were identified: low stress at all times, high, clinically significant distress at all times, high distress over several years with low distress only at final assessment, high distress during the first several months with decline thereafter, or fluctuating distress levels. The study found that patients showing any distress were more likely to have had a pre-transplant psychiatric history, worse social supports, more physical impairment early post transplant, and continued physical impairment early post transplant. In these five identified groups, the data showed that each transplant recipient had their own unique psychological and social needs in regards to their care. The study, however, was unable to assess what types of interventions the subjects received post transplant. Treatment for depression and anxiety appeared to have been severely under-utilized in transplant populations than in the general community (Dew, Myaskovsky, Switzer, & et al., 2005). In all of the studies presented, there was no mention of what type of intervention or treatment was provided for patients in any of their pre- and post transplant assessments.

Previous studies have shown that pre-transplant assessments were good indicators of post transplant success, making one question what studies found about patients in regards to quality of life and symptomology post-transplant. A multisite study looking at the emotional adjustment of patients five years post heart transplant by Rybarczyk et al. (2007) wanted to see what levels and factors were associated with depressive and negative affect post heart transplant. The cardiac depression scale was employed, which

assesses symptoms of depression that is relevant to cardiac patients. Symptoms include sleep disturbances, anhedonia (loss of pleasure), uncertainty, decreased mood, concentration difficulty, hopelessness and inactivity, and the positive and negative affect schedule (PANAS) to assess moods. These questionnaires and rate scales were given to the 370 adult participants. Rybarczyk et al. (2007) was able to do a stepwise multiple regression analyses to test 32 potential medical, demographic, functional, and psychosocial factors during the five-year post heart transplant.

Results showed that the best predictors of depression were low satisfaction with emotional support, younger age, lower recreational functioning, and neurological symptoms. In PANSAS negative affect was seen as comparable to the general population, but psychosocial variables of emotional support satisfaction and perceived healthy uncertainty were able to explain a significant amount of variance. These two psychosocial variables were also predictors of adjustment (Rybarczk et al., 2007). Even though the study found that the emotional adjustment of post heart transplant patients was comparable to non-transplant patients, the study acknowledges that detection and treatment of psychological adjustment problems were not only important to quality of life, but were likely to have benefits in terms of reducing physical morbidity and mortality.

It is evident that many studies have demonstrated that psychosocial issues appear to have some effect on how transplant patients physically recover following surgery. Patients in the 1st year following heart transplant had the highest rate of psychopathology. It appeared that the first year demonstrated the most adjustment difficulties for transplant patients overall in all aspects of transplantation due to the change of lifestyle in the

stringent medical regimen, medication compliance, and mood changes (Olbrisch, Benedict, Ashe, & Levenson, 2002).

A 10-year follow-up clinical case review done by Hategan et al. (2008) followed a patient who did not undergo any formal psychosocial assessment before transplant, but did have a post transplant regimen that included follow-ups at the hospital to ensure that the patient was adhering to the standard of care medical plan. The patient reported social disconnection and marital issues. The patient was able to receive close psychiatric monitoring, which later resulted in his OQ-45.2 (Outcome Questionnaire) having stable levels of symptom distress and satisfaction with social role and interpersonal relationships. Also, this particular patient struggled with the issue around possessing someone else's heart and wanted to work through contacting the donor's family. This case review demonstrated that greater collaboration between psychiatry/psychology and the cardiology team before the transplant process may be necessary to assess psychiatric and personality factors that could influence medical and psychological recovery. In this way, peer and professional supports could then be offered as needed to buffer the transplant recipient from the exceptional stress of recovery (Hategan, Nelson & Jarman, 2008).

This longitudinal study indicated that the patient experienced significant anxiety after receiving his transplant. A study performed by Fusar-Poli et al. (2005) showed that 30-45% patients with cardiovascular disease reported having depressive symptoms. Another study by Karaplot et al. (2007) looked at the relationship between depressive symptoms, anxiety, quality of life and functional capacity in heart transplant patients. As

indicated earlier from previous studies, psychological disorders and pre-transplant depressive symptoms appear to place a patient at higher risk of post-operative morbidity.

