

Prospective Validation of the San Francisco Syncope Rule to Predict Patients With Serious Outcomes

James Quinn, MD, MS
Daniel McDermott, MD
Ian Stiell, MD, MSc
Michael Kohn, MD, MPP
George Wells, PhD

From the Division of Emergency Medicine, Stanford University, Palo Alto, CA (Quinn); the Department of Medicine, University of California-San Francisco, San Francisco, CA (McDermott, Kohn); the Department of Emergency Medicine (Stiell), and the Department of Epidemiology and Community Medicine, University of Ottawa (Wells) Ottawa, Canada.

Study objective: We prospectively validate the San Francisco Syncope Rule (history of congestive heart failure, Hematocrit <30%, abnormal ECG result [new changes or non-sinus rhythm], complaint of shortness of breath, and systolic blood pressure <90 mm Hg during triage).

Methods: In a prospective cohort study, consecutive patients with syncope or near syncope presenting to an emergency department (ED) of a teaching hospital were identified and enrolled from July 15, 2002, to August 31, 2004. Patients with trauma, alcohol, or drug-associated loss of consciousness and definite seizures were excluded. Physicians prospectively applied the San Francisco Syncope Rule after their evaluation, and patients were followed up to determine whether they had had a predefined serious outcome within 30 days of their ED visit.

Results: Seven hundred ninety-one consecutive visits were evaluated for syncope, representing 1.2% of all ED visits. The average age was 61 years, 54% of patients were women, and 59% of patients were admitted. Fifty-three visits (6.7%) resulted in patients having serious outcomes that were undeclared during their ED visit. The rule was 98% sensitive (95% confidence interval [CI] 89% to 100%) and 56% specific (95% CI 52% to 60%) to predict these events. In this cohort, the San Francisco Syncope Rule classified 52% of the patients as high risk, potentially decreasing overall admissions by 7%. If the rule had been applied only to the 453 patients admitted, it might have decreased admissions by 24%.

Conclusion: The San Francisco Syncope Rule performed with high sensitivity and specificity in this validation cohort and is a valuable tool to help risk stratify patients. It may help with physician decisionmaking and improve the use of hospital admission for syncope. [Ann Emerg Med. 2006;47:448-454.]

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INTRODUCTION

Background

Approximately a quarter of the population will experience syncope (fainting) during their lifetime. Frequently, these patients will present to emergency departments (EDs), accounting for 1% to 2% of all ED visits and hospital admissions.¹⁻⁵ Syncope occurs in the old and the young; it can be infrequent or recurrent; and although usually a benign symptom, it is occasionally associated with significant morbidity, such as arrhythmia, myocardial infarction, pulmonary embolism, occult hemorrhage, or death.⁶⁻⁹ As a

result, syncope is often referred to a “low-risk/high-stakes” symptom,¹⁰ with physicians admitting many patients who they believe are at low risk because of the high stakes if something adverse happens.

Importance

It is estimated that the cost of admission because of syncope in the United States may be as high as \$2 billion annually.¹¹ Specialty guidelines have tended to be conservative on admission recommendations, often citing a lack of clear evidence or criteria, and it is unclear if followed whether these recommendations would lead to an increase or decrease in admissions.¹²⁻¹⁵ Furthermore, it has been demonstrated that

Editor's Capsule Summary

What is already known on this topic

Emergency departments evaluate and admit many adult patients with syncope; however, few of these patients have adverse events.

What question this study addressed

This study was designed to validate the San Francisco Syncope Rule in a California teaching hospital.

What this study adds to our knowledge

The San Francisco Syncope Rule is positive if the patient has any history of congestive heart failure, hematocrit level less than 30%, an abnormal ECG (new changes or non-sinus rhythm), a complaint of shortness of breath, or a systolic blood pressure of less than 90 mm Hg at triage. In this study of 791 consecutive patients, the rule was 98% sensitive (95% confidence interval [CI] 89% to 100%) and 56% specific (95% CI 52% to 60%) to predict adverse events.

