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Original Contributions

PREDICTING ADVERSE OUTCOMES IN SYNCOPE

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□ **Abstract—Syncope is a common presentation to the Emergency Department (ED); however, appropriate management and indications for hospitalization remain an ongoing challenge. The objective of this study was to determine if a predefined decision rule could accurately identify patients with syncope likely to have an adverse outcome or critical intervention. A prospective, observational, cohort study was conducted of consecutive ED patients aged 18 years or older presenting with syncope. A clinical decision rule was developed a priori to identify patients at risk if they met any of the following 8 criteria: 1) Signs and symptoms of acute coronary syndrome; 2) Signs of conduction disease; 3) Worrisome cardiac history; 4) Valvular heart disease by history or physical examination; 5) Family history of sudden death; 6) Persistent abnormal vital signs in the ED; 7) Volume depletion; 8) Primary central nervous system event. The primary outcome was either a critical intervention or an adverse outcome within 30 days. Among 362 patients enrolled with syncope, 293 (81%) patients completed their 30-day follow-up. Of these, 201 (69%) were admitted. There were 68 patients (23%) who had either a critical intervention or adverse outcome. The rule identified 66/68 patients who met the outcome for a sensitivity of 97% (95% confidence interval 93–100%) and specificity of 62% (56–69%). This pathway may be useful in identifying patients with syncope who are likely to have adverse outcome or critical interventions. Implementation and multicenter validation is needed before widespread application. © 2007 Elsevier Inc.**

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INTRODUCTION

Syncope is a common presentation to the Emergency Department (ED), however, a universally applied approach to appropriate management and criteria for hospitalization is lacking. Syncope accounts for approximately 1–3% of all ED visits and up to 6% of all hospital admissions nationwide (1,2). The cost of care per hospital admission has been estimated at roughly $5300 per stay, for a total cost of over $2 billion per year nationally (1–7).

The ED workup of syncope centers on several goals. First, the Emergency Physician (EP) must identify those patients with life-threatening causes requiring immediate treatment. Second, the EP must identify those who would benefit from specific treatment or intervention. Third, the EP must identify those who remain without a diagnosis, despite appropriate workup, and who will require further evaluation. Central to this final goal is the determination of the appropriate setting for such evaluation, inpatient vs. outpatient (6). Despite these clear objectives, the ED

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evaluation of syncope is challenging. The differential diagnosis of syncope ranges from benign to immediately life-threatening conditions. Patients presenting to the ED with a complaint of syncope are often asymptomatic and well-appearing on arrival. Despite thorough evaluation, a cause is not established in 38–47% of cases (1,7,8). This presents a challenge to EPs as syncope patients are at risk for significant dysrhythmia and sudden death and could be among the well-appearing group (9). This concern is the impetus behind a great deal of research to assist the EP in identifying those patients at risk for cardiac mortality and significant dysrhythmia; and, ultimately deciding who should be admitted to the hospital for further evaluation and who is safe for discharge. Recommendations for hospital admission should be based on the potential for adverse outcomes if further evaluation and workup is delayed (10).

We, therefore, developed a clinical decision rule with the intent of validating it as the basis for this study (Table 1). This rule was designed by using criteria extracted primarily from the American College of Emergency Physicians' (ACEP) clinical policy and recommendations of the San Francisco Syncope Rule as well as the clinical acumen of a group of expert emergency physicians, cardiologists, electrophysiologists, and internists (12–14). The objective of this study was to determine if our decision rule could accurately discriminate patients with syncope likely to have a critical intervention or adverse outcome. Ultimately, our goal is to enable the emergency practitioner to better discriminate syncope patients who require hospitalization from those who may be safely discharged home from the ED. We hope to ensure that no patient with a possible life-threatening etiology of syncope is discharged home, and at the same time institute a more judicious approach in deciding which patients require hospital admission for syncope.

