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Comparison of 30-day serious adverse clinical events for elderly patients presenting to the emergency department with near-syncope vs. syncope

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Abstract

Study Objectives: Controversy remains regarding the risk of adverse events for patients presenting with syncope compared to near-syncope. The purpose of our study was to describe the difference in outcomes between these groups in a large multi-center cohort of older ED patients.

Methods: From April 28th, 2013 to September 21st, 2016, we conducted a prospective, observational study across 11 EDs in adults (age ≥ 60) with syncope or near-syncope. A standardized data extraction tool was used to collect information during their index visit and at 30-day follow-up. Our primary outcome was the incidence of 30-day death/serious clinical events. Data were analyzed using descriptive statistics and multivariate logistic regression analysis adjusting for relevant demographic/historical variables.

Results: A total of 3,581 patients (mean age of 72.8 years and 51.6% male) were enrolled into the study. There were 1,380 (39%) presenting with near-syncope, and 2,201 (61%) patients presenting with syncope. Baseline characteristics revealed a greater incidence of: 1) congestive heart failure, 2) coronary artery disease, 3) previous arrhythmia, 4) non-Caucasian race and 5) presenting dyspnea in the near-syncope compared to syncope cohort. There were no differences in the primary outcome between the groups (near-syncope 18.7% vs. syncope 18.2%). A multivariate logistic regression analysis identified no difference in 30-day serious outcomes for patients with near-syncope [O.R. 0.94, (95% CI 0.78 to 1.14)] when compared to syncope.

Conclusion: Near-syncope confers similar risk to patients as syncope for the composite outcome of 30-day death/serious clinical event.

Introduction:

Syncope is the transient loss of consciousness followed by spontaneous and complete recovery.[1] Syncope accounts for 740,000 emergency department (ED) visits and 250,000 hospital admissions in the US annually.[2] Alongside syncope, there is a less well-defined cohort of patients who present with near-syncope. The true incidence of near-syncope is difficult to define though it is commonly believed to represent an even larger group of patients that those who present with syncope.[3] This likely stems from the nebulous nature of near-syncope with patients describing a wide variety of possible chief complaints including: ‘lightheadedness’, ‘dizziness’, ‘feeling hot or cold’ or ‘spells’.

It is generally considered that syncope and near-syncope represent a spectrum of symptomatology. However, the relationship between these two presentations may not follow a linear pathophysiological pattern. For example, a similar run of supraventricular tachycardia may result in either syncope or near-syncope given each patient's underlying medical comorbidities, concurrent illness and medications.[4] Therefore some clinicians recommend assigning near-syncope and syncope patients with similar levels of risk.[5] However, the published literature on this topic is less consistent, with one study suggesting that near-syncope is associated with less risk compared to syncope.[6] Other authors describe the rates of life-threatening arrhythmias and disease to be equivalent between the groups.[7] These studies have been limited by single center methodology or relatively small sample sizes. Achieving a more complete understanding of the risk associated with near-syncope would inform clinical decision making.

Our study objective was to compare rates of death and serious clinical events between these two related chief complaints. We analyzed data from a large multi-center observational cohort including patients enrolled from both academic and community hospitals.

Methods:

Study Design

We conducted a multi-center prospective cohort study (ClinicalTrials.gov Identifier: NCT01802398). The study was approved by the Institutional Review Boards at all sites, and study staff obtained written, informed consent from all participating subjects or their legally authorized representatives.

Study Cohort

We conducted the study at 11 geographically distributed academic and community EDs in the US between April 28, 2013 and September 21, 2016. We enrolled patients ≥ 60 years who presented with syncope or near-syncope as determined by the treating ED physician. Syncope was defined as transient loss of consciousness (LOC), associated with postural loss of tone, with immediate, spontaneous and complete recovery. Near-syncope was defined as imminent sensation of syncope, but without LOC. Both near-syncope and syncope patients with a presumptive cause of loss of consciousness due to seizure, stroke or transient ischemic attack, or hypoglycemia were excluded.[8] Patients who were intoxicated from alcohol or other drugs, hospice and 'Do Not Resuscitate' patients, patients requiring medial or electrical intervention to restore consciousness, and patients who were unable or unwilling to provided informed consent or follow-up information were also excluded.