How this might change clinical practice

This rule defines a group of patients who are at very low risk for acute complications and are candidates for discharge from the ED. The lower limit of its 95% CI for sensitivity is only 89%, so more large studies may be needed to further define its safety.

many patients who are admitted receive little or no diagnostic evaluation as part of inpatient care.^{16,17} This inefficient use of expensive hospitalization has resulted in a need for a more cost effective approach.¹⁸⁻²⁴

Goals of This Investigation

We believe efficiencies can be realized through improved risk stratification and started a multiphase study to address this important problem. Using strict methodologic criteria for decision rule development, we first derived the San Francisco Syncope Rule, as illustrated in the [Figure](#). We believe this highly sensitive clinical decision rule can augment physician judgment and allow physicians to rationally decide which patients with syncope need admission.^{4,25} The purpose of this study is to validate the decision rule in a prospective cohort of consecutive ED patients by determining whether it can predict short-term serious outcomes not determined during the initial ED evaluation.

MATERIALS AND METHODS

Setting

This prospective cohort study was conducted at the ED of the University of California at San Francisco, a large university

teaching hospital. It received approval from the institution's Committee on Human Research. Patients presenting with acute syncope or near syncope for their ED visit were considered for the study. To identify patients, we informed physicians that we were doing the study and used an electronic tracking system to identify all possible patients with a symptom of syncope.²⁶ As an operational definition for the study, we defined syncope to all providers as a "transient loss of consciousness with return to baseline neurologic function."

We specifically excluded patients with trauma-associated loss of consciousness and alcohol or drug-related loss of consciousness, as well as patients with a definite seizure. Patients with loss of consciousness associated with an altered level of consciousness or persistent new neurologic deficits did not meet our operational definition of syncope and were excluded.

Selection of Participants

After assessing the patients and confirming eligibility, physicians completed a short Web-based data form and enrolled the patient. The questionnaire contained the components of the rule (history of congestive heart failure, hematocrit <30%, abnormal ECG result [any non-sinus rhythm or any new changes], a patient complaint of shortness of breath, and a triage systolic blood pressure <90 mm Hg) and asked whether the rule predicted the patient as high or low risk and whether a serious outcome had already been diagnosed and was present during ED presentation or evaluation. We also ascertained physician comfort with the rule but asked the physicians to treat and admit patients in their usual manner without any specific study intervention. All data forms were reviewed by the study investigators to ensure that the rule was interpreted correctly.

Outcome Measures

For the purpose of the validation study, we completed follow-up 30 days after the patients' index ED visit to determine short-term outcomes that would mandate emergency admission. We defined short-term serious outcomes as death, myocardial infarction, arrhythmia, pulmonary embolism, stroke, subarachnoid hemorrhage, significant hemorrhage or anemia requiring transfusion, a procedural intervention to treat a related cause of syncope or any condition causing or likely to cause a return ED visit, and hospitalization for a related event. This definition was purposely broad and inclusive and was established before the start of the derivation study.

Outcomes were determined using the following operational definitions. Death was confirmed with findings in the medical record, Social Security Death Index, or death certificate.

The definition of myocardial infarction used in the study was any elevation of troponin or ECG change with an accompanying diagnosis of myocardial infarction on the discharge diagnosis and confirmed by the cardiology service or primary physician involved in the care of the patient. Arrhythmia was defined as any non-sinus rhythm (previously known or new) captured on monitoring and thought to have

