Incidence of Depression and Anxiety in Patients Awaiting Heart Transplants at Home versus in the Hospital

Polly

A. Study Purpose and Rationale

The wait for a heart transplant is extremely stressful. Every year, approximately 30% of candidates will die before an organ becomes available. Previous studies have shown that pre- transplant rates of anxiety disorders and major depression are higher than community rates but are similar to other cohorts with serious, chronic physical conditions. In, these cohorts the median lifetime rate of major depression is 29% (range 9% to 54%) as compared with approximately 10% in the community. For Generalized Anxiety Disorder (GAD), the median lifetime rate is 12% (range 2% to 14%).

Many candidates await transplants while in the hospital because of the need for multiple intravenous inotropes, mechanical ventilation or intra- aortic balloon pumps. This waiting period presents unique stresses to the patient including the loss of autonomy, inability to continue normal daily activities the frequent death of peers before an organ becomes available. In general, patients waiting in the hospital are sicker than patients waiting at home and are exposed to more procedures and testing. One would hypothesize then that patients waiting for heart transplants in the hospital would have a higher incidence of depression and anxiety than patients waiting at home.

The purpose of this study is to compare the incidence of anxiety and depression in patients awaiting transplant at home versus in the hospital and to examine the overall trends in symptoms of anxiety and depression over time in these two groups.

B. Study Design and Statistical Analysis

The study would be a prospective observational study comparing two groups: hospitalized transplant candidates and candidates waiting at home. At the time a candidate is evaluated, all participants would undergo a formal psychiatric evaluation as well as completion of two surveys: the Beck Depression Scale (BDS) and the State/ Trait Anxiety Index (STAI). All Interviews would be structured according to the DSM 11-V guidelines for clinical interviews and an assessment would be made as to whether the patient had a current or prior diagnosis of anxiety or depression. Baseline data that could potentially confound the study would be collected initially and periodically reassessed where appropriate including age, sex, socioeconomic status, educational level, duration of illness, family or personal history of psychiatric disorder, cause of CHF, NYHA functional class and medications.

At the time a candidate is listed, patients would again undergo a psychiatric evaluation and complete the BDS and STAI if more than two weeks had elapsed since the initial evaluation. Thereafter, candidates would complete the BDS and the STAI serially every two weeks and have a formal psychiatric evaluation every month. The surveys would be used to assess overall trends in anxiety and depression over time and the interview would be used to make the diagnosis of a major depression and/ or generalized anxiety disorder. All interviews would be conducted by a single investigator. The endpoint of the study would be transplant, death or removal from list due to overall improvement in functional status.

Statistical analysis would be completed comparing the two groups to see if a significant difference existed between the two groups in 1) the incidence of a major depression 2) the incidence of an anxiety disorder and 3) the overall trends towards anxiety and/ or depression. Data would be adjusted to account for the difference in baseline rates of anxiety and depression prior to the onset of illness if these rates differed. To assess whether a significant difference in the incidence of anxiety and depression exists between the two groups, the proportion of patients who had a an event ie. the diagnosis of major depression or generalized anxiety disorder at six months would be calculated and a chi square analysis

would be performed to determine statistical significance. In order to assess overall trends, the scores on the BDS and STAI over time would be plotted and the slope representing the overall trend in symptoms would be calculated for every participant. A ttest would be used to determine statistical significance.

C. Study Questionnaires

Beck Depression Scale State/ Trait Anxiety Index

D. Study Subjects

Eligible subjects would include all candidates > 18 years old who are listed as UNOS status I or II over a two year period at CPMC. Annually, over 100 patients are currently listed at CPMC and on average 60 transplants are performed. According to current UNOS guidelines, a patient is listed as I A if they meet one of the following criteria: a) require assistance with a ventilator b) require assistance with a balloon pump or c) require high dose or multiple inotropes. A patient is listed as UNOS IB if they require low dose inotropes. All other candidates, are listed as UNOS H.

Candidates would be excluded if they had a prior transplant or if they required mechanical ventilation greater than 50% of the time. Patients who were temporarily not listed because of contraindications to transplant ie. renal failure but who were subsequently re-listed would be included in the final analysis. Subjects would be followed until one of the following endpoints was reached: 1) transplant 2) death or 3)removal from transplant list because of improvement or recovery from underlying disease.

E. Recruitment of Subjects

All patients eligible for cardiac transplantation at CPMC over a two year period would meet with an investigator who would recruit them for the study at the time of their initial evaluation. In order to encourage a high rate of participation, a small donation would be given to research in cardiac transplantation for every patient who participated.

E. Potential Conflict of Interest

Data collected from this study would be separate from data collected by the transplant team because it could potentially affect transplant eligibility. All data would remain confidential.

F. Location of Study

Columbia Presbyterian Medical Center in- patient wards and a separate study site for outpatients.

G. Risks to Subjects

None

H. Benefits to Subjects

This study provides no direct benefits to participants but would hopefully benefits future patients awaiting transplantation.

I. Compensation to Subjects

All Subjects would be volunteers. However, a small donation would be given to transplantation research at the time of initial enrollment and after a study endpoint is reached.

J. References

1. Maricle, Robert et al., Depression in Patients Being Evaluated for Heart Transplantation. General Hospital Psychiatry 11. 1989, 418- 424.
2. Myers, Jerome K. et al, Six month Prevalence of Psychiatric disorders in Three Communities. Arch Gen Psychiatry- Vol 41, Oct 1984. 959-967.
3. Watts, Deborah et al., Psychiatric aspects of Cardiac Transplantation. Heart Transplantation, III, May 1984, 243-247.
4. Dew, Mary et al. Prevalence and Predictors of Depression and Anxiety- Related Disorders During the Year After Heart Transplantation. General Hospital Psychiatry 18, 1996. 48S-61S.
5. Von Ammon Cavanugh, Stephanie. Diagnosing Depression in the Hospitalized Patient with Chronic Medical Illness. J Clin Psychiatry 45: March 1984. 13- 16.
6. Deshields, Teresa. Psychological and Cognitive Status Before and after Heart Transplantation. General Hospital Psychiatry 18, 1996. 62S- 69S.
7. WWW. UNOS.COM