A Randomized Controlled Clinical Trial Evaluating the Effect of a Standardized Pre-Travel Intervention Versus Standard Care on Reducing Rates of Hospitalization in Latino Patients with Congestive Heart Failure

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A. Study Purpose and Rationale

Approximately 30% of the patient population at the Associates in Internal Medicine Clinics (AIM) at Columbia Presbyterian Medical Center (CPMC) is Latino (personal communication with Dr. Matthew Maurer, cardiologist at CPMC 7/19/02). Many of these patients travel regularly to and from their country of origin, often for extended periods of time. As a result, those patients with chronic medical problems frequently receive medical care both in Latin America as well as at CPMC. The effect of such travel on health care and management of chronic illnesses remains largely unexplored. Potential problems these patients face include running out of maintenance medications, substitution of maintenance medications with medications of a different class or dosage and lack of continuity of care. For patients with illnesses such as congestive heart failure (CHF) these situations can place them at increased risk for morbidity and mortality.

CHF is the number one cause of hospitalization in patients greater than 65 years old in the United States with readmission rates noted to be 29-47% within three to six months of discharge (Hoyt and Bowling, 2001; Rich et al., 1996). It is also the number one cause of hospitalization at CPMC with an average of three to four hospitalizations per day at both Milstein Hospital and the Allen Pavilion secondary to CHF (personal communication with Dr. Maurer, 7/19/02). For these patients in particular, medication adherence and regimen can influence rates of clinical decompensation and hospitalization over a relatively short period of time (Rich et al., 1996). The purpose of this study is to evaluate the effect of a standardized pre-travel session versus standard care on hospitalization rates of Latino patients with CHF who plan on staying in Latin America for more than three months but less than six months of a given year. The intervention will include providing the patient with prescriptions to ensure that the patient has enough medications to cover the duration of the trip and/or a list of suitable alternatives available in the planned destination of travel. Additionally, patients in the intervention group will receive a letter addressed to potential health care providers in Latin America detailing the patient's medical problems, list of medications and contact information at CPMC should the health care practitioner have any questions. The hypothesis is that such pre-travel preparation, which is of minimal cost, will have a clinically significant effect on rates of hospitalization, measurements of compensated CHF, and adherence to medical regimens. The primary outcome will be rates of hospitalization related to CHF. Secondary outcomes will include factors which have been shown to correlate with the of degree of compensation or decompensation of CHF such as New York State Heart Association (NYSHA) CHF class, levels of B-type natriuretic peptide (Cowie and Mendez, 2002; Hulsmann et al., 2002; Maisel et al., 2002), and the six-minute walk test (Hulsmann et al., 2002). Changes in class of medication and mortality rates will also be assessed.

B. Study Design and Statistical Analysis

a. Description of study arms and how subjects will be assigned to each group

Patients will be referred to the study by residents, fellows and attending physicians from the AIM practice, heart failure clinic and cardiology clinic at CPMC and will receive the standard care provided by the clinic from which he or she is referred. At the time of referral, if the patient agrees to participate and

qualifies for enrollment according to inclusion and exclusion criteria, the patient will be asked to return for official enrollment and randomization within one week of departure date. Subjects will be randomized into intervention and control groups. Both groups will participate in a pre-travel session during which a list of the patients' medications and dosages in Spanish and English will be provided. The intervention group will also receive an assessment of the number of pills the patient has to cover the travel period. If the number of pills does not cover the length of stay of the trip, an additional prescription providing enough pills to cover the trip will be written or the maximum number that can be dispensed if the number needed exceeds the maximum number dispensable. Subjects in the intervention group will also receive a list of suitable alternatives available in the country of travel. Finally, subjects in the intervention arm will be given a letter addressed to potential health care providers in Latin America detailing the subject's medical problems, list of medications and contact information (phone number, fax and e-mail) at CPMC should the health care practitioner have any questions. The contact information provided will be that of the study investigators.

b. Number of subjects to be enrolled

According to a recent study of hospital readmissions in the U.S. and Europe, the age-adjusted rate of readmission for CHF-related hospitalizations excluding deaths over 1-30 days post-discharge in New York state was 4.3% (Westert et al., 2002). Using this number, the expected rate of hospitalization during the course of six months is estimated to be 25.8% for the control group. Using the chi-square test to approximate 80% power testing at p=0.05 to detect a decrease in hospitalization rate to 10.8% (or 15% decrease in rate of hospitalization) the number of subjects needed in each group is estimated to be 117. To account for potential loss to follow-up, goal recruitment will be 140 in each arm. With an estimated 2500 heart failure patients seen at the heart failure clinic alone, it is felt that there will be enough subjects for recruitment at CPMC (personal communication with Dr. Maurer, 7/19/02).

