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Quality of Life after Heart Transplantation

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SCHOOL OF NURSING**

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The project and the manuscript have been successfully completed and meet the standards of the School of Nursing University. The project demonstrates the application of professional knowledge, clinical expertise, and scholarly thinking. An abstract of the project and two copies of the manuscript are attached.

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5/19/04

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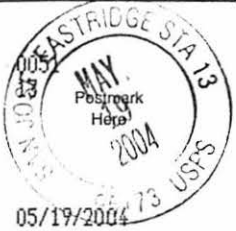
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Quality of Life after Heart Transplantation

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Abstract

Background: Cardiac transplantation has been a treatment option for patients with end stage heart failure for the past 35 years. As evaluation and treatment protocols emerge and evolve it is the responsibility of the healthcare provider to assist the recipient in attaining the best quality of life (QOL) possible.

Method: A demographic survey, along with the SF-36v2 generic survey, which measures quality of life in physical and functioning domains, was mailed to 100 heart transplant recipients in a large health plan in Northern California. The data from sixty five surveys were analyzed for any relationships between time from transplantation, employment status, expectations of transplantation and the SF-36v2 scores. General comparison to U.S. norms for the SF-36 was also performed.

Results: Lower physical functioning scores were noted among participants that were not able to find work, had longer time from transplant and higher expectations. Mental health scores only achieved statistical significance in the category of recipient expectations ($P < .0001$). The physical component was the domain that was affected most by transplantation.

Conclusion: Interventions, such as lifestyle management, that target improved long-term outcomes may improve this area of transplantation.

Key Words: Quality of Life, Heart transplantation, SF-36 survey

Quality of life after heart transplantation

Background

Cardiac transplantation has been a viable option for the treatment of end-stage heart disease for the last 35 years. It offers patients dying from heart disease symptomatic relief, an improved chance of survival, and an improved quality of life (QOL). In the early 1980's, the introduction of cyclosporine immunosuppressive therapy revolutionized transplantation, significantly improving graft, and patient survival. This allowed for the use of lower doses of corticosteroids, and thereby decreased the risk of steroid-related co-morbidities such as osteoporosis, diabetes, and peptic ulcer disease. As rejection rates and death from infection fell, patient survival improved and late complications of chronic immunosuppression became apparent. Several important sequelae and causes of death specific to this population are graft vasculopathy, the development of coronary artery disease in the transplanted heart, post-transplant lymphoproliferative disorder (PTLD), and non-lymphoma cancers. In addition, chronic health problems affect a significant percentage of transplant recipients, including obesity¹, osteoporosis², hypertension, renal dysfunction, hyperlipidemia, diabetes³, and depression.⁴

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Health related outcomes regarding mortality and morbidity have been the traditional measures of success after heart transplantation. Data from The United Network for Organ Sharing (UNOS) reports heart transplant recipients' survival at 85.3%, 77.2%, and 70.6% at 1 year, 3 years and 5 years respectively.⁵ As survival has stabilized quality of life has become more important to providers and to recipients.

This study investigated the perceived QOL of 65 heart transplant recipients in a large healthcare organization. The research questions explored were: 1) Is there a correlation between perceived QOL and number of years since transplant? 2) Do the expectations of recipients effect the perception of QOL? 3) Does employment status have an effect on QOL? 4) How do the recipients' perceived QOL compare with that of healthy persons in the United States?

Conceptual Framework

Health, by broad definition, is "a state of complete physical, mental, and social well-being and not merely absence of disease or infirmity."⁶ In that context the exploration of quality of life in transplant recipients is imperative since the absence of death or severe heart failure symptoms is insufficient in itself to impart a high QOL. Individual perceptions of QOL represent a person's perception of health,

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happiness and general well-being at any given time. QOL is unique to each individual and is influenced by external environments including social interaction and economics and internal environments including health and emotional). In 1990 Ferrans, after extensive literature review, developed a conceptual model of QOL based on the individuals experience in life. She proposed that all persons bring a unique focus to quality of life and only that individual can be the proper judge of his/her personal QOL. She defined QOL in terms of life satisfaction, how satisfied an individual is with the aspects of life that are important to them. Using qualitative methods she was able to cluster the elements into 4 domains that interact to maintain a person's QOL: health and functioning; psychological/spiritual; social and economic; and family.⁷ This model was used to develop the Quality of Life Index and has been used extensively over the years in QOL research.