Study Procedures

All patients underwent standardized history, physical examination, and electrocardiogram (ECG) testing by study protocol. ECGs were abstracted by study physicians (K=0.8).[8] An initial ECG was considered abnormal in the presence of: 1) non-sinus rhythms (including paced rhythms), 2) multiple PVC (> 1), 3) sinus bradycardia (< 41 bpm), 4) left ventricular hypertrophy (LVH) or right ventricular hypertrophy (RVH), 5) left or right axis deviation, 6) short PR interval (< 100 ms), 7) first degree AV block(> 200ms), 8) complete right of left

bundle branch block (RBBB or LBBB, 9) Brugada pattern, 10) delta waves, 11) prolonged QRS (> 120 ms), 12) prolonged QTc (> 450ms), or13) Q/ST/T changes consistent with acute or chronic ischemia. We also collected in real-time the overall ED physician's predicted risk of 30-day risk of mortality or adverse cardiac event in both cohorts. This variable had a range from 0% to 100% and served as a surrogate for the treating physician's subjective level of concern regarding the potential form a short-term adverse outcome.

Any additional diagnostic testing and management was performed at the discretion of the treating providers. Trained research assistants collected data variables consistent with reporting guidelines for ED-based syncope research, and patients directly reported symptoms.[9] We abstracted objective quantitative data, such as laboratory test results, from the electronic medical record. We collected data on all other variables from the treating physician (e.g., co-morbidities, medications). All data was compiled by trained research personnel into a structured online database (REDCap).[10] Any missing or incomplete data was flagged by the database and resolved locally by the site investigator and coordinating center, were possible. Direct patient phone contact and chart review 30-days after the index ED visit was performed either by the local research staff or centrally by the OHSU research team. Furthermore, study staff obtained outside hospital records if the patient had a visit to a facility different from the index ED visit.

Outcomes

Our primary composite outcome included 30-day all-cause mortality or serious clinical events. We used the 2017 ACC/AHA/HRS Guidelines to define serious clinical events, which included cardiac arrhythmias [ventricular fibrillation, ventricular tachycardia (> 30 secs or symptomatic), sick sinus disease with altered mental status, sinus pause > 3 secs, Mobitz type II atrioventricular block, complete heart block, symptomatic supraventricular tachycardia, symptomatic bradycardia, pacemaker and implantable cardioverter/defibrillator malfunction], myocardial infarction, cardiac intervention (pacemaker or defibrillator placement, coronary artery revascularization), new diagnosis of structural heart disease (e.g. critical aortic stenosis), stroke, pulmonary embolism, aortic dissection, subarachnoid hemorrhage, cardiopulmonary resuscitation, internal hemorrhage/anemia, and recurrent fall/ syncope resulting in major injury.[11]

Exposure and Other Measures

The exposure of interest was whether a patient experienced syncope or near-syncope. The exposure was based on the determination of the treating emergency physician. Additionally, we collected data on potential predictors of serious outcomes identified in a prior meta-analysis.[12] These included selected demographic characteristics, symptoms associated with syncope, co-morbidities, physical exam findings, and initial electrocardiogram (ECG).

Statistical Analysis

We generated baseline characteristics of the patient cohort, stratified by syncope versus near-syncope. To compare patients who experienced near-syncope with those who experienced syncope, we performed a multivariate logistic regression predicting 30-day serious clinical events, adjusting for gender, race, history of congestive heart failure, history of coronary

artery disease, history of arrhythmia, abnormal ECG, dyspnea, physician risk assessment, and hypotension. All statistical analyses were performed using R.[13]

Results

There were 6,930 subjects that met inclusion and exclusion criteria, of which 3,686 (53.2%) subjects consented and were enrolled into the study. The final cohort of 3,581 patients available for analysis excludes 105 patients who were lost to follow-up or withdrew after consent (Figure 1). Subjects had a mean age of 72.8 years (SD 9.0 years), 1848 (51.6%) were male, and 2974 (82.7%) were white or Caucasian. Characteristics of the study population, separated across both cohorts, are described in Table 1. Patients with a history of congestive heart failure, coronary artery disease, arrhythmia and patients with complaints of dyspnea were more prevalent in the near-syncope group. In the syncope cohort, patients were more likely to be white or Caucasian and had a higher subjective risk assessment assigned to them by the ED physician (9.8% vs. 8.2%). There was no difference in the groups with regards to age, gender, initial ED ECG abnormality or hospital length of stay.

All 30-day serious clinical outcomes were described in Table 2. A total of 658 30-day serious outcomes (18.4%) were present within the study cohort. This percentage was not different between the near-syncope and syncope groups, at 18.7% and 18.2% respectively. There were no differences in major categories of serious clinical events (e.g. arrhythmias) between the two groups. Of note certain serious clinical events, are the pre-requisite for other serious clinical events, such as a dysrhythmia leading to pacemaker/AICD placement. The overall number of these events was both infrequent and similar between both cohorts.