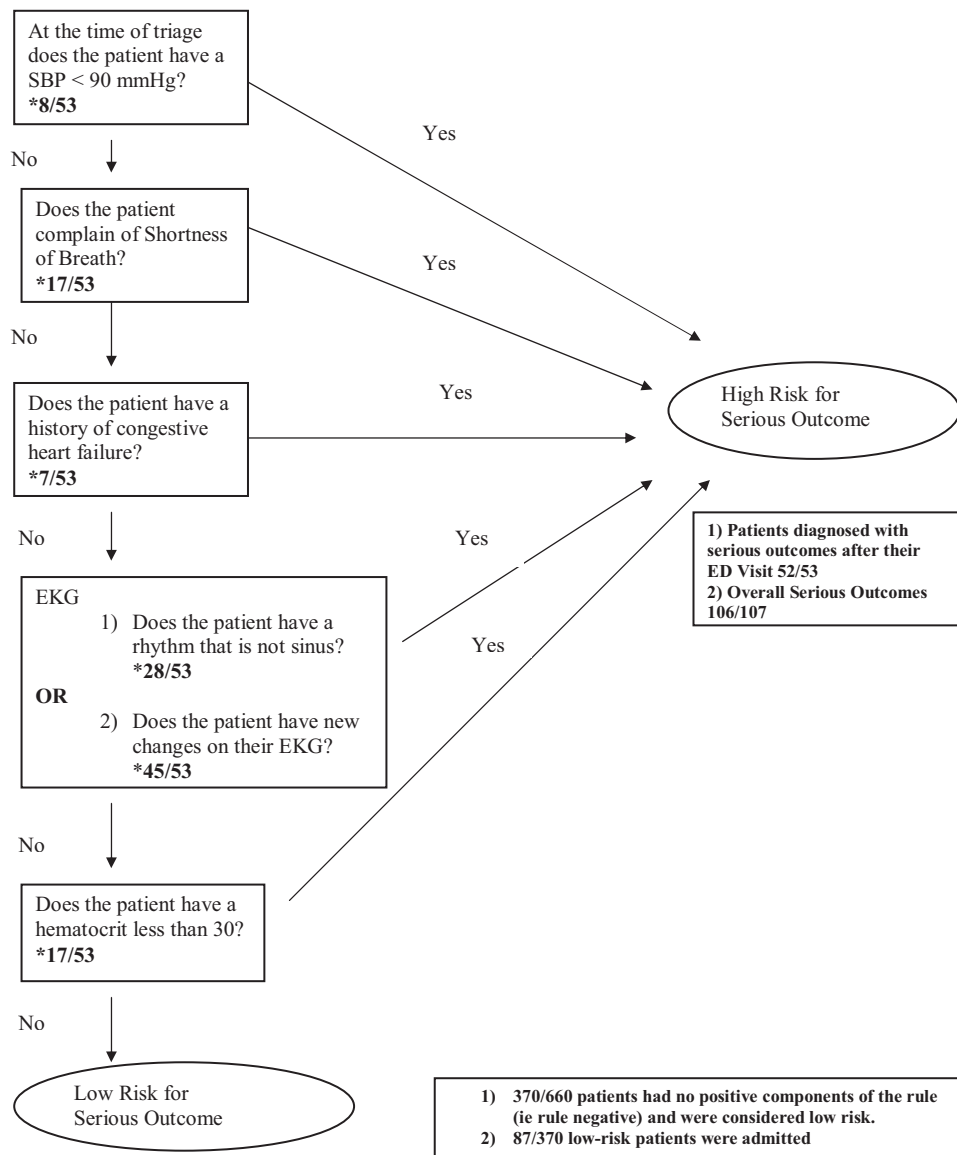


Figure. San Francisco Syncope Rule: breakdown of the validation cohort.
 *Some patients had more than one high-risk component.

Table 1. Performance of the San Francisco Syncope Rule in the validation cohort.*

Decision Rule	Serious Outcome	
	Yes	No
Rule positive	52	290
Rule negative	1	370

*Sensitivity 98% (95% CI 89% to 100%). Specificity 56% (95% CI 52% to 60%). Negative predictive value 99.7% (95% CI 98% to 100%). Positive predictive value 15% (95% CI 12% to 20%). Likelihood ratio negative 0.03 (95% CI 0.01-0.24). Likelihood ratio positive 2.23 (95% CI 2.03-2.45).

had a temporal relationship to the symptom of syncope or near syncope or that required treatment. This determination was made through direct interview of the treating physician.

Pulmonary embolism was determined by ventilation/perfusion scanning, computed tomography of the chest, or angiography. It also had to be confirmed on discharge diagnosis, and the patient needed to have received treatment for the pulmonary embolism or had it confirmed on autopsy.