Table 1. Risk Factors for Adverse Outcomes in Syncope*

I. Signs and symptoms of Acute Coronary Syndrome
1. Complaint of chest pain of possible cardiac origin
2. Ischemic ECG changes (ST elevation or deep [*>0.1 mV*] ST depression)
3. Other ECG changes VT, VF, SVT, rapid atrial fibrillation or new (or not known to be old) STT wave change
4. Complaint of shortness of breath

II. Worrisome cardiac history
5. History of CAD, including deep q waves, hypertrophic or dilatated cardiomyopathy
6. History of congestive heart failure or LV dysfunction
7. History of or ventricular tachycardia, ventricular fibrillation
8. History of pacemaker
9. History of ICD
10. Prehospital use of antidysrhythmic medication excluding beta blockers or calcium channel blockers

III. Family history of sudden death
11. Family history (1st degree relative) with sudden death, HOCM, Brugada's syndrome or long QT syndrome

IV. Valvular heart disease
12. Heart murmur noted in history or on ED examination

V. Signs of conduction disease
13. Multiple syncopal episodes within the last 6 months
14. Rapid heart beat by patient history
15. Syncope *during* exercise
16. QT interval > 500 ms
17. Second- or third- degree heart block or intraventricular Block

VI. Volume depletion
18. Gastrointestinal bleeding by hemoccult or history
19. Hematocrit < 30
20. Dehydration not corrected in the ED per treating physician discretion.

VII. Persistent (> 15 min) abnormal vital signs in the ED without the need of concurrent interventions such as oxygen, pressors, temporary pacemakers
21. Respiratory rate > 24 breaths/min
22. O_2 saturation < 90%
23. Sinus rate < 50 beats/min or sinus rate > 100 beats/min
24. Blood pressure < 90 mm Hg

VIII. CNS
25. Primary CNS event (i.e., SAH, stroke)

* According to the Boston Syncope Criteria for predicting adverse events or critical interventions. If a patient has a risk factor, the patient should be admitted; otherwise that patient may be safely discharged home.
ECG = electrocardiogram; CAD = coronary artery disease; LV = left ventricular; ICD = implantable cardiac defibrillator; HOCM = hypertrophic obstructive cardiomyopathy; ED = Emergency Department; CNS = central nervous system; SAH = subarachnoid hemorrhage.

METHODS

Study Design and Setting

We conducted a prospective, observational, cohort study of consecutive patients presenting with syncope 24 h a day, 7 days a week between September 2003 and April 2004. All patients presented to the ED of a large urban teaching hospital with an annual ED census of 48,000 visits. Institutional review board (IRB) approval was received before initiation of the study.

Syncope was defined as a sudden and transient (< 5 min) loss of consciousness, producing a brief period of unresponsiveness and a loss of postural tone, ultimately resulting in spontaneous recovery requiring no resuscitation measures (10,11). Given a lack of a well-described definition of near syncope, these patients were not included.

Selection of Participants

Inclusion criteria included patients aged 18 years or older who met our definition of syncope. Exclusion criteria were persistent altered mental status, alcohol

or illicit drug-related loss of consciousness, seizure, coma, hypoglycemia, or transient loss of consciousness caused by head trauma.

Interventions

A clinical decision rule was developed a priori using evidence-based criteria. Our rule identified patients at risk for an adverse outcome or critical intervention if they had any of eight symptom categories (Table 1). These criteria can be categorized as follows: 1) Signs and symptoms of an acute coronary syndrome (ACS); 2) Signs of conduction disease; 3) Worrisome cardiac history; 4) Valvular heart disease by history or physical examination; 5) Family history of sudden death; 6) Persistent abnormal vital signs in the ED; 7) Volume depletion such as persistent dehydration, gastrointestinal bleeding, or hematocrit < 30; and 8) Primary CNS (central nervous system) event.

This study was observational; thus, the treating MDs were not directed to perform specific tests or workup. Patients were admitted to the hospital solely at the discretion of the treating MD.