In the multivariate logistic regression analysis, we found no difference between near-syncope versus syncope (OR: 0.94, 95% CI 0.78 – 1.14) (Table 3). History of arrhythmia, abnormal ECG and presence of dyspnea remained the highest predictors of 30-day serious clinical events with odds ratios of 2.06 (95% CI 1.68 – 2.53), 1.74 (95% CI 1.42 – 2.15) and 1.78 (95% CI 1.44 – 2.19), respectively. Physician risk assessment for the possibility of a serious clinical event did remain predictive in the multivariate analysis with an odds ratio of 1.03 (95% CI 1.02 – 1.03).

Limitations

There are some limitations with our study that need to be addressed. First, approximately half of eligible patients declined to participate in our study, and there is the potential for sampling bias. By including 11 geographically diverse sites into the largest study of elderly syncope and near-syncope in the United States to date, we hoped to mitigate the effects of any such bias. Second, the presence of ‘near-syncope’ was assigned by the treating physician. We did not assess inter-rater reliability of this assignment, and inconsistent assignment may introduce measurement bias. However, a prior study reported high inter-rater reliability (K=0.88) in the determination of near syncope.[7] Finally, our study was limited to older adults and should be replicated in other populations.

Discussion

In our multi-site observational cohort of older adults, we found that patients with a presentation of near-syncope had similar 30-day clinical event rates as those with syncope. Furthermore, the specific event types were similar between both groups. Also, despite a higher prevalence of cardiac co-morbidities and dyspnea associated with a presentation of near syncope, treating physicians generally assigned a lower risk to patients with near-syncope. Our findings suggest that ED physicians should manage older adults with near syncope or syncope in a similar fashion.

Traditionally, the management of patients who present with a chief complaint of near-syncope encapsulates all the nuances and challenges within emergency medicine. The difficulty begins with the definition of near-syncope, also referred to as presyncope.[7] Near-syncope is typically described as the sense of "lightheadedness derived from feeling an impending loss of consciousness." The vagueness of this definition results in a wide variety of presenting complaints which must be sifted through to determine whether a patient's "lightheadedness", "dizziness", "not feeling right" or "unsteadiness" can definitively be categorized as a near-syncopal event. [14] Even standard emergency medicine reference material is ambiguous where to house a discussion of near-syncope; placing it under the title of vertigo, syncope, seizure, and dysrhythmia.[15] In contrast to near-syncope, the presence or absence of a syncopal event is usually more definitive. This results in near-syncope and syncope appearing to align themselves across a spectrum of disease, with near-syncope appearing definitionally less malicious than syncope.

Our study's results should recalibrate the emergency physician's intuitions regarding the expected risk of 30-day serious clinical events for near-syncope patients. Though certain outcomes, such as symptomatic SVT, appear to occur more frequently in near-syncope vs. syncope (5.5% to 3.3%); there is very little difference across all major outcomes in this older population. Prior studies have reported conflicting results, and near-syncope has been considered inherently difficult to study given the nebulous nature of the presentation. Traditionally, the literature regarding the risk assessment was extrapolated from authors studying syncope and secondarily reporting on their near-syncope outcomes.[16,17] For example, Krahn AD et al in 2001 studied patients with unexplained syncope who received implanted loop recorders. They noted that patients who continued to experience syncope were more likely to have an arrhythmia identified than those who reported near-syncope (64% vs. 25%).[18] Although the difference between these groups appears definitive, the emergency department patient does not typically provide this level of pre-test probability for disease, i.e. repeated episodes of unexplained syncope stable enough to be evaluated in the outpatient setting.

Some of the literature has attempted to evaluate near-syncope more directly. In 2009 Sun et al conducted a chart review of 2,871 ED patients across 3 hospitals, and identified that near-syncope was associated with lower risk compared to syncope. In contrast, Grossman et al in 2012 studied 244 patients at a single site and found similar outcomes between patients with near-syncope and syncope.[19] These authors went on to note that despite similar outcome rates, near-syncope patients were discharged more frequently. Finally in 2015

Thiruganasambandamoorthy et al conducted a prospective observational study of 881 near-syncope patients and assessed for 30-day serious outcomes. [7] They noted that 5.1% of their patients had serious outcomes and that 1.7% of their cohort had serious outcomes occurring outside of the hospital. Notwithstanding their low serious adverse event rate due to a broader inclusion criteria (5.1% vs. 18.1%); the authors confirm that emergency care providers have difficulty in risk stratifying near-syncope patients. Emergency physicians had difficulty in predicting whether near syncope patients would experience a serious outcome (area under ROC: 0.58).[7]

