Development Of A Syncope Screening Questionnaire For Use In The Emergency Department: A Prospective Study

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A. Statement of study rationale and purpose

Syncope is a common medical problem accounting for approximately 3% of all emergency department (ED) visits and 6% of all hospital admissions. Syncope recurs in up to 35% of patients after the index event. ii Admissions for syncope at CPMC are long (mean LOS = 6 days) and costly (mean hospital charges = $12,000) [preliminary data]. Patients with syncope can be stratified into high and low risk groups based on the presence or absence of a cardiovascular cause. For patients with organic heart disease, syncope is a predictor of sudden cardiac death with a rate of 30% + 6% at one year. Patients suffer significant morbidity related to injuries secondary to syncope.

Recent practice guidelines for the diagnostic work-up of syncope have been proposed based on an evaluation of the current literature. However, there are few prospective studies in the current literature regarding the initial evaluation of patients with syncope in the ED, the point of first contact. Furthermore, there are few prospective studies regarding risk stratification of patients with syncope into groups that should be admitted, and those who can be safely sent home for an outpatient work-up. One recent report, based on data collected in the 1980's, suggests that risk for sudden cardiac death can be predicted by positive responses to one or more of a few queries in the ED (age >45, history of CHF, history of ventricular arrhythmia, and an abnormal ECG). However, the screening criteria for the diagnosis of syncope used in this study were not made clear.

In order to study the question of risk stratification in a prospective fashion, we must be able to characterize the syncope population at large, not just those that are admitted to the hospital for syncope. Therefore, there must exist a sensitive mechanism for recognizing patients with syncope when they present to the ED. As the point of first contact, the triage process plays a prominent role in this initial assessment.

A screening questionnaire to identify patients with Carotid Sinus Hypersensitivity was recently developed for an ongoing, multi-center study sponsored by Medtronics, Inc. (preliminary data presented at NASPE). We have modified this questionnaire for use in the triage area of our ED to screen for patients with fainting or passing out. We will also screen for patients with unexplained or recurrent falls, since several studies suggest that a subset of falls may be due to cardiovascular events 20% in community dwelling elderly). In these patients, the absence of a history of 11syncope" alone is unreliable, since many patients with falls exhibit retrograde amnesia for the event. Furthermore, preliminary data from a group in Newcastle have found a very large incidence of Carotid Sinus Hypersensitivity (CSH) in unexplained falls (30%), one of the potential causes of syncope.

a. Hypothesis

Use of the syncope -targeted questionnaire (STQ) will improve the sensitivity of the triage process for the diagnosis of syncope.

b. Study Objectives

1. To characterize the baseline incidence of visits for syncope to an emergency department at an academic medical center.
2. To compare the current incidence of syncope with the "potential" incidence using a screening questionnaire targeted at the diagnosis of syncope.
3. To characterize the pattern of disposition (discharge home, admission to hospital) and discharge diagnoses of patients visiting the ED for syncope in both the unscreened group and the group screened using our questionnaire.

B. Study Design and Statistical Analysis

a. Methods

This study is a prospective trial. The intervention is the administration of the syncope -targeted questionnaire (STQ). The study will take place in the CPMC Emergency Department and will be conducted in two sequential phases. *Phase* I (Current Practice): Discharge diagnoses and hospital admission diagnoses will be collected for all patients visiting the ED during the study period. This will characterize, in a prospective fashion, the incidence of syncope diagnosed in our ED using current practice patterns. The incidence will be defined as the number of final diagnoses of syncope over the total population seen in the ED during this phase of the trial.

Phase II (Screening for Masked Syncope): As in Phase 1, all ED discharge diagnoses and hospital admission diagnoses for patients seen in the ED will be collected. During Phase II, however, the Syncope -Targeted Questionnaire (STQ) will be asked of all patients as they are seen in the triage area. The incidence of "potential syncope" in this group of patients will be defined by a positive response to one or more of the elements in the questionnaire over the total population seen in the ED during this phase of the trial. The syncope -targeted questionnaire will be brief and easy to administer. It will consist of three questions. An answer of yes to any one of the three questions will be considered a positive response and thus, a patient who may have syncope.