Outcome Measures

The primary outcome was either a critical intervention or an adverse outcome noted during the ED stay or hospitalization, or on follow-up phone call within 30 days after the initial visit. Critical intervention was defined as pacemaker/implantable cardiac defibrillator placement, percutaneous coronary intervention, or surgery, blood transfusion, cardiopulmonary resuscitation (CPR), alterations in antidysrhythmic therapy, endoscopy with intervention, or correction of carotid stenosis. Adverse outcome was defined as: death, pulmonary embolus, stroke, severe infection/sepsis, ventricular dysrhythmia, atrial dysrhythmia (including SVT [supraventricular tachycardia] and atrial fibrillation with rapid ventricular response), intracranial bleed, hemorrhage, myocardial infarction, cardiac arrest, or life-threatening sequelae of syncope (i.e., Rhabomyolysis, long bone or cervical spine fractures).

All enrolled patients had at least one episode of syncope meeting the above definition to be eligible for enrollment. All adverse outcomes or clinical interventions, such as CPR, stroke, or cardiac arrest were noted after spontaneous recovery from the initial syncopal episode. Outcomes were determined by inpatient diagnosis, 30-day follow-up phone call, and subsequent medical records review.

Data Collection and Processing

A trained research assistant prospectively screened patients with complaints of syncope or loss of consciousness and reviewed daily patient logs to ensure completion of documentation and to identify missed patients. Patients were identified in the ED and brought to the attention of the physician caring for that patient who made the final decision of whether the patient, met enrollment criteria, and would consent and enroll the patients. Attending physicians were both consulted and instructed before study initiation as to the details of enrollment criteria. The treating physician under guidance from the attending physician completed a questionnaire similar to Table 1 about characteristics present at the time of ED evaluation. Questionnaires were completed either on initial ED evaluation or shortly afterward by the physician caring for that patient.

The final outcome status was assigned by a reviewer who was blinded to the status of the subject's classification according to the decision rule. Criteria were not used in patient care decisions. The study investigator or trained research assistant carried out follow-up telephone calls with a structured follow-up form and medical record review at 30 days after initial presentation to the ED to determine whether a serious outcome or critical intervention occurred either in the hospital or after discharge. All patients had an electronic medical record review and attempted telephone contact. Patients were considered lost to follow-up if they had no new electronic information available at 30 days and could not be reached by telephone.

Primary Data Analysis

The results are reported as percentages along with the operating characteristics of the rules. Sensitivities, specificities, and positive and negative predictive values are reported along with 95% confidence intervals (CI) around the point estimates.

RESULTS

There were 384 patients who had syncope and met inclusion criteria, 362 (94%) of whom were included in the study. There were 293/362 (81%) patients who completed their 30-day follow-up and were included in the analysis. Of patients lost to 30-day follow-up, admission rates and rates of adverse outcomes in the ED and during hospitalization were similar to those of patients who remained in the study. A total of 201/293 (69%) patients were admitted, with 56 outcomes occurring dur-

Table 2. Comorbidity and Adverse Outcomes/Critical Intervention

Comorbidity	Outcome Present (n = 68)	Outcome Absent (n = 225)	Total (n = 293)
Admitted to hospital	97%	60%	69%
Age (mean ± SD)	70.2 ± 21.4	54.9 ± 24.0	57.8 ± 24.2
Sex (% female)	41%	64%	58%
I. Signs and symptoms of Acute Coronary Syndrome	31%	31%	31%
Chest pain	4%	9%	8%
Ischemic ECG	1%	2%	2%
Abnormal heart rhythm or new ECG changes	15%	15%	15%
SOB	10%	5%	6%
II. Worrisome cardiac history	44%	31%	35%
History of CAD	28%	18%	20%
History of CHF/LV dysfunction	7%	5%	5%
Ventricular tachycardia	0%	0.4%	0.3%
History of pacemaker	4%	3%	3%
ICD	1%	0.4%	2
Antdysrhythmic medication	3%	5%	13
III. Family history of sudden death	1%	2%	2%
IV. Significant heart murmur	3%	1%	3%
V. Signs of conduction disease	13%	17%	16%
Recurrent syncope	6%	14%	12%
Palpitations	6%	0.4%	2%
Syncope during exercise	0%	0.4%	0.3%
QT interval > 500 ms	0%	0%	0%
Heart block	1%	2%	2%
VI. Volume depletion	10%	4%	5%
GI bleed	4%	0.9%	2%
Hematocrit < 30	3%	2%	6
Profound dehydration	3%	0.9%	1%
VII. Persistent abnormal vital signs	12%	8%	9%
Respiratory rate > 24 breaths/min	0%	0%	0%
O_2 sat < 90%	0%	0%	0%
Sinus rate < 50 or > 100 beats/min	6%	5%	5%
Blood pressure < 90 mm Hg	4%	2%	3%
VIII. Primary CNS event	1%	0.4%	0.7%