This tendency to underappreciate the risk of short term serious clinical events in near-syncope patients was evident in our own analysis. Even after correcting for other variables the emergency physicians' subjective assessment regarding the likelihood of 30-day serious adverse events undervalued the risk of near-syncope. Our study attempted to clarify near-syncope's role as alongside rather than behind syncope in predicting 30-day serious clinical events. Following the guidelines laid out by the First International Workshop on Syncope Risk Stratification in the Emergency Department, we conducted the largest multi-center prospective observational study of near-syncope and syncope patients to date.[20] The results of this analysis erode any meaningful difference in patient risk afforded by either chief complaint. Also, it is always important to appreciate that the individual risk to any single patient cannot be determined by the broad nature of the claims made through this study. The emergency physician, as always, must evaluate each the patient based on their unique clinical picture.

In summary, there was no significant difference in the 30-day composite outcome of death or serious clinical events between older patients presenting to emergency departments with either near-syncope or syncope. Clinicians should consider using a similar risk stratification and management approach to both near-syncope and syncope.

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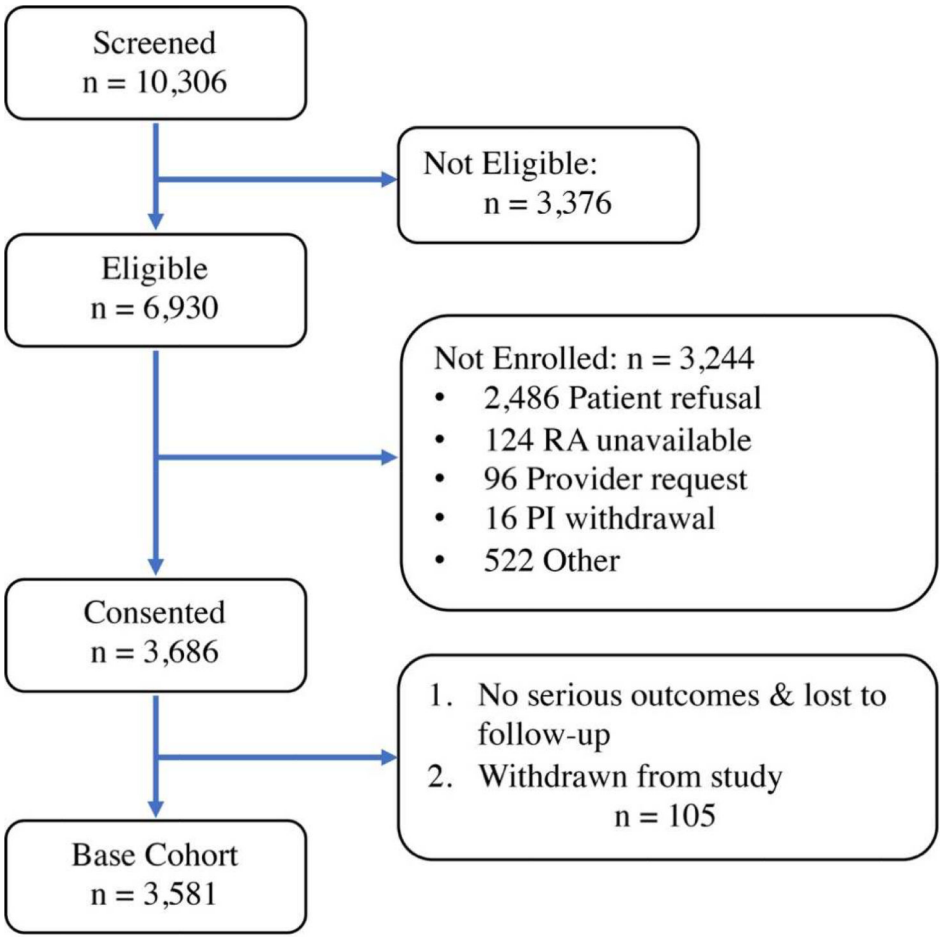

Figure 1.
Enrollment Diagram

Table 1.