Karaplot et al. (2007) worked with thirty four patients who were given four tests: Beck Depression Inventory (BDI), Spieldberger's State-Trait Anxiety Inventory (STAI), Short form 36 for quality of life (SF36) and Cardiopulmonary exercise test. Results indicated that the symptoms of depression and anxiety were both related to the quality of life and functional capacity in heart transplant patients. It was also demonstrated that depression and quality of life scores improved after the transplant. Researchers in this study stated that to achieve clinically successful transplants, psychological variables should be strongly considered in the treatment and care of heart transplant candidates. This goes hand in hand with demographic variables, such as time on waiting list, rejection episodes, and pre-transplant depression, which are predictors of quality of life post transplant (Karaplot et al., 2007).

Another study done by Havik et al. (2007) observed the impact of depression on the mortality of heart transplant patients. This prospective, cross-sectional study looked at 147 heart transplant patients using the Beck Depression Inventory (BDI) with a minimum of 5-year follow-up. The study found that depressive symptoms ultimately increased the risk of mortality during the follow-up period. The study's main finding presented was that symptoms of depression are common following heart transplant and that it was an important independent risk factor for all-cause mortality during the 5-year follow-up. Findings also indicated that the reporting of depressive symptoms reflected actual depression rather than somatic complaints or lack of vitality originating from the heart condition itself (Havik et al., 2007). The study points out that better screening may

be needed and that subsequent diagnostic evaluation with a focus on depressive syndromes should be looked at pre-transplant and post transplant.

Olbrisch, Benedict, Ashe, & Levenson (2002) reported that the first-year post transplant demonstrated the most adjustment difficulties for patients overall in all aspects of transplantation. Thus, this provokes the question of what quality of life is like for patients during their first-year post transplant as well as what factors may influence this quality of life.

Grady, Jalowiec, and White Williams (1999) looked at the predictors of quality of life in patients at 1-year post heart transplant by examining the relationships between quality of life and demographic, physical and psychosocial variables. There were 232 patients who were given booklets, which consisted of different types of questionnaires and tests. The study revealed that the patients were most satisfied with areas of quality of life in their social interaction and least satisfied with their psychological state, where psychological state was indicative of health perception, satisfaction with surgical outcome, overall effectiveness of coping, use of evasive, fatalistic, and emotional coping style, total stress, helpfulness of information provision to patients, difficulty complying with the transplant regimen, and compliance with the transplant regimen. Even though patients were dissatisfied in this area of the study, this was still seen as moderately satisfied compared to that of the pre-transplant data.

The study reported that when social interaction was found as the most satisfied aspect, it was also indicated in the patient's pre-transplant data. It was important to be aware of the fact that patients were still learning to live with having a new heart following transplantation, but overall quality of life was nonetheless better compared to

quality of life pre-transplant. Patient responses showed that predictors of better quality of life at 1-year post transplant were less stress, more helpfulness of information, better health perception, better compliance with transplant regimen, more effective coping, less functional disability, less symptom distress, older age, and fewer complications (Grady, Jalowiec, and White Williams, 1999).

According to data collected in the previous study, patient responses regarding the least satisfied aspect of their quality of life demonstrated that the studies have presented issues, concerns, and data around the importance of pre-transplant assessments in relation to patient post transplant success. This data also included the impact of post transplant depression and anxiety on quality of life. However, there have been few studies on the impact of psychosocial care on post heart transplant patients or what interventions were used to improve quality of life post transplant.

This was acknowledged by a report done by Cupples et al. (2006), which ultimately reviewed the status of the research on psychosocial outcomes in cardiothoracic transplantation and presented recommendations for the field. The report was drafted by a workgroup comprised of members in the realms of nursing, psychology, psychiatry, epidemiology, and social work. These individuals looked at empirical literature on adult cardiothoracic transplantation from 1980 through 2004 and determined the gaps within the literature. In doing so, they were able to formulate specific recommendations to guide future research. They were able to identify 5 major domains of psychosocial outcomes: Physical (functional capacity & performance, perceived physical health & symptoms, sexual functioning), behavioral (medical compliance, substance use/abuse), global quality of life (perceived overall well-being, happiness, satisfaction),

psychological (clinical disorder & subclinical distress, cognitive functioning), and social (return to work relationship stability, social adjustment).