In 1992, Zahn developed a model of QOL based on "the degree to which a person's life experiences are satisfying."⁸ Building on the Ferrans model, Zahn proposed that personal background, social situation, culture, environment and age also influence perceptions of QOL. Zahn's model utilizes 4 domains that describe aspects that are important to the assessment of QOL: Life satisfaction, self-concept, health and functioning, and socioeconomic factors. Life satisfaction is a cognitive

evaluation of how a person perceives his attainment of needs, wishes and expectations and provides a feeling of general well being. It is influenced by changes in the external environment and is global in nature making this difficult to measure. Self-concept, how one views himself or herself and the ability to self examine influences an individual's perception of QOL. A positive self concept is a coping resource for the individual. Health and functioning is a major component of QOL. Although the measurement of health and functioning is considered objective, the way health is viewed may differ from person to person based on external factors like access to care and family views. Socioeconomic factors encompass occupation, education and income all being dependent on the individual's expectations and needs.⁸

The Zahn model differs from the Ferrans model in its acceptance of the influence of external forces on an individual's QOL and how those external forces color the 4 domains measured. The Zahn model is used as the basis for this investigation of the quality of life in heart transplant recipients.

More recently Hathaway et al. developed quality of life framework for researching the impact of transplantation consisting of 5 domains: health factors, social factors, major life events, major health events and quality of life.⁹ This model although specific for transplantation is not as comprehensive in the assessment of quality of life. Where Zahn

and Ferrans clearly assess for the recipient's life satisfaction as a major component of QOL taking into account the individual's world view the Hathaway model does not.

Review of Literature

As technology and immunosuppression regimens have improved over the past years QOL research in transplantation has become more abundant and more urgent. QOL in transplantation has been studied extensively but gaps in knowledge may or may not be filled based on the design of a study. The knowledge gained from these studies is being used to make treatment decisions and allocate resources.¹⁰

What constitutes QOL of life is an individual response as has been discussed above. Influences on QOL have been studied usually using a cross-sectional design assessing recipients after transplantation. More recently designs have become prospective measuring the QOL when substituting one set of problems experienced prior to transplantation; for a different set after transplantation.^{11,12} Studies have shown that there is an improvement in QOL after heart transplantation even though it is still below the healthy U.S. population particularly when assessing the physical components of QOL.^{9,13}

Most of the studies done to date have addressed the overall QOL after transplantation, usually within the first 5 years.

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Recently studies based on data that has been collected in registries have looked at the QOL in the long-survivor of transplantation, greater than 5 years. Salyer, Sneed and Corley (2001) looked at lifestyle and health status in the long-term population. They found that health promoting activities that would prevent or manage co-morbid conditions were followed inconsistently: stress management and spiritual growth were incorporated most frequently and physical activity the least.¹⁴ Obesity, osteopenia and acute rejection have been shown to negatively correlate with QOL.¹⁵

Mental health is another component of QOL. Poor psychological adjustment including increased episodes of major depressive disorder (MDD) and anxiety is a major contributor to reduced quality of life although the incidence of new diagnosis of MDD and anxiety decrease with time.⁴ Heart transplant recipients demonstrate a high rate of post traumatic stress disorder, particularly if there is not a cohesive family unit for support during the pre-transplant waiting period and post-transplant care.¹⁶ Both physical and psychological components have been shown to be impacted positively by persons who were employed.¹⁷

Instruments

The SF-36v2® (QualityMetric, Boston, Mass) is a thirty six question, generic health survey that assesses basic human values that affect everyone's functional status and well being.

Designed for self-administration, telephone administration or administration during a personal interview; it is brief and comprehensive. The SF-36 was developed when patients refused to complete the lengthy surveys included in the Health Insurance Experiment (HIE) and Medical Outcomes Study (MOS).¹⁸ The SF-36v2 consists of 8 domains: Physical functioning, role functioning both physical and mental, bodily pain, social functioning, mental health, vitality, and general health perception; the SF-36 short form includes the major concepts addressed in the more lengthy surveys.