The diagnosis of stroke and subarachnoid hemorrhage was determined by discharge diagnosis and reviewing the patient’s medical record to see whether the symptoms were temporally related to the admission and confirming that the admitting attending thought that the findings were related or a cause of the symptom of syncope. Significant hemorrhage was defined as any episode of syncope or near syncope associated with a source of bleeding that required transfusion.

Any patients discharged from the ED or hospital after an episode of syncope and then readmitted for the same or similar symptoms related to the initial event were considered to have had a serious outcome. Patients with related return visits who were not admitted were not considered to have had a serious outcome. Admitted patients who required an acute intervention during their stay that would have caused them to return if they were discharged were also considered to have had a serious outcome. An acute intervention was any procedure required to treat a condition related to the patient's symptom of syncope: dialysis, pacemaker insertion, surgery for valvular heart disease, balloon-pump insertion, use of vasopressors, surgery to treat an abdominal aortic aneurysm, surgery for ruptured spleen, surgery for ruptured ectopic pregnancy, and endoscopic treatment of esophageal varices. Monitoring of patients, medication changes, intravenous therapy for medications, or rehydration was not considered an acute intervention.

Outcomes were uniformly determined and reported. A trained research nurse and the study investigators independently reviewed outcomes and were blinded to the predictor variables when making their determination of a serious outcome. Follow-up was completed by review of inpatient records, discussion with their primary physicians, or discussion with the patients or family members. In circumstances in which patients could not be located on follow-up, possible death was checked using the Social Security Death Index (SSDI). We also searched local hospitals within San Francisco to determine whether any of these patients had been admitted to other institutions.

Sensitivity Analysis

The sensitivity and specificity, with 95% confidence intervals (CIs), were calculated to determine how well the rule could predict serious short-term outcomes. A power analysis done in advance of the study determined that approximately 50 outcomes would be needed to achieve an estimate of the sensitivity and specificity, with a bound on the error of estimation of 10% (ie, a 95% CI width of less than 10%). The interpretation accuracy of the physicians completing the forms was compared with the correct interpretation by study personnel.

RESULTS

During the study period, 760 patients had 791 visits for syncope, representing 1.2% of all ED visits. Of the 791 visits, physicians prospectively completed forms for 767 of the visits, and direct follow-up was completed on 752 visits. We were unable to directly contact 39 patients (5%) but found through a check of local hospitals and the Social Security Death Index that there were no unknown local admissions or deaths among these 39 patients.

The average age in the cohort was 61 years, 54% were women, and the overall admission rate of the cohort was 59% (see Table 2). Of the visits, 108 (13.7%) patients had defined serious outcomes within 30 days. Fifty-four outcomes were

Table 2. Characteristics of patients presenting with syncope (N=791).

Characteristic	No. (%)
Age, mean (SD), y	61 (22)
Range, y	6–99
Female	427 (54%)
Admitted	469 (59%)
Patients with serious outcomes after ED visit	54 (6.8%)
Death	3
Arrhythmia	23
Myocardial infarction	11
Valvular heart disease	1
Significant hemorrhage	7
TIA/stroke	3
Sepsis	3
Admission after ED discharge	3

present or diagnosed during the ED visits, with the remaining 54 (6.8%) occurring within 30 days of their ED visit. Physicians admitted 51 of these 54 patients who had serious outcomes declared after their ED visit. Of these 54 cases, 53 had data forms prospectively completed, and these cases were used to assess the ability of the clinical decision rule to predict serious outcomes.

The most common serious outcome was cardiac arrhythmia. There were 23 arrhythmias diagnosed after the initial ED visit and within 30 days of the visit. Sixteen of these were bradydysrhythmias or sick sinus syndromes, 5 were supraventricular dysrhythmias, and 2 were ventricular dysrhythmias.