The report indicated that after reviewing all the literature in 1980-2004, there was little information available regarding the impact of psychosocial domains on post transplant clinical outcomes. Given the little information that was found on the impact of psychosocial outcomes in predicting clinical morbidity and mortality, it was acknowledged within the report that there needs to be a way to be able to identify strategies that would greatly improve post transplant psychosocial functioning.

It was also found that standardized assessment instruments have been improving throughout the years, by utilizing psychometric properties. This new change has allowed a better understanding of the nature of post transplant psychosocial outcomes. However, even with improvements, what elements are considered psychosocial continue to remain ambiguous. This is mostly due to the inconsistency of researcher statements about how or why they choose certain measures in their psychosocial studies and not others. This idea is further supported by the idea that there needs to be some form of conceptual or measurement base that is purely around the unique domains of transplantation (Cupples et al., 2006).

The report indicated that there needs to be longitudinal or prospective study designs to allow for clearer conclusions regarding which variables are predictors or risk factors versus those that are outcomes (Cupples et al., 2006). According to recommendations made by Cupples et al. (2006), it was evident that there have been few studies evaluating the impact of psychosocial care on patients. The report acknowledged that given all the literature that has been reviewed, it was apparent that transplant patients

are highly affected in the psychosocial realm of their lives and the impact of psychosocial issues on morbidity and mortality rates for patients.

Given the report and literature presented here, it is evident that a study needs to be an overall push to acknowledge and raise awareness around the psychosocial issues around heart transplant patients and how subsequent interventions may impact a transplant recipient's life.

CHAPTER 3

METHODOLOGY

The goal of this study was to determine if psychosocial interventions in heart transplant patients who were identified as at-risk preoperatively and who received post-operative interventions, yielded better non-standardized hospitalization and survival outcomes than compared to patients who did not receive post-operative psychosocial interventions. A quantitative correlational study was designed by utilizing retrospective data from a medical institution that had an established cardiac transplant program. The data allowed examination of the relationship between post-operative psychosocial intervention and the frequency of non-standard of care hospitalizations following heart transplantation.

Non-standard of care refers to any type of care that is not normally required in the medical post-care treatment. At UCLA, the standard of care included 14 scheduled clinic visits which encompassed medical examination and psychosocial care on a needed basis per patient or physician requests within the first year after transplant with 1 annual visit for each consecutive year. The data was derived from patients who were deemed at-risk preoperatively and received a heart transplant. The aim was to determine which sample of individuals from the pre-operative at-risk group received psychosocial interventions post-operatively. The control group would thus consist of patients determined to be at-risk preoperatively who did not receive any psychosocial interventions post-operatively.

Design and subjects

Medical records of 567 patients from a single center that received a heart transplant between January 1994 and May 2008 were retrospectively reviewed. Of these 567 patients, 46 were deemed to be at-risk in their psychiatric and/or social work evaluations. Pre-transplant at-risk determination was asserted if a patient met one or more of the following criteria: history of mood or anxiety disorder, history of substance abuse, history of non-adherence to medical therapy, or concerns regarding level of social support. These 46 patients were a part of the previous retrospective study that evaluated the correlation between pre-transplant social work and psychiatric assessments and post transplant outcomes in patients who were deemed to be at-risk.

Patients were divided into groups based on whether or not they received post transplant psychosocial care in the first year following heart transplantation. As psychosocial protocol following heart transplantation at the center is not standardized, post transplant psychosocial care included any inpatient or outpatient visits with the transplant social worker and/or transplant psychiatrist for any of the pre-transplant psychosocial at-risk criteria.

Outcome measures

Information on the following relevant data was collected: pre-transplant psychosocial diagnoses, post transplant psychosocial diagnoses, pre-transplant psychosocial interventions, post transplant psychosocial interventions, and transplant outcomes (survival and non-standardized hospitalization). Baseline assessments were completed and compared using all demographic data. The primary end-points for this

study included 5-year actuarial survival and 1-year and 5-year freedom from any hospitalization, where hospitalization referred to any inpatient admittance.

Statistical Analysis

Two-tailed *t*-tests and chi-square tests were utilized in order to assess the variation between groups (demographic variation). The Wilcoxon log-rank statistic (compared two Kaplan-Meier over time) was used to compare Kaplan-Meier (shows outcome over time) survival curves. $P < 0.05$ was considered statistically significant.