The Physical Functioning Scale captures the presence and extent of physical limitations measured on a three level response continuum. Role limitations due to health problems are addressed in the Role Functioning Scale with differentiation between limitations due to physical health and mental health captured. Frequency of pain and the extent to which it interferes with normal activities are captured in the Bodily Pain domain and the effects of physical health and emotional problems on social activities are captured in the Social Functioning domain. The five-item Mental Health Scale includes

items from the four major mental health dimensions; anxiety, depression, loss of behavioral or emotional control, and psychological well being. Energy level and fatigue are captured in the Vitality scale. The General Health Perceptions scale is a 5 item scale rating health, ranging from excellent to poor. It was constructed from the Health Perceptions Questionnaire (HPQ) and correlates highly ($r=0.96$) with the 22-item General Health Rating Index also constructed from the HPQ and is less redundant.¹⁹

When analyzed for correlations among the eight scales, two factors, the mental and physical dimensions, accounted for 80-85 percent of the reliable variance in health status. The construction of two summary measures, the Physical Component Summary (PCS) scale and the Mental Component Summary (MCS) scale, were developed from this concept. This allows for analysis of statistical comparisons required to be reduced from eight to two without substantial loss of information.²⁰

The survey has been tested extensively for reliability and validity both for the 8 individual domains and for two summary scales; and has been used extensively in QOL studies alone and in conjunction with other health and well-being scales. Reliability coefficients for the PCS and MCS summary scales have been estimated, using the internal consistency method, to have a reliability of 0.89-0.94 and 0.74-0.91 respectively.²⁰

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Important health concepts that are not addressed within the survey are health distress, family functioning, sexual functioning, cognitive functioning, and sleep disorders.²¹ All of these concepts can influence a person's perception of his/her QOL and are pieces of Zahn's QOL model.

A demographic questionnaire was developed to describe the population that was surveyed and to capture some demographic factors that have been shown to influence QOL. Included were age, ethnicity, years since transplant, employment status, number of medications, co-morbidities and whether or not transplantation had met the individual's expectations.

Methods

Licensing for use of the SF-36 was obtained from QualityMetric, Inc. of Lincoln, RI. Approval for this study was sought and received from the Investigational Review Boards for the health care institution and the University. Subject selection was attained by convenience sampling of the living adult cardiac transplant recipients that are members of a single large Health Plan in Northern California. A total of 100 questionnaires were mailed to all subjects currently followed or authorized for adult post cardiac transplantation care by the Health Plan.

A contact letter with consent to participate information was included in the mailing which explained the intent of the survey and assured confidentiality of the reply. Return of the questionnaire constituted consent to participate. Also included was a self addressed stamped return letter to verify return of the survey and to notify the researcher of request for survey results. Over the course of 6 weeks 65 surveys were returned.

Results

The SF-36v2 survey data was scored in accordance with the manual provided with the survey, with missing data scored as the average of items answered in that domain.²² The SPSS version 11.5 (SPSS Inc., Chicago, September 2002) statistical software for graduate students was used for statistical analysis.

The data were presented in a descriptive cross-sectional manner. Significance testing was conducted for comparisons of interest:

Sixty five heart transplant recipients in the Northern California region responded to the survey. Two failed to fill out the demographic questionnaire and were not included in the analysis of data. Seventy percent of the responding population was in the age group 51-70 years old with the balance distributed across the remaining age groups; 18-50 & 70+. This correlates with the most recent national transplant data.⁵ Males outnumbered females 77.8% to 22.6%; respectively (Table 1). The

population was predominantly Caucasian, with all other races equaling just over 26%. This is consistent with the national statistics of heart transplant recipients, based on Organ Procurement and Transplantation Network (OPTN) data as of April 2, 2004.