Although it could be argued that the appropriate rate of hospitalization for the control group should be estimated to be greater than that of the New York state age-adjusted rate, a more conservative estimate equal to the New York state age-adjusted rate was used. The rationale is that patients involved in this study will be able to travel and are therefore likely to be less sick and less likely to be hospitalized than all patients with CHF state-wide.

c. Method of randomization

At the time of enrollment, patients will be asked to choose a number from an envelope that corresponds with his or her age group. Ages will be separated into 40-50, 51-60, 61-70 and > 70 years old. Each envelope will have ten slips of paper with half of the numbers marked "1" and the other half marked "2". Each number corresponds with either control or intervention group. Once all of the slips of paper for an envelope for a particular age group have been selected a new envelope for that age group will be used for randomization.

d. Crossover

None

e. Methods of statistical analysis

See description of power analysis above.

Rates of hospitalization will be compared using a chi-square test.

Continuous variables will be expressed in terms of mean +/= SD and will be compared using a two-tailed student's t-test.

Categorical variables will be evaluated by Fisher's exact test.

Multiple regression analysis will be used to adjust for age, comorbidities, smoking, and alcohol use.

C. Study Procedure

a. Schedule of repeated measurements or procedures

At the time of enrollment all subjects will receive a full physical examination including weight, electrocardiogram and will complete a six-minute walk test performed according to Guyatt et al. (1985). Blood will be drawn for assessment of levels of B-type natriuretic peptide and basic metabolic panel. NYSHA CHF class will be assigned according to symptom assessment. The six-minute walk test involves patients walking at a fast pace until the point of exhaustion for a period of 6 minutes on a level surface 50m in length. The total distance walked in meters during the test will be recorded.

Demographic information, travel itinerary, contact information and frequency of travel over the past 5 years will also be assessed at enrollment. Hospitalizations over the prior year, comorbidities and presence or absence of pacemaker and/or AICD will be noted and confirmed by hospital records and/or patients' primary health care providers.

Subjects will then participate in the pre-travel session as described in section B1. Patients will be reassessed within one week of return from travel during which physical exam, electrocardiogram, six-minute walk test and blood test for B-type natriuretic peptide and basic metabolic panel will be repeated. CHF class will be determined by symptom report. Interim hospitalizations, reason for hospitalization, changes in medications and mortality will be noted and confirmed by hospital records and/or health care provider. All patients will be contacted at three months after enrollment either with reassessment if the patient is in the U.S. or via telephone. If the patient is out of the country, interim hospitalizations, CHF class and medication list will be obtained via phone interview in addition to full assessment upon return to the U.S. Subjects will be followed only for the period of time surrounding one trip.

b. Duration of study

Likely duration of study is 1.5 years; duration of subject participation is approximately three to eight months.

D. Study Drugs

None

E. Medical Device

None

F. Study Questionnaires

A questionnaire to collect demographic information, travel itinerary, contact information, prior travel history and symptom description will be developed.

G. Study Subjects:

a. Inclusion criteria

- This study is restricted to subjects of Latino descent who are traveling to Latin America for greater than three months but less than six months. It will not include patients of other ethnic backgrounds because the primary population who engages in this type of travel within this community is Latino.
- Greater than or equal to 40 years old
- NYSHA Class I-III Heart failure to be confirmed by Framingham criteria (Ho et al., 1993) and/or TTE within one year of enrollment
- Able to give informed consent as determined by clinical interview and MMSE

b. Exclusion criteria

- Life-threatening comorbidity with life expectancy less than six months (i.e. end-stage malignancy, end-stage COPD)
- End-stage renal disease (dialysis dependent)
- Liver failure
- Myocardial infarction within three months of expected date of travel
- Hospitalization for any reason within one month of expected date of travel

H. Recruitment of Subjects

Residents, fellows and attendings who see patients in clinics affiliated with CPMC will refer patients to the study.

I. Confidentiality of Study Data

All study data will be coded and stored in a secured location accessible only to investigators. Unique identification numbers will be created for each subject.

J. Potential Conflict of Interest

None

K. Location of Study

The study will be conducted at the AIM-East clinic at the Russ Barrie Pavilion at CPMC.

L. Risks

There are no anticipated risks to participation in this study.

M. Benefits

Potential benefits include greater patient knowledge of his or her medications and anticipation of possible medical problems during extended travel. Collegial relationships with health care providers in other countries may also be established through use of the letter describing patients' medical problems and providing CPMC contact information.

N. Alternative Therapies

None

O. Compensation

Subjects will receive a total of $60 for participation in the study, half of which he or she will receive at the time of enrollment and the other half at the time of follow-up visit. If the patient does not arrive for follow-up visit he or she will not receive the other half of payment. Payment will be distributed in the form of cash. Those who require contact by telephone at three months after enrollment will receive an additional $15 in Metro subway passes for participation in telephone interviews.

P. Costs to Subjects

Subjects will incur no additional costs as a result of study participation.

Q. Minors as Research Subjects

None

R. Radiation or Radioactive Substances

None

S. References

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