CHAPTER 4

RESULTS

Among the study groups, there were found to be no significant differences in terms of baseline demographics including mean recipient age, mean donor age, gender, reason for transplantation, and ischemic time (time elapsed between explant of organ from donor and implant of organ to recipient)(table 1).

Table 1. Clinical Characteristics of the adult heart transplant patients in the study

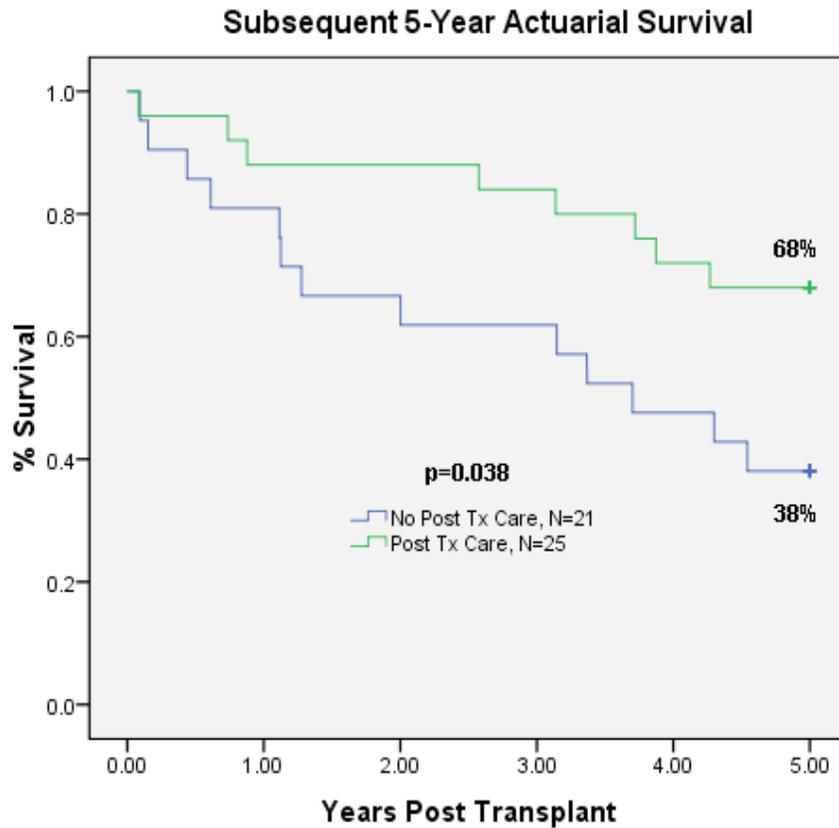
	No Post Tx Care	Post Tx Care
N	21	25
Mean Recipient Age (years)	49 ± 14	53 ± 10
Mean Donor Age (years)	31 ± 14	32 ± 14
Gender (%Female)	38%	32%
Reason for Transplant		
Idiopathic (%)	24%	24%
Ischemic (%)	43%	44%
Other (%)	33%	32%
Ischemic cardiomyopathy	31%	41%
Idiopathic cardiomyopathy	55%	53%
Other	14%	6%
Ischemic Time (minutes)	196 ± 62	200 ± 76

P= Not significant in all groups.

25/46 patients (54%) of the at-risk patients received psychosocial care in the first year post transplantation, and 21/46 (46%) did not receive any care in the first year post transplantation. Of these 25 patients, 20 received post transplant care for depression and/or anxiety, 4 received care for substance abuse, 3 received care for non-compliance issues, and 2 received care for social support issues, where some patients received multiple types of post transplant care.