The rule was 98% sensitive (95% CI 89% to 100%) and 56% specific (95% CI 52% to 60%) for predicting serious outcomes (Table 1). The one patient the rule failed to predict was a 54-year-old diabetic man without an adverse cardiac history who was admitted and had a subsequent negative cardiac evaluation result. During his admission, he was found to have extensive disease in all carotid and vertebral arteries. His treating physician and consulting neurologist believed that his episode of syncope was likely caused by a transient ischemic attack, and the patient had a stent placed in one of his vertebral arteries during the admission.

We found that physicians accurately interpreted the rule 95% of the time. They felt comfortable using the rule in 79% of the cases, felt neutral about it in 15% of cases, and were uncomfortable with the rule in 6% of cases. In this cohort, the San Francisco Syncope Rule would have classified 52% of the patients as high risk, potentially decreasing overall admissions by 7%. If the rule had been applied only to the 453 patients admitted, it might have decreased admissions by 24%.

LIMITATIONS

This study did have some challenges and limitations. Despite our study's size, all our patients came from a single hospital, although the demographics and admission rates of our patients appear to parallel those reported from other centers in the

United States and Europe.^{27–30} Also, decision rules have traditionally focused on areas in which the outcome measure is discrete, clearly defined, and easily measured, such as fracture versus no fracture on radiograph.³¹ For the purpose of a decision rule for syncope, we had to derive a composite serious outcome for a symptom. We did this by obtaining a consensus of experts and defining the outcomes before undertaking our work. Because serious outcomes were rare, we considered them together and in doing so made it impossible to determine how sensitive the rule is for infrequent individual serious outcomes such as pulmonary embolism. Considering the sensitivity of the rule for each outcome would require an extremely large cohort.

For these reasons, and also because the decision rule was not 100% sensitive, physicians should use it as a risk stratification tool to help with decisionmaking as opposed to traditional decision rules often used to replace judgment. The rule should be part of a thorough medical history and physical examination, and the rule itself should not prevent the investigation for other associated symptoms.

Finally, the decision rule was set up to risk stratify patients based on short-term serious outcomes that would for the most part require hospital admission. As such, our goal was to help improve the efficiency of admission through risk stratification. The rule was not designed to determine either who should receive outpatient evaluation or the extent of outpatient evaluation. One should also realize that the reason to admit patients often takes other social factors into consideration that were not considered in our study, and the efficiencies of the rule in terms of avoidable admissions may be overstated. The true benefits of this clinical decision rule will not be realized until an implementation study is undertaken.

DISCUSSION

In this prospective validation study of consecutive ED patients with syncope, we have demonstrated that patients with undeclared serious outcomes can be accurately predicted by our previously derived clinical decision rule. If the decision rule were used to improve risk stratification and augment physician judgment, it could save millions of dollars by improving the use of hospital admission for patients with syncope.¹¹

Evidence demonstrates that many admissions for syncope are inefficient. In the United States and Europe, syncope accounts for 1% to 2% of ED visits, and roughly 60% result in hospitalization.²⁷ After admission, approximately 50% of syncope patients may still have unclear diagnoses, and only about half of the hospitalized patients have any specific investigations such as tilt table or electrophysiologic studies.^{27,28} Other investigators have reported inconsistencies among physicians and hospitals in their approach to the patient with syncope.²⁹ In our earlier prospective cohort, we found that admitted patients stayed only 1 to 2 days, and only 16% of patients had any testing beyond simple monitoring.¹⁷ Specialty guidelines have the potential to help with physician decisionmaking, but in general the guidelines are conservative, rely on retrospective studies, and err on the side of caution, with

age limitations that are impractical. As a result, the guidelines are often not followed and, when followed, may in fact contribute to the number of inefficient admissions.^{18,24,29,32,33}

We believe risk stratification with simple guidelines that are clinically derived is necessary to help with physician decisionmaking and improve the efficiency of the use of hospitalization for syncope. Martin et al³⁴ attempted the first risk stratification of syncope patients. Based on 1-year outcomes, they found 4 predictors of death at 1 year; age greater than 45 years, history of ventricular dysrhythmias, history of congestive heart failure, and an abnormal ECG result. Colivicchi et al³⁵ also used 1-year outcome to develop a risk score for ED risk stratification and found similar results, except they increased the age at risk to 65 years.