ECG = electrocardiogram; SOB = shortness of breath; CAD = coronary artery disease; CHF = congestive heart failure; LV = left ventricular; ICD = implantable cardiac defibrillator; GI = gastrointestinal; CNS = central nervous system.

ing hospitalization and the other 12 outcomes occurring during the follow-up period. The presence of adverse outcomes by comorbidity is depicted in Table 2. The average age of the patient population was 57.8 ± 24.2 SD; 58% were female.

A total of 68 patients (23%) met the primary outcomes of critical intervention or adverse outcome within 30 days (Table 3). Figure 1 represents a flow diagram of performance of the Boston Syncope Criteria in predicting a critical intervention or adverse outcome. Our criteria identified 66/68 patients with subsequent critical intervention or adverse outcomes for a sensitivity 97% (95% CI 93–100%) and specificity of 62% (95% CI 56–69%), with a negative predictive value of 99% (95% CI 97–100%) (Figure 2). For the two patients missed by the rule, one had isolated bradycardia during hospitalization that did not recur with further outpatient monitoring, and the other had SVT during hospitalization that was ablated. Admitting only those identified by the decision rule would have reduced admissions by 48% (43–54%) with the two adverse outcomes described above (Figure 1).

Although the study did not mandate testing, all patients had a complete history, physical examination, and electrocardiogram (ECG).

DISCUSSION

This study suggests that the Boston Syncope Rule may be helpful in accurately identifying ED patients at risk for adverse outcomes. Utilizing our risk factors to screen syncope patients yielded a sensitivity of 97%, specificity of 62%, with a negative predictive value of 99%. In this population, admitting only those patients identified by the decision rule admissions would have led to a 48% reduction in hospital admissions. Clearly, in an overburdened health care system, the ability to safely reduce unnecessary hospital admissions should have a positive impact.

Several prior attempts have been made to focus the evaluation and hence disposition of syncope patients based on outcome. Martin et al. found four risk factors

Table 3. Adverse Outcomes or Critical Interventions

Outcome	No. Identified/Performed in ED/ Hospital Post-Syncope	No. Identified/Performed Within 30 Days After Initial Visit	Total No.
Pacemaker/ICD placement	7	4	11
Myocardial infarction	2	1	3
PCI or surgery	1	0	1
Alteration in antidysrhythmic therapy	1	0	1
Stroke	2	1	3
Cardiac arrest/CPR	1	0	1
Death	4	3	7
Cerebral bleed	3	0	3
Other hemorrhage	1	0	1
GIB*	8	0	8
V dysrhythmia	4	0	4
Atrial dysrhythmia†	7	3	10
Sepsis	9	0	9
PE	2	0	2
Carotid stenosis	2	0	2
Life-threatening sequelae of syncope‡	2		2
Total	56	12	68

* GIB was defined as HCT < 30, or need for blood transfusion or endoscopy.
† Includes SVT, tachy/brady syndrome, and atrial fibrillation with rapid ventricular response.
‡ Includes rhabdomyolysis, long bone or cervical fractures.
ICD = implantable cardiac defibrillator; PCI = percutaneous coronary intervention; CPR = cardiopulmonary resuscitation; GIB = gastrointestinal bleeding; PE = pulmonary embolus.