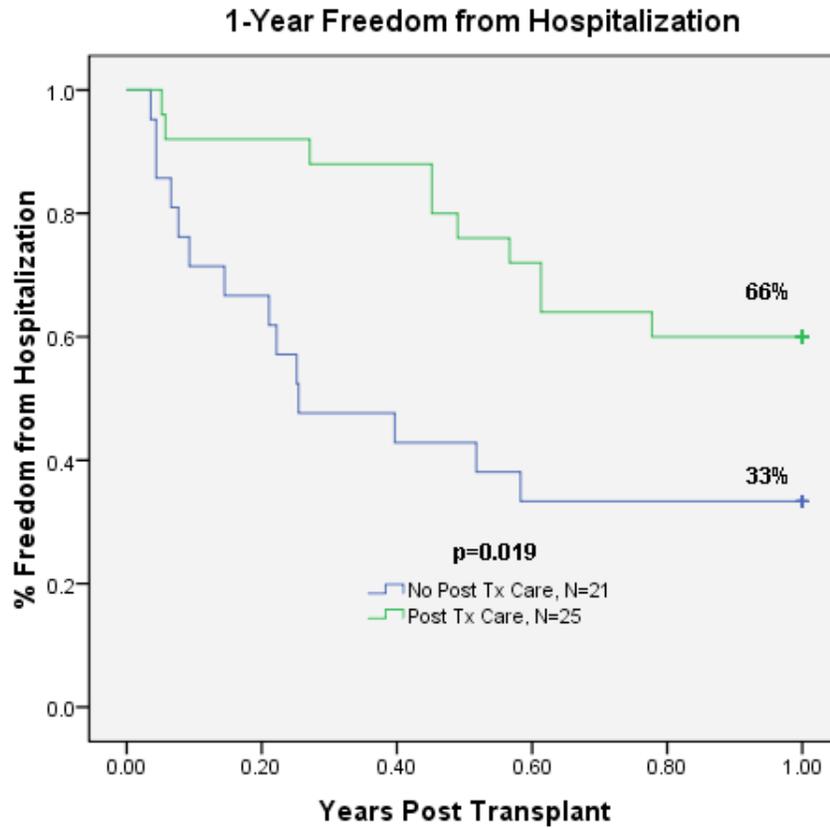
Patients that received post transplant psychosocial care demonstrated a significantly higher 5-year actuarial survival compared to patients that did not receive post transplant psychosocial care (68% vs. 38%, $p=0.038$)(figure 1).

Figure 1.



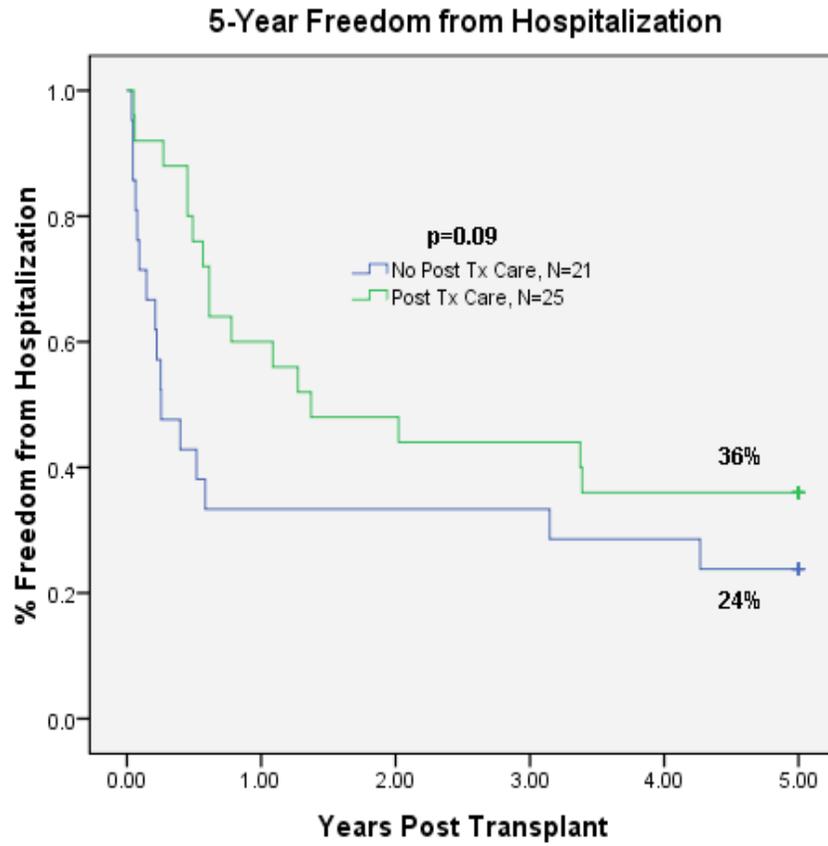
Similarly, patients in the post transplant psychosocial care group exhibited a significantly higher 1-year freedom from any hospitalization compared to the patients without psychosocial care following transplantation (66% vs. 33%, $p=0.019$)(figure 2).

