Randomized Clinical Trial of an Emergency Department Observation Syncope Protocol Versus Routine Inpatient Admission

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Study objective: Older adults are frequently hospitalized from the emergency department (ED) after an episode of unexplained syncope. Current admission patterns are costly, with little evidence of benefit. We hypothesize that an ED observation syncope protocol will reduce resource use without adversely affecting patient-oriented outcomes.

Methods: This randomized trial at 5 EDs compared an ED observation syncope protocol to inpatient admission for intermediate-risk adults (≥50 years) presenting with syncope or near syncope. Primary outcomes included inpatient admission rate and length of stay. Secondary outcomes included 30-day and 6-month serious outcomes after hospital discharge, index and 30-day hospital costs, 30-day quality-of-life scores, and 30-day patient satisfaction.

Results: Study staff randomized 124 patients. Observation resulted in a lower inpatient admission rate (15% versus 92%; 95% confidence interval [CI] difference −88% to −66%) and shorter hospital length of stay (29 versus 47 hours; 95% CI difference −28 to −8). Serious outcome rates after hospital discharge were similar for observation versus admission at 30 days (3% versus 0%; 95% CI difference −1% to 8%) and 6 months (8% versus 10%; 95% CI difference −13% to 9%). Index hospital costs in the observation group were $629 (95% CI difference −$1,376 to −$56) lower than in the admission group. There were no differences in 30-day quality-of-life scores or in patient satisfaction.

Conclusion: An ED observation syncope protocol reduced the primary outcomes of admission rate and hospital length of stay. Analyses of secondary outcomes suggest reduction in index hospital costs, with no difference in safety events, quality of life, or patient satisfaction. Our findings suggest that an ED observation syncope protocol can be replicated and safely reduce resource use. [Ann Emerg Med. 2014;64:167-175.]

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INTRODUCTION

Background

Syncope represents a common and vexing chief complaint in emergency departments (EDs). In the United States alone, syncope accounts for 740,000 annual ED evaluations[1] and yearly hospital costs of more than $2.4 billion.[2] Because patients have recovered by ED presentation, it is often difficult to distinguish among the many potential causes that include benign and life-threatening conditions. Despite international efforts to develop clinical guidelines,[3-7] diagnostic pathways,[8-11] and risk prediction tools,[12-18] there remains considerable uncertainty about how to optimally manage patients at intermediate risk of adverse outcomes.[19] As a result, providers often hospitalize older adults without a clear cause for syncope for diagnostic evaluation.[1,20-22] However, current admission practices are characterized by low diagnostic yield and significant practice variation,[23] do not clearly improve outcomes,[24] and are costly.[2,25] These findings have been reported from multiple countries.[26-33] Efforts by the Centers for Medicare & Medicaid Services to deny hospital payments for "unnecessary" inpatient admissions have further intensified the need to develop an alternative diagnostic pathway; syncope was recently identified as the top diagnosis associated with payment denials by Centers for Medicare & Medicaid Services recovery audit contractors.[34]

Importance

An ED observation syncope protocol may safely reduce hospitalizations by expediting and standardizing the evaluation of syncope. A previous single-center randomized evaluation of an ED-based syncope evaluation unit suggested a 55% reduction in hospital admissions without increase in mortality.[35] However,

Editor's Capsule Summary

What is already known on this topic

Hospitalization for syncope has a low diagnostic yield.

What question this study addressed

Can patients with syncope be more efficiently managed in an emergency department observation unit under protocol?

What this study adds to our knowledge

In this randomized controlled trial of 124 intermediate-risk adults with syncope, those treated in the observation unit left the hospital an average of 18 hours earlier than those admitted. They had lower treatment costs and similar outcomes.

How this is relevant to clinical practice

For syncope patients at intermediate risk, an observation unit protocol is more efficient than hospitalization and appears safe.

these results have not been replicated at other sites, and there is no information about how such an approach may affect costs, nonfatal clinical events, and patient-centered outcomes such as quality of life and satisfaction. Evaluating the efficiency and safety of this alternative delivery approach has important health delivery implications; 36% of US EDs operate an observation unit and have the potential ability to implement an ED observation protocol.[36]

Goals of This Investigation

We compared an ED observation syncope protocol versus routine inpatient admission for intermediate-risk patients after an unrevealing ED evaluation for syncope. We tested the primary hypotheses that an ED observation protocol would reduce hospital admissions and hospital length of stay.

We originally intended to collect planning data for a definitive noninferiority trial of safety, costs, and quality of life. Because of changes in payer audit and payment policies during the study period,[34] however, it is unlikely that US hospitals will participate in future randomized studies of ED observation unit care. In exploratory analyses, we assessed the effect of the ED observation protocol on safety, costs, quality of life, and patient satisfaction.

MATERIALS AND METHODS

Study Design and Setting

We conducted a randomized clinical trial at 5 EDs from March 1, 2010, to October 1, 2011 (ClinicalTrials.gov identifier NCT01003262). Study staff completed participant follow-up on April 31, 2012. We include the trial protocol and Consolidated Standards of Reporting Trials (CONSORT) checklist as Appendix E1 (available online at http://www.annemergmed.com).

The study sites represent a diversity of hospital characteristics, geography, and patient populations (Table E1, available online at http://www.annemergmed.com). All ED observation units are located in a distinct physical space adjacent to the main ED, supervised by attending emergency physicians, and staffed by midlevel providers.

The Institutional Review Boards of the coordinating center and all enrolling sites approved this study. An independent safety monitor reviewed all data on clinical events.

Selection of Participants

Patients aged 50 years or older were prospectively screened in the ED for a complaint of syncope or near syncope. Syncope was defined as a sudden, transient loss of consciousness. Near syncope was defined as a sensation of imminent loss of consciousness, without actual syncope.

Using specialty society guidelines, the study team developed risk-stratification guidelines for short-term, dangerous clinical events after syncope (Figure 1).[4,6,37] We included additional feedback from enrolling physicians to ensure that the guidelines were feasible and acceptable at the study sites. Treating physicians used these criteria to categorize patients as high, intermediate, or low risk. Patients at intermediate risk were eligible for study enrollment. Although we considered objective risk scores, none have been validated for routine clinical use[38] and were not thought to be feasible at our enrolling sites.

We excluded patients with a serious condition identified during the ED visit, including symptomatic arrhythmias,

High Risk Criteria
- Serious condition identified in the ED
- History of ventricular arrhythmia
- Cardiac device with dysfunction
- Exertional syncope
- Presentation concerning for acute coronary syndrome
- Severe cardiac valve disease (eg, aortic stenosis <1 cm2)
- Known cardiac ejection faction <40%
- Electrocardiogram findings of QTc>500 mS, pre-excitation, non-sustained ventricular tachycardia
- Emergency physician judgment

Intermediate Risk Criteria
- No high risk features **AND**
- No low risk features **AND**
- Clinical judgment by emergency physician that patient requires further diagnostic evaluation

Low Risk
- Symptoms consistent with orthostatic or vasovagal syncope
- Emergency physician judgment that no further diagnostic evaluation is needed

Figure 1. Risk stratification guidelines.