Recently, a group of Swiss investigators developed a risk score for predicting arrhythmias in patients with unexplained syncope.³⁶ The score generated 3 main factors associated with increased risk (abnormal ECG result, a history of congestive heart failure, and age >65 years), but the study included only patients deemed to have unexplained syncope after a thorough specialist evaluation, only predicts cardiac arrhythmias, and did not specify when outcomes or diagnoses occurred.³⁷

All of these investigations emphasize the importance of an abnormal ECG result and a history of congestive heart failure or existing heart disease in risk stratification, which has been pointed out in earlier retrospective studies as well.³⁸ However, it is hard to justify short-term management strategies and the need for emergency hospitalization based on 1-year outcome. For example, recommending that all people older than 45 years be admitted because it predicts 1-year death is impractical. In our derivation set, we found using age as a hard guideline for emergency admission of patients with syncope problematic; although it was a significant variable and sensitive (older people die sooner than younger people, and health problems in general increase with age), it was nonspecific for short-term prediction, and although age greater than 75 years was considered an important cut point, it was not determined to be an important variable during our multivariate methods to derive a rule for acute risk stratification. Other studies have also shown that age alone is a poor predictor of 30-day serious outcomes in ED patients who have unknown syncope and are older than 50 years,³⁰ and age greater than 60 years is only a class B recommendation by the American College of Emergency Physicians when combined with a history of cardiovascular disease.¹³

In 2000, we started a multiphase study to address the important problem of acute risk stratification of ED patients with syncope and followed published methodologic guidelines in search of a solution.^{25,39} In a prospective multiphase study, we examined physician judgment and admission patterns and found that there was great potential for a decision rule. We found that physicians had good judgment but did not trust it and still admitted many patients they believed were at low risk.⁴⁰ We derived the San Francisco Syncope Rule by assessing

the accuracy and reliability of 50 predictor variables used in the evaluation of patients with syncope and developed a highly sensitive clinical decision rule that we believed would augment physician judgment and allow physicians to rationally decide which patients with syncope need admission based on their short-term risk.⁴

The rule is not complex and is easily remembered by a simple mnemonic: CHESS (history of Congestive heart failure, Hematocrit <30%, abnormal ECG, a patient complaint of Shortness of breath and a triage Systolic blood pressure <90 mm Hg) (Figure). Remarkably, the rule reinforces most of the key risk factors identified in retrospective studies and guidelines⁴¹ but is the first large multiphase prospective consecutive cohort study to first derive and then validate these risk factors. Given the methodologic standards we followed and the number of patients involved, we are confident in our results and believe that physicians should be ready to use the rule in a prospective trial to determine the true impact of the rule.

To determine the potential impact of the rule, we examined physician-designated low-risk syncope patients currently being admitted. We found that absolute admission rates could be decreased by 10% in this low-risk group with the implementation of the decision rule. We believed that this was an important analysis because it is this low-risk group that physicians would be most likely to discharge from the ED if such a rule confirmed their judgment.⁴⁰

Syncope is a common and dramatic symptom that is concerning for patients, as well as those witnessing these events. As we have confirmed in our study, most of the causes and outcomes associated with the symptom of syncope are benign. Even with our broad and inclusive outcome definition, few patients with syncope had serious outcomes or death occur within 30 days of their ED visit. Most important, our decision rule was highly sensitive in predicting these serious outcomes when they occurred. We are not advocating that physicians should replace their judgment, but our earlier work showed that ED physicians admit many patients who they correctly believe are low risk.⁴⁰ We believe that our rule would support the safe discharge and efficient disposition of many of the low-risk patients with syncope whom many physicians might still admit despite their correct judgment.

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Address for correspondence: James Quinn, MD, MS, Division of Emergency Medicine, Stanford University, 701 Welch Rd, Suite C103, Palo Alto, CA 94304; 650-736-4391, fax 650-723-0121; E-mail quinnj@stanford.edu.

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