Study Cohort Characteristics

Variable	Overall Cohort (n=3581) N (%)	Syncope (n=2201) N (%)	Near Syncope (n=1380) N (%)
Demographics			
Age, mean (SD)	72.8 (9.0)	72.9 (9.04)	72.6 (8.9)
Age			
60 to <70	1539 (43.0)	926 (42.1)	613 (44.4)
70 to <80	1156 (32.3)	720 (32.7)	436 (31.6)
80 to <90	729 (20.4)	449 (20.4)	280 (20.3)
90+	157 (4.4)	106 (4.8)	51 (3.7)
Male	1848 (51.6)	1147 (52.1)	701 (50.8)
Race			
White or Caucasian	2974 (83.5)	1860 (84.9)	1114 (81.4)
Black or African American	478 (13.4)	271 (12.4)	207 (15.1)
Asian	41 (1.2)	26 (1.2)	15 (1.1)
Other	67 (1.9)	35 (1.6)	32 (2.3)
History of			
Congestive Heart Failure	449 (12.5)	249 (11.3)	200 (14.5)
Coronary Artery Disease	979 (27.4)	575 (26.1)	404 (29.3)
Arrhythmia	803 (22.4)	458 (20.8)	345 (25.0)
Dyspnea	747 (21.4)	384 (17.9)	363 (26.8)
Hypotension	382 (10.7)	220 (10.0)	162 (11.7)
Abnormal ECG	1948 (55.4)	1180 (54.4)	768 (56.9)
Physician Risk Assessment, mean (SD)	9.2 (13.2)	9.8 (13.6)	8.2 (12.5)
Length of Stay (hours)			
Admitted, mean (SD)	96.4 (110.2)	98.4 (119.3)	92.5 (90.5)
Observed, mean (SD)	36.4 (38.5)	36.9 (38.0)	35.6 (39.4)
Discharged, mean (SD)	9.0 (40.3)	12.0 (55.3)	5.6 (3.7)

Table 2.

Serious Clinical Events Outcomes Stratified by Near-Syncope

Outcome	Overall Cohort (n=3581) N (%)	Syncope (n=2201) N (%)	Near Syncope (n=1380) N (%)
Any 30 day serious outcome	658 (18.4)	400 (18.2)	258 (18.7)
30 Day Death	44 (1.2)	31 (1.4)	13 (0.9)
Serious Cardiac Arrhythmias			
Any Arrhythmia	308 (8.6)	188 (8.5)	120 (8.7)
Ventricular Fibrillation	8 (0.2)	7 (0.3)	1 (0.1)
Ventricular tachycardia (>30 secs)	15 (0.4)	10 (0.5)	5 (0.4)
Symptomatic ventricular tachycardia (<30 secs)	17 (0.5)	14 (0.6)	3 (0.2)
Sick sinus disease with alternating sinus bradycardia and tachycardia	23 (0.6)	16 (0.7)	7 (0.5)
Sinus Pause > 3 seconds	14 (0.4)	12 (0.5)	2 (0.1)
Mobitz II atrioventricular heart block	12 (0.3)	8 (0.4)	4 (0.3)
Complete heart block	23 (0.6)	18 (0.8)	5 (0.4)
Symptomatic supraventricular tachycardia	149 (4.2)	73 (3.3)	76 (5.5)
Symptomatic bradycardia	45 (1.3)	29 (1.3)	16 (1.2)
Pacemaker or implantable cardioverterdefibrillator malfunction with cardiac pauses	2 (0.1)	1 (0.0)	1 (0.1)
Other Serious Outcomes			
Myocardial Infarction	69 (1.9)	37 (1.7)	32 (2.3)
Cardiac Intervention	162 (4.5)	108 (4.9)	54 (3.9)
New diagnosis of structural heart disease	36 (1.0)	22 (1.0)	14 (1.0)
Stroke	29 (0.8)	15 (0.7)	14 (1.0)
Pulmonary Embolism	34 (0.9)	15 (0.7)	19 (1.4)
Aortic Dissection	0 (0.0)	0 (0.0)	0 (0.0)
Subarachnoid Hemorrhage	2 (0.1)	1 (0.0)	1 (0.1)
Cardiopulmonary resuscitation	8 (0.2)	4 (0.2)	4 (0.3)
Internal hemorrhage/anemia	169 (4.7)	105 (4.8)	64 (4.6)
Recurrent syncope/fall resulting in major injury	12 (0.3)	9 (0.4)	3 (0.2)

Table 3.

Multivariable Logistic Regression Model Predicting 30 Day Composite Serious Outcomes

Variables	OR	95% CI
Near Syncope	0.94	(0.78, 1.14)
Male	1.19	(0.98, 1.44)
Race (not White)	0.75	(0.57, 0.97)
History of Congestive Heart Failure	1.37	(1.05, 1.78)
History of Coronary Artery Disease	0.99	(0.80, 1.23)
History of Arrhythmia	2.06	(1.68, 2.53)
Abnormal ECG	1.74	(1.42, 2.15)
Dyspnea	1.78	(1.44, 2.19)
Physician Risk Assessment	1.03	(1.02, 1.03)
Hypotension	1.65	(1.26, 2.15)