Figure 2.



In addition, patients in the post transplant psychosocial care group exhibited a trend toward a higher 5-year actuarial freedom from any hospitalization compared to the group without post transplant psychosocial care (36% vs. 24%, $p=0.09$)(figure 3).

Figure 3.



CHAPTER 5

DISCUSSION

The results of this study have revealed that evaluating the psychosocial impact on post heart transplant yields positive correlations in regards to the percentage of non-standardized hospitalizations and survival rates, as was evident in evaluating the 46 subjects considered to be at-risk for complications post transplant. Meaning, that post heart transplant patients who received psychosocial care had higher survival rates and less non-standardized hospital visits compared to the patients who did not receive post heart transplant psychosocial care. Studies by Dew et al. (2005) have shown that patients who were showing any psychosocial and physical distress post-operatively were more likely to have had pre-morbid issues. They were diagnosed with (some overlapping symptoms): History of mood or anxiety disorder (n=34), history of substance abuse (n=31), history of non-adherence to medical therapy (n =14), concerns with level of social support (n=27). As mentioned previously, there is no standardized protocol or assessment for psychosocial care for post heart transplant patients in the treatment plan at UCLA following surgery and many other institutions. There were no indications as to why certain subjects received post heart transplant psychosocial care and others did not. Psychosocial care was voluntary or referred by their physicians.

5-year actuarial results indicated that patients who received some form of psychosocial care had a higher survival percentage compared to those who did not. Even though this is so, it is possible that there are existing confounding variables such as

patient socioeconomic status, marital status, familial support, and psychosocial care outside of their medical institution that may impact the results, but overall the study aimed to see if there was any type of correlation between psychosocial care and survival rates. Thus, within the pool of patients who did receive some form of psychosocial care, 86% (n=17) of the 24 patients survived after 5 years compared to 33% (n=8) of 21 patients who did not receive psychosocial after 5 years.

Patients that received psychosocial care met with a psychiatrist or social worker to deal with psychosocial issues ranging from psycho-pharmaceutical medications to simple case management, such as financial complications. It was evident that regardless of the situation for patients who were deemed to be at risk pre-transplant, those that received some form of continual psychosocial care post transplant survived longer compared to their counterparts who did not receive any care. This supports the conclusions that patients may indeed need to receive similar care pre-transplant and post-transplant (Evangelista et al., 2005).

In the study by Olbrisch et al. (2002), it was mentioned that the first year following heart transplant represented the time with the most adjustment difficulties for patients overall in all aspects of transplantation due to the severe change in lifestyle in the stringent medical regimen, medication compliance, and mood changes. Figure 2 indicated that at-risk patients who received psychosocial care post heart transplant had a higher percentage rate of coming back less for non-standardized hospital visitations. Standardized care consisted of fourteen scheduled visits within the first year post heart transplant. 66% of patients who received psychosocial care came back less, while only 33% of patients who did not receive any psychosocial care came back less. Figure 3

looked at non-standardized hospitalization at 5-years, yielding results of 36% for those with post transplant care and 24% for those who did not receive any care. Therefore, the study revealed that psychosocial intervention post heart transplant appears to yield better survival and decreased number of non-standardized hospitalizations.

Of those who received care, most were diagnosed with depression and/or anxiety. This correlates positively with reports that depression is a high risk for post heart transplant patients (Havik et al., 2007). A study indicating that patients are more likely to have depressive and anxiety symptoms post transplant is further solidified by the twenty patients within this study who were assessed post transplant as having some form of depressive and/or anxiety disorder.

Despite the positive correlations that have been found in this study, it also maintains certain limitations. For instance, one limitation is that there could be confounding variables in this study that may have altered the results found. There could be additional issues as to why some patients received psychosocial care compared to those who did not. Since there is no standardized protocol in regards to psychosocial care, documentation could have been lacking even if care was actually given to the patients. There was also the inability to assess the degree of intervention utilized with patients. As such, interventions were unique to patient needs, thereby making it more difficult to assess this variable. If confounding variables are indeed present, then the issues pertaining to patients receiving additional care compared to other groups not receiving this care may not have directly been the cause for statistical difference in the outcomes listed in the results section. Despite these limitations, several other transplant

variables have been accounted for such as demographics, which were found to be similar in the two groups (see results section).