Twenty six percent of the recipient population was unable to return to work after transplantation and another 24.6% declared themselves retired. Full time work was reported by 18.5% of the respondents, and part time work was reported by 16.9% (table 2). A one-way ANOVA showed significance relationship in the PCS score, $P < .0001$ and the MCS showed no significance, $P = 0.115$. The number of recipients that returned to full time work, 29%, reported lower than the national average. Recipients reporting part time employment, 8.5%, was higher than the national average.³ Fifty percent of the respondents reported that they were no longer employed in the same occupation as prior to transplantation. Only 3.2%, $N=2$, reported difficulties with their employer due to their heart transplant status.

Cross sectional longitudinal data gathered were measured by distance from transplantation. The most heavily represented groupings of years since transplantation were the groups 1-3 years, 33.3%; 6-10 years, 25.4%; and 11-15 years, 19.0% (table 3). A one way ANOVA showed significance in the PCS score, $P = 0.03$ but none was shown in the MCS (figure 1).

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Respondents reporting co-morbid conditions revealed that 11% of the sample, N=17 stated that they had no co-morbidities, 35.4% reported hypertension, 13.8% reported diabetes, 18.5% reported renal problems, 15.4% reported coronary artery disease, 9.2% reported cancer of any kind and 13.8% a co-morbid condition that was not listed. Also of note six respondents had 2 co-morbid conditions, six had 3 co-morbid conditions, two had 4 co-morbid conditions and one respondent had 5 co-morbid conditions. One way ANOVA showed significance only in the relationship between the number of co-morbid conditions and the PCS score ($P=0.004$).

Fifty three recipients, 84.1%, stated that they had no rejection episodes in the past 12 months; 9.5% had one episode and 6.3% reported having 2 to 3 rejection episodes. Most recipients were taking, at the time of the survey, 6-15 different medications with 33.3%, N=21, taking 6-10 and 31.7%, N=20, taking 11-15 different medication. Very few were taking 5 or fewer medications, 7.9%.

Expectations after transplantation revealed that 58.7% thought life was better than they had expected after transplantation, 23.8% thought their experience was what was expected and 17.5% thought the post transplant experience was worse than expected (table 4). This proved significant in both the PCS and the MCS arms, $P < 0.001$ in both.

Discussion

Many factors influence QOL and the response to many of the domains is very individualized. The present study found results that are consistent with previous QOL research involving transplant recipients.

When considering the research question "Is there a correlation between perceived QOL and number of years since transplant?" the results of this study question a presumption that mental health decreases over time as physical functioning decreases. The mental scores increased even as the PCS score continued to decline. Years since transplantation showed only significance in a one-way ANOVA for the physical combined score. Salyer, Flattery, Joyner and Elswick (2003) also found that longer time from transplantation was a predictor of more favorable outlook on QOL and may explain the dichotomy between the two composite component scores.¹⁴ Dew et al. noted that the incidence of MDD and anxiety reported conditions decreases as time from transplant progresses.⁴ The reason for this is unclear but may be related to coping mechanisms and acceptance of the future.²³

With regard to the second research question, "Do the expectations of recipients' effect the perceptions of QOL?", the results were not surprising. When asked the question "Is life after transplant what you expected?", over half of the study

subjects reported that the post transplant experience was better than expected, while about one fourth of the subjects reported that their post-transplant experience was what they expected. Less than one fifth of the subjects reported their experience fell below their expectations of post transplant life. This may be explained by only those with a good QOL thinking that life is better and those with a lower QOL thinking that life should have been better; with the group reporting life after transplant was what expected scoring in the range between the two extremes.

(Figure 2)

With regard to the third research question, "Does employment status have an effect on QOL?", studies in the past have shown that persons not employed after heart transplantation experienced lower QOL than patients who are employed.²⁴ The findings in this study also supported the claim with the lowest MCS and PCS scores being found in the unemployed group and the highest in those with full time and part time employment. Many of the respondents are retired, also scoring high in the MCS. This was most likely due to the high numbers in the 51-70 age groups. The lower than U.S. norm for the PCS scores across the board may also account for the inability of many to attain or hold employment after transplantation. Employer biases in hiring did not seem to be an issue in the group that responded to the survey.

Considering the fourth research question, "How do the recipients' perceived QOL compare with that of healthy persons in the United States?", overall QOL was lower in the transplant recipients with co-morbid conditions than the general U.S. population norms provided by the SF-36 health survey. However, the transplant recipients in this study scored higher than those with congestive heart failure, which one would hope since this is the reason they were transplanted.²⁰ Scores correlated with, or were lower than that of the general U.S. population with the same chronic conditions. Impaired physical scores were more predominate than mental scores.