that may increase the risk of death and significant dysrhythmia in patients with syncope including: age $>$ 45 years, a history of congestive heart failure, an abnormal ECG, and a history of ventricular dysrhythmia (8). Seventy-two-hour cardiac mortality and dysrhythmia for those with none of the above risk factors was 0 and 0.7%, respectively. One-year cardiac mortality and dysrhythmia rates ranged from 7% in those with no risk factors to 57% in those with three and 80% in those with four (8). Kapoor and Hanusa have shown that cardiovascular co-morbidities increase the risk of sudden death in the patient with syncope (9). Furthermore, 1-year mortality for patients with cardiac syncope is significantly higher (18–33%) than for those with no cardiac syncope (3–4%) (9). Finally, a cardiac cause of syncope has been shown to be an independent predictor of mortality at 1 year (10).

With these results, the ACEP published its 2001 clinical policy and recommendations for the management of patients presenting with syncope. In it they urge EPs to admit patients with syncope and an abnormal ECG, history of congestive heart failure (CHF), history of ventricular dysrhythmia, symptoms compatible with acute coronary syndrome, or evidence of CHF or valvular heart disease. Consideration of admission should also be extended to those with congenital heart disease, a family history of sudden death, exertional syncope in a young healthy patient, and those aged $>$ 60 years (12). Elesber et al. tested these recommendations retrospectively and found that they would result in a significant reduction in the hospital admission rate (13).

More recently, Quinn et al. published the San Francisco Syncope Rule as a means of predicting patients with serious outcomes at 1 week (14). Their data suggest that age $>$ 75 years, an abnormal ECG, hematocrit $<$ 30, a complaint of shortness of breath, and a history of CHF are all significant risk factors for poor outcome at 1 week (14). The San Francisco Syncope Rules had a sensitivity of 96% and specificity of 62%, which is comparable to our findings. Although the San Francisco Syncope Rule performed with high sensitivity and specificity in their own validation cohort, their rule did not validate well in our patient population (15,16). Although very carefully derived and internally validated, their rule was perhaps too finely tuned to the population of patients seen at their ED in San Francisco and could not be generalized to our population. Despite these prior data, there exists little consensus between EPs with regard to a commonly accepted and utilized hospital admission criteria for patients presenting to the ED with syncope. Hence, many patients who might otherwise be safely discharged home are admitted to the hospital for observation and further evaluation. Yet, we have shown previously that approximately 4% of patients discharged from the ED with syncope return within 72 h and are admitted or die (17). Similarly, a number of studies have suggested that current utilization of hospitalization for patients with syncope is both inefficient and inconsistent (6,10,18–24). Quinn et al. suggest that unaided physician judgment was