There have been many studies within the literature regarding the importance of psychosocial assessments as a pre-transplant requirement for patients, which may function to assist medical care professionals in ascertaining the level of risk that patients may experience during the post heart transplant recovery. For instance, the Moreno et al. (2009) study further indicated that patients who were considered to be at-risk pre-transplant were still considered highly at-risk post transplant. As such, with the plethora of studies that have reported the importance of assessing and evaluating pre-transplant conditions as well as its effects on post transplant quality of life, then why does there appear to be so little research regarding psychosocial involvement post transplant?

In conclusion, based upon the analyzed pool of data from this cohort of patients, I believe that further study is needed in order to look at the impact of psychosocial care for patients following heart transplantation. Ongoing psychosocial assessments for transplant patients post-operation may be beneficial for patients and medical staff to assess patient needs and wellbeing, therefore allowing preventive psychosocial care. Much research has evaluated the importance of psychosocial assessments prior to transplant, but very little analysis has been performed in the time following transplantation. It would be beneficial to conduct a retrospective or even a prospective study about psychosocial care in a controlled and structured manner as to minimize the limitations of the study. If it is determined that psychosocial assessments may indeed improve long-term outcomes, then there is certainly a need for follow through.

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APPENDIX A



APPROVAL NOTICE

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
11000 Kinross Avenue, Suite 102
169407
www.oprs.ucla.edu

DATE: November 24, 2009

TO: Abbas Ardehali, M.D.
Principal Investigator

FROM: Alison A. Moore, M.D., M.P.H.
Chair, South General Institutional Review Board

RE: UCLA IRB #G03-12-039-13
Approved by Expedited Review
(Approval Period from 11/24/2009 through 11/23/2010)
Risk Factors and Outcomes Post Heart Transplantation: 20 Year Experience at UCLA [includes addendum
changes: addition of co-investigator: Dr. Jon Kobashigawa]

Please be notified that the UCLA Institutional Review Board (UCLA IRB) has approved the above referenced research project involving human subjects in research. The UCLA's Federalwide Assurance (FWA) with the Department of Health and Human Services, Office for Human Research Protections is FWA00004642.

PLEASE COMPLY WITH THE FOLLOWING CODICIL(S) IMPOSED BY THE IRB:

1. The UCLA IRB waived the requirement for research informed consent under 45 CFR 46.116(d).
2. The UCLA IRB waived the requirement for HIPAA Research Authorization for the research.

A handwritten signature in black ink, appearing to read 'Alison A. Moore'.

Approval Signature of the UCLA IRB Chair

PRINCIPLES TO BE FOLLOWED BY PRINCIPAL INVESTIGATORS:

APPROVAL NOTICE
IRB #G03-12-039-13

As the Principal Investigator, you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the UCLA IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved protocol.
2. Do not implement changes in the approved protocol or consent form without prior UCLA IRB approval (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects.)
3. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved UCLA-IRB stamped consent form.
4. Promptly report all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within ten working days of occurrence. All fatal or life-threatening events must be reported to the UCLA IRB in writing within 2 working days after discovery.
5. In clinical medical research, any physician(s) caring for your research subjects must be fully aware of the protocol in which the subject is participating.
6. No subjects may be identified, contacted, recruited, or enrolled until the contract with the sponsor is finalized by the University.
7. Ensure that all individuals who will interact with subjects and/or have access to identifiable research data have completed the UCLA Protection of Human Research Subjects Certification.
8. Ensure that all individuals who will access subjects' medical records have completed the UCLA HIPAA Research Training Certification.
9. If non-UCLA sites or personnel are involved, follow all study-specific requirements and consent processes approved by the UCLA IRB.

FUNDING SOURCE(S):

According to the information provided in your application, the funding source(s) for this research project may include the following: extramural.

PI of Contract/Grant: Abbas Ardehali
Funding Source: California Heart Center Foundation
Contract/Grant No: 20082173
Contract/Grant Title: Risk Factors and Outcomes Post Heart Transplantation: 25 Year Experience at UCLA