The transplant team is a collaborative practice consisting of the nurse coordinators, physicians, social workers, psychiatrists, and dieticians. The family and adult nurse practitioner as a coordinator is in the unique position of being skilled in the art of patient education along with the ability to intervene with medical knowledge to attenuate many of the co-morbid conditions that are common in the pre and post transplant population. By focusing on health promotion and disease prevention, the nurse practitioner in the transplant program can help decrease the risk of long-term post transplant complications that may lead to a decreased survival and quality of life and an increased cost to the health care system.²⁵

Limitations

This is a cross sectional study that involved small numbers and only one heart transplant program. The extrapolation of these data to other transplant programs should be done with caution. Also the population is weighted heavily with Caucasians and the 50-70 year old age group. Multi-center, long-term prospective trials need to be done to determine the overall effects that post transplantation issues have on life. The PORTEL registry⁹ and the Transplant Learning Center sponsored by Novartis¹⁰ may be able to provide many answers to the long-term QOL of post transplant patients. Interventional studies involving health promotion strategies by advanced practice nurses could offer avenues to improving long-term quality of life for transplant recipients of any kind.

Conclusion

As medication regimens and management protocols for heart transplant recipients evolve, it will be the health care provider's responsibility to monitor the effects of emerging therapies and maintain an improved outcome for the recipient. The long-term sequelae of new and old protocols will need to be monitored and lifestyle management will need to be addressed as many recipients fall back into prior unhealthy habits that impact QOL and led to the need for transplantation, such as

smoking, lack of exercise and obesity.¹⁴ A stronger emphasis on adoption of a healthy lifestyle during the pre and post transplantation periods could have a large impact on raising PCS scores. A focus on this type of patient education and management by the advanced practice nurse may help establish appropriate expectations for life as years from transplantation progress and may allow recipients greater physical ability and the chance to return to work.

This study reinforces the concept that each recipient is an individual and brings to the experience of heart transplantation a life full of diversity. Future studies would be strengthened by including surveys that address family, socioeconomic, psychosocial, spiritual, and health data in more detail to be able to correlate major factors that put recipients at a higher risk for reduced quality of life scores. Interventional studies involving the impact of health promotion and disease prevention on long term QOL will further assist advanced practice nurses, whether in primary care or in the transplant program, in leading the heart transplant recipient to a longer more satisfying life.

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Appendix

Table 1. Demographic Data

Variable	# of recipients	Valid %
Total	65 (63 valid)*	
Age		
18-30	3	4.8
31-40	5	7.9
41-50	6	9.5
51-60	20	31.7
61-70	24	38.1
71-80	5	7.9
Ethnicity		
Asian	4	6.3
African American	4	6.3
Caucasian	46	73.0
Hispanic-White	6	9.5
Other†	3	4.8
Gender		
Male	49	77.8
Female	14	22.8

• 2 respondents did not fill in demographic questionnaire

† 3 respondents declined to declare their ethnicity

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Table 2. Employment status after Tranplantation

Employment status	# of recipients	Valid %
No	17	26.2
Full time	12	18.5
Full time now retired	1	1.5
Part time	11	16.9
Retired	16	24.6
Not applicable	6	9.2

