

Abnormal but Non-diagnostic Echocardiograms in Predicting Recurrent Syncope: A Prospective Study

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A. Study Purpose & Rationale

Syncope is an extremely common problem in the general population, accounting for approximately 3% of hospital admissions. In the diagnostic workup after a syncopal episode, the significance of some echocardiographic findings is unclear, especially when they are not obvious causes of syncope.

B. Study Design and Statistical Analysis

This is a prospective observational study with 2 years of follow-up, to be done at CPMC. Patients who are admitted to CPMC with diagnosis of syncope will be screened. Those with diagnosis of syncope of unknown cause will be approached to enroll in the study. Exclusion criteria will include patients with findings which are likely to explain their syncopal episode, those with known arrhythmias, pacemakers, AICDs.

After informed consent is obtained, subjects will undergo an echocardiogram if they have not had one as part of their syncope workup. Further diagnostic tests or treatment may then be done as clinically indicated. Subsequently subjects will be followed for 2 years, with a routine telephone interview every 3 months, documenting recurrent syncopal episodes, near-syncopal episodes, further diagnostic tests for syncope, pacemaker and implantable cardioverter-defibrillator placement, hospitalizations, cardiovascular events such as MI and stroke, and death.

Primary endpoint will be syncope recurrence or definitive management of specific cause of syncope found. Secondary endpoint will be death.

Statistical analysis will be performed with a chi-squared test with alpha of 0.05 and beta of 0.80.

C. Study Procedure

Only one echocardiogram will be used in classifying subjects into abnormal or normal group. This echocardiogram will be the one done during patient's admission for syncope workup, in which case it will have been part of the clinical workup, or be performed additionally after enrollment in the study. Patients with echocardiographic findings of severe or critical aortic stenosis, left ventricular outflow obstruction, a regional wall motion abnormality, or left ventricular ejection fraction less than 50% on the initial echocardiogram will be excluded from the analysis since these findings are suspicious as causes of syncope and would immediately prompt further workup or definitive treatment. Patients with other abnormal but less definitive (non-diagnostic) findings (including moderate LVH, mild-moderate aortic stenosis, mitral valve prolapse) will be compared to those with normal echocardiograms.

As described above, subjects will be followed for 2 years. During the follow-up period, any additional echocardiograms will alter the subjects' initial classification.

D. Study Subjects

Inclusion: Patients age 40 or older discharged with diagnosis syncope of unknown cause after first syncopal episode.

Exclusion: Suspected cause of syncope found; previous syncopal episodes; previous myocardial infarction, stroke, or known coronary artery disease; known significant structural heart disease: severe aortic stenosis, regional wall motion abnormalities, LV ejection fraction less than 50%.

E. Recruitment of Subjects

Patients qualifying for inclusion in study will be contacted via telephone or mail and asked if they wish to enroll. If they wish, they will have the opportunity to come and discuss the study in person with one of the investigators prior to enrollment. Patients wishing to enroll will be asked to sign the informed consent form in person.

F. Confidentiality of Study Data

Subjects' personal identifiers will be blacked out of all copies of medical records retained by the investigator, and unique codes will be assigned at enrollment, and only the research team (investigators and study coordinator) will have access to all subject information.

G. Potential Conflict of Interest

None.

H. Location of the Study

This study will be carried out at CPMC, including the main campus and the Allen Pavilion.

I. Potential Risks and Benefits

There are minimal risks in this observational study. Subjects may or may not benefit from being in this study. However, there is potential benefit in terms of the information about syncope that can be gained, and hence lead to better management of this disorder in everyone.

J. Compensation and cost to Subjects

There will be no compensation or cost to the subjects. If an echocardiogram needs to be done after enrollment, it will be paid for by the study.