Nishant Verma

Continuous Activity Monitoring with Actigraphy in Heart Failure Patients Undergoing Cardioversion for Atrial Fibrillation

Background

Prior studies have shown no mortality benefit with rhythm control as compared to rate control for atrial fibrillation (Wyse, 2002) (Roy, 2008). Despite that, symptomatic benefit, improved exercise tolerance and increased quality of life are often used as reasons to pursue a rhythm control strategy amongst patients with heart failure. Oftentimes, rhythm control is achieved by the use of DC cardioversion. Small studies have shown different results when examining functional capacity with rhythm control; however, there have been some data which indicate a benefit in cardiopulmonary exercise measures including 6 minute walk time (Chung, 2005) (Shelton, 2009). These measures are generally collected under very controlled testing situations within a clinic or inpatient setting. There is a lack of data on real time activity measurement amongst this population. The Actigraph is a wrist watch like device created by GE which has widespread use in sleep studies. Recent work has demonstrated its' efficacy to determine activity levels amongst patients with heart failure. One prior study has shown that the watch is able to detect a significant difference between heart failure patients with atrial fibrillation and those without atrial fibrillation (Verma, 2009). We propose to use this watch as a tool to determine whether DC cardioversion changes activity levels in heart failure patients with atrial fibrillation.

Our hypothesis is that DC cardioversion will result in an increase in activity levels amongst heart failure patients with atrial fibrillation

Study Design/Statistical Analysis

This study will be an unblinded, prospective trial with a total population of 96 individuals with congestive heart failure and persistent atrial fibrillation undergoing cardioversion. Prior literature has determined that approximately 20% of individuals undergoing cardioversion fail to remain in normal sinus rhythm. Using a more conservative estimate of a 10% failure rate, the study population will consist of 87 individuals who remain in normal sinus rhythm and the control group will consist of 9 individuals who convert back into atrial fibrillation immediately after cardioversion. Actigraphy will be used to collect continuous activity data for two weeks prior to the procedure and two weeks immediately after the procedure. Quality of life (QOL) data will be assessed in both groups pre and post procedure. In addition rhythm data will be collected over this time period with a continuous ambulatory EKG monitoring. We will be powered to detect a 100 minute daily difference between the two groups with a power of 80% assuming a p-value of 0.05.

Primary endpoint:

Time spent in light activity (minutes)

Secondary Endpoints:

Most active 6 minutes daily

Total Energy Expenditure

QOL data

Study Procedures:

Patient recruitment will occur through referral for DC cardioversion from the patient's primary cardiologist. Informed consent will be obtained from each subject

Study Devices/Drugs:

Actigraph by GE

Study Questionnaires:

SF-36

MLWHF questionnaire

Study Subjects:

Inclusion Criteria

- Class I-III Congestive Heart Failure
- Persistent Atrial Fibrillation
- Outpatients
- Ambulatory
- In residence which allows for free movement

Exclusion Criteria

- Skin or limb problems precluding the use of the watch for 24 hours per day
- Use of continuous inotropes or mechanical circulatory supports
- Inability to provide informed consent

Subject Recruitment:

Patients will be recruited from the Advanced Cardiac Center at Columbia University. Eligible patients will be referred by their cardiologist to the Columbia University Electrophysiology Lab for DC Cardioversion.

Confidentiality of Data:

Data will be kept on secure servers which will only be accessible to individuals doing data analysis.

Location of Study:

Columbia University Medical Center

Potential Risks:

Potential reaction to the watch is no different than those posed by a wristwatch. DC cardioversion poses a risk of arrhythmia, cardiac arrest and death.

Potential Benefits:

Further information regarding the potential utility of actigraphy for continuously measuring activity data and the utility of DC cardioversion for rhythm control.

Alternative Therapies:

None

Compensation to Subjects:

None

Costs to Subjects:

None

Radiation or Radioactive Substances:

None

Works Cited

Chung, M. (2005). Functional Status in Rate-Versus-Rhythm-Control Strategies for Atrial Fibrillation. *Journal of the American College of Cardiology , 46* (10), 1891-1899.

Roy, D. (2008). Rhythm Control versus Rate Control for Atrial Fibrillation and Heart Failure. *NEJM , 358* (25), 2667-2677.

Shelton, R. (2009). A randomised, controlled study of rate versus rhythm control in patients with chronic atrial fibrillation and heart failure: (CAFE-II Study). *Heart , 95*, 924-930.

Verma, N. (2009). Continuous Actigraphy Monitoring in Elderly Patients with A-Fib. *JAGS , 57* (S1), S170.

Wyse, D. (2002). A comparison of Rate Control and Rhythm Control in Patients with Atrial Fibrillation. *NEJM , 347* (23), 1825-1833.