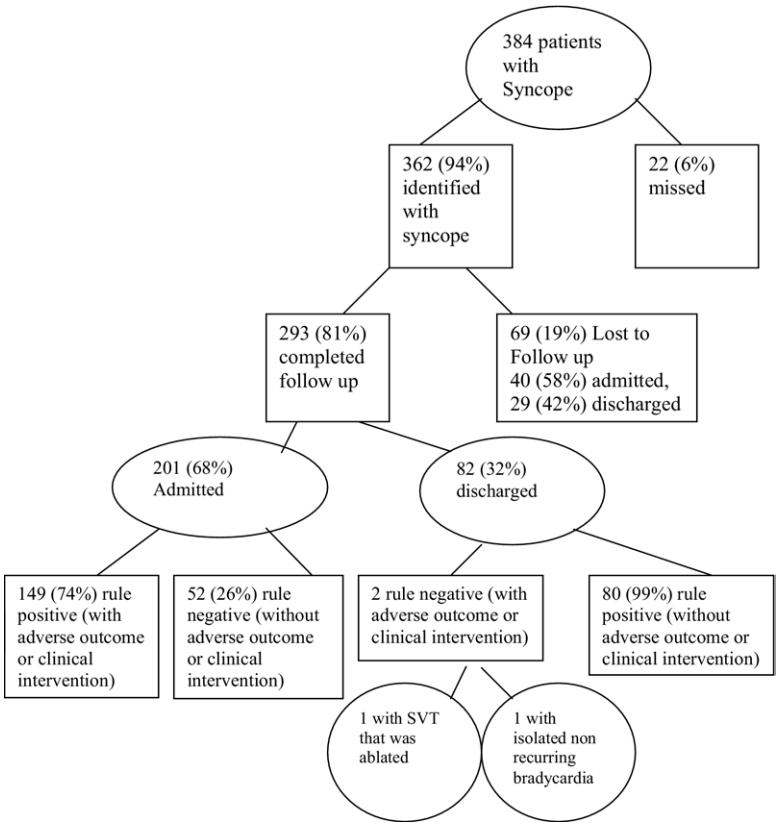

Figure 1. Flow diagram of performance of the Boston Syncope Criteria in predicting a critical intervention or adverse outcome.

able to predict short-term adverse outcome with 89% accuracy (85–93%) and the decision to admit with 83% accuracy (81–87%) (14). Unaided, physician judgment seems to perform worse than our proposed rule.

This rule was created by combining elements of the ACEP guidelines, the San Francisco Syncope rules, prior data, and our own clinical experiences. Worrisome syndromes are grouped together into major complaint categories (i.e., worrisome cardiac history) and components of these categories are explicitly defined (i.e., pacemakers, history of left ventricular dysfunction). These rules present an organized and reproducible way of evaluating a patient with syncope. Although complex and comprehensive, so are the differential diagnoses and considerations needed to evaluate the syncope patient. We feel that it reproduces the approach to the syndrome that would be taken by a prudent physician, while including evidence-based risk factors from prior investigations.

Decision Rule	Outcome +	Outcome −	Total
Admit	**66**	**85**	151
Discharge	**2**	**140**	142
	68	225	293

	%	(95% CI)
Sensitivity	97%	(93–100%)
Specificity	62%	(56–69%)
Negative Predictive Value	99%	(97–100%)
Positive Predictive Value	44%	(36–52%)
Reduction in Admissions	48%	(43–54%)

Figure 2. Performance of the decision rule.

LIMITATIONS

There are a number of limitations of this study, including use of a single testing site, small sample size, and lack of long-term follow-up. The 19% of patients who were lost to 30-day follow-up may have caused us to underestimate the true number of adverse events and critical outcomes. If this were the case, then our estimates of the accuracy and safety of our rule may be overestimated. A total of 25 risk factors are a large number to remember, however, they can be shortened to the eight categories listed above, which enhance easy recall. Or, they could be implemented as a computer or PDA (personal digital assistant)-assisted algorithm. In addition, we could have looked at our data and then derived risk factors; however, the purpose of this study was not to derive a new rule, but

to validate a rule that we created a priori based on existing recommendations and evidence. This is a limitation as there are variables in our rule that actually may not be predictive, or other variables not included that may predict outcome. We also did not assess inter-rater reliability. As with any rule of this nature derived or validated at a single center, generalizability to other settings is limited. Lastly, the major limitation of the proposed rule is that prospective validation has not been implemented in an interventional trial to confirm safety and efficacy. This is needed before widespread application.

CONCLUSION

In summary, despite careful history and physical examination, the EP can be assisted in discerning both etiology and, more importantly, outcome in syncope. Our syncope pathway may be useful in guiding the EP by helping to identify which patients are likely to have adverse outcomes or the need for critical interventions. Ultimately, this rule may significantly reduce hospital admissions and serve as a vehicle to contain both rising medical costs and adverse outcomes associated with unnecessary hospitalization. Implementation and multicenter validation is needed before widespread application.

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