Table 3. Years since transplantation

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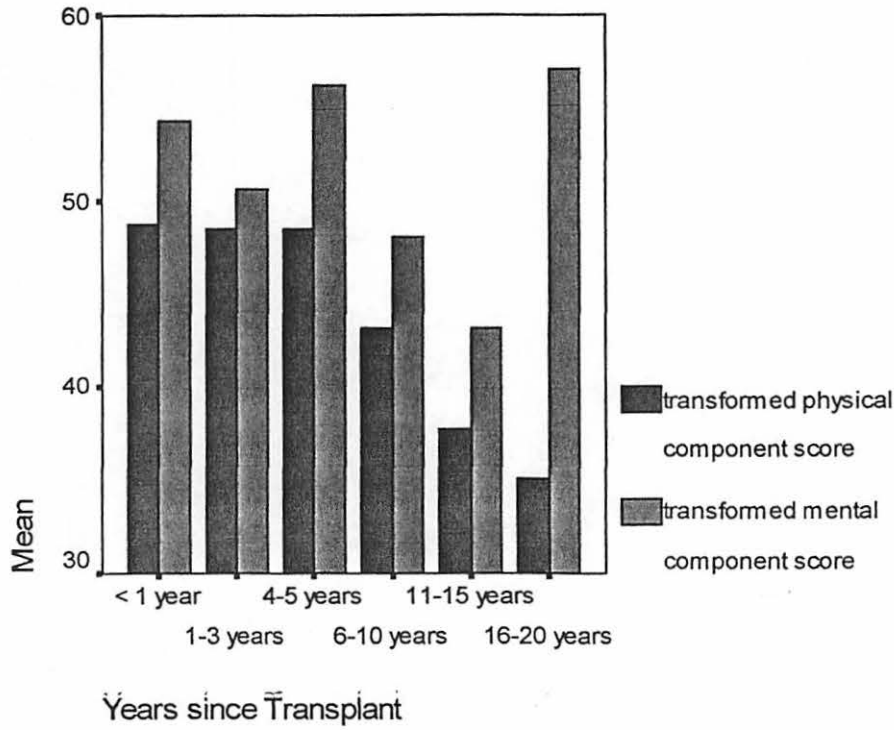
Years since Transplant	# of recipients	Valid %
<1	2	3.2
1-3	21	33.3
4-5	8	12.7
6-10	16	25.4
11-15	12	19.0
16-20	4	6.3
21-30	0	0

Table 4. Expectations

Quality of Life After Heart Transplantation

Is your life after transplant what you expected?	# of recipients	Valid %
Better	37	58.7
What I expected	15	23.8
Worse	11	17.5

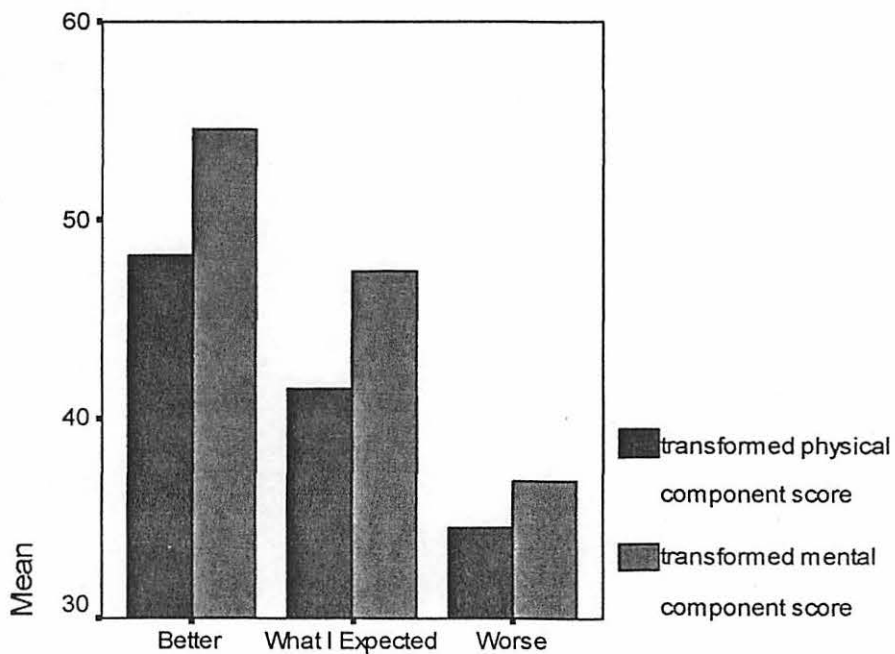
Figure 1 Years since Transplantation



Transformed physical component score (PCS) at $P=0.03$

The mental component score (MCS) was not significant.

Figure 2 Expectations



Is your life after transplant what you expected?

both PCS and MCS significant $P < 0.001$

PCS = transformed physical component score

MCS = transformed mental component score