Data collection and administration of the STQ will be performed by two trained individuals working in the ED. During these preliminary phases, the data they gather will not be incorporated into the patients' records. The effect of providing the care-givers with our screening data will be assessed in a subsequent study, once the STQ has been shown to be more, not less, sensitive than the current triage process. A Custom Clinical Query will be designed by the Clinical Information Service to capture all ED visits and their discharge diagnoses for the duration of the study. Patients identified as having syncope by either current practice or the STQ who are subsequently admitted (and their admission diagnoses) will be captured by review of the Medical Admitting Resident records and a second Custom Clinical Query. Hospital discharge diagnoses will be collected from the CIS at the time of discharge for those patients admitted.

Current Practice	**"Potential Syncope"**
20 twelve hour shifts	20 twelve hour shifts
- 1600 patients total	- 1600 patients total
No STQ	STQ administered
Measure incidence of -final dx of syncope	Measure incidence of >= 1 positive responses
Expect incidence of - 5%	Predict incidence of - 7.5%

b. Analysis

Primary Analysis: The number of syncope diagnoses/total visits to ED in the control group (Phase I) versus the ratio of patients with one or more positive responses to questionnaire/total visits to ED in the screened group (Phase 11).

Secondary Analyses: The incidence of syncope diagnosed in the subgroup of patients who have unexplained falls and/or recurrent falls. The incidence of syncope in patients who respond in the negative to all elements of the questionnaire (the STQ false negative rate). We will collect % of discharges home, % referred to ED, and % admitted to hospital in each phase in patients with and without syncope. We will also assess the incidence of discharge diagnoses that could be missed diagnoses of syncope (i.e. dizziness, vertigo, loss of consciousness, unresponsiveness, weakness, malaise and fatigue). We will assess the incidence of "potential syncope" as measured by our STQ as a function of age < 45, > 45.

c. Power calculation

The power calculation is based on an estimate of a 5% incidence of syncope in patients presenting to the ED. With an 80% power to detect a 50% difference with and alpha error of 0.05, 1600 hundred patients must be interviewed in each phase. If approximately 60,000 patients/year visit our ED, and shifts are 12 hours long, one shift yields 80 patients. That means each phase of the study must collect 20 shifts to see 1600 patients.

C. Description of Study Procedures

None

D. Study Drugs

None

E. Medical Devices

None

F. Study Questionnaire

The Syncope -Targeted Questionnaire will consist of three questions. It is a modified version of a questionnaire being administered for a study in progress (SAFE-ER, Medtronics, Inc.).

1) Are you here because you fainted, lost consciousness, passed out or felt like you were going to do any of the above?
2) Are you here because you fell?
3) Have you had 2 or more falls in the last year?

See sample questionnaire.

The questionnaire will be administered by trained personnel in the employ of the aforementioned principal investigators. Training will include an explanation of the study, orientation to the triage environment, orientation to the consent required, and practice administration of the above questions to sample subjects not enrolled in the study. They will ask the questions in both English and Spanish, and when required will enlist the help of the Translator Corp for other languages.

G. Description of study subjects and recruitment

a. Inclusion

In phase I and phase II, all patients visiting the ER for the randomly selected 20 shifts will be eligible for the study.

b. Exclusion

There are no exclusion criteria for phase I in which no intervention is being made. Patients assessed in phase Il will be excluded if any of the following conditions are met: 1) Unable to answer screening questions because of medical impossibility or cognitive impairment and there is no parallel history available from family or a health proxy. 2) The patient signs out against medical advice before a complete work-up has been performed in the ED.

H. Confidentiality of study data

All patients will receive a unique numeric code at the time of triage. No personal identifiers will be used in the reporting of study data. All patients asked the STQ questions will be made aware of these requirements.

I. Location of Study

The CPMC Emergency Department triage area, examination rooms, waiting area and nursing stations. Dr. Giglio, Director of the Department of Emergency Medicine has approved the study.

J. Risks and Benefits

There is a small chance that the time it takes to triage will be prolonged by one or two minutes. However, the questionnaire will be administered by study employees *L* separate from the current triage process in a way designed to minimize the impact of time. There are no treatments or procedures involved in these two phases of the study. The potential benefit is achieved for future patients who have syncope if this study can show that improved screening leads to better risk stratification and treatment of the underlying causes of syncope, and prevention of morbidity and mortality associated with syncope. All patients screened will be reminded that any serious concerns raised in the screening process should be relayed by the patient to the doctor who cares for them in the ED.

K. Alternative Therapies

None

L. Compensation and Cost

None

M. Minors

None

N. Radiation or radioactive substances

None

O. References

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