Short and Long Term Outcomes of Patients Admitted with Unexplained Syncope Using a Simple Novel SELF-Pathway

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Disclosures: None for all authors
St. Luke’s Hospital
Introduction

- Syncope is a syndrome consisting of a relatively short period of self-limited loss of consciousness caused by transient diminution of blood flow to the brain\textsuperscript{1,2}.

- The incidence of self-reported syncope is 6.2 per 1000 person-years in the Framingham study with a cumulative incidence of approximately 3\% to 6\% over 10 years.

- In selected patient populations, the lifetime prevalence of syncope could reach almost 50\%.

- In the United States, 1 to 2 million patients are evaluated for syncope annually, making up 3\% to 5\% of emergency department visits, and 1\% to 6\% of urgent hospital admissions\textsuperscript{3}.

3. Win K, Shen, MD; Wyatt W. Decker, MD; Peter A. Smars, MD; Deepi G. Goyal, MD; et al. Syncope Evaluation in the Emergency Department Study (SEEDS). A Multidisciplinary Approach to Syncope Management: Circulation 2004; 110:3636-3645.
In 2004 The “Advanced Cardiac Admission Program” (ACAP) was developed and implemented at St. Luke’s and Roosevelt Hospitals, New York, NY.

ACAP consists of tools and strategies for implementing ACC/AHA guidelines.

Up-to-date the ACAP program includes 9 state of the art pathways for the management of cardiovascular diseases.

Emad F. Aziz, Balaji Pratap, Maria E. De Benedetti Zunino et al., Success in Implementing a Hospital Wide Evidence-Based Clinical Pathways System for the Management of Cardiac Patients; the ACAP Program Experience. *Crit Pathways in Cardiol* 10(1):22-28, March 2011
ACAP Main Projects

- **PAIN** Pathway including STEMI and NSTEMI patients.
- **Heart Failure** Pathway for Acute management of Heart Failure.
- **RACE** Pathway for Atrial fibrillation & Flutter.
- **Hyperglycemia** Pathway for management in Critical & Cardiac Care Units.
- **SELF** Pathway for management of Syncope patients.
- **Hypertension** Pathway for management of hypertensive patients.
- **ESCAPE** Pathway, for Sudden Cardiac Death Prevention.
- **MOHCA** Pathway for the management of out of hospital cardiac arrest.
- **CHASER** Pathway for the management of pericardial disease.
Key features of the ACAP program

- Building partnership between emergency room physicians, internists, cardiologists and intensivists.
- Tools derived directly from published guidelines
- Involvement of caregivers across the continuum of care, not only physicians, - nurses, social workers and administrators
- Involvement of patients in their care
- Use of champions/opinion leaders (attending, specialists)
- Flexibility to allow local adaptation
- Use of data to change behavior and measure effectiveness of the approach.
Initial Assessment: (1) History and physical exam (including supine and standing blood pressure after 3 minutes)
(2) 12 lead electrocardiogram
(3) Labs: Basic Metabolic Panel, CBC.

All four SELF should be met:  
- Short period, Self limited Spontaneous recovery  
- Early - Rapid onset  
- Loss of consciousness-LOC (transient)  
- Full recovery, Fall
Initial assessment of a patient with syncope

Definition of true syncope (SELF-1 Criteria)

All four SELF should be met:
- **S**hort period, **E**self limited, **F**pontaneous recovery
- **E**arly - Rapid onset
- **L**oss of consciousness-LOC (transient)
- **F**ull recovery, **F**all

To be SELF-1 Positive, Subjects have to meet **ALL** the criteria

If the subjects do not meet either one of the SELF-1 criteria they are categorized as SELF-1 negative
The SELF Pathway for the Management of Syncope

Initial Assessment: (1) History and physical exam (including supine and standing blood pressure after 3 minutes)
(2) 12 lead electrocardiogram
(3) Labs: Basic Metabolic Panel, CBC

All four SELF should be met:
- Short period, Self-limited, Spontaneous recovery
- Early - Rapid onset
- Loss of consciousness - LOC (transient)
- Full recovery

Not True Syncope:
- Psychogenic
- Somatoform disorder
- TIA of Cerebral origin
- Drug induced

True Syncope:
- Transient LOC
- Is there a suspected diagnosis?

Unexplained syncope:

(1) Admit to telemetry for a minimum of 24 hours
(2) Echocardiogram

Is there evidence of?
- Structural Heart Disease
- Abnormal EKG
- Abnormal Telemetry

Consider:
1. Head up tilt table test
2. Prolonged EKG monitoring
   - Holter
   - Transtelephonic monitoring
   - Implantable loop recording
3. D/C home

Is there evidence of?
- Cardiovascular Disease
- Cardiac Arrhythmia or abnormal EKG
- Structural Heart Disease

Medical Therapy
- Imaging Stress Test
- Cardiac Cath
- Cardiac Surgery

Structural Heart Disease
- LV Systolic Dysfunction
- Wall Motion Abnormality
- Critical Valvular Heart Disease
- Aortic Stenosis
- Other
- Hypertrophic CM
- Other Etiologies (Congenital, infiltrative, etc.)

Abnormal EKG
- Sinus Bradycardia
- Bundle Branch Block
- 2nd and 3rd AV Block
- WPW
- Long QT Syndrome
- Brugada's Syndrome
- Other

Abnormal Telemetry
- Tachyarrhythmia
- Bradycardia
- Ventricular Tachycardia
- Supraventricular Tachycardia
- A. Flutter/A. Fibrillation

SELF Cardiac Syncope

EP Consult
- ICD
- Ablation
- Pacemaker

Tachyphysiology Study
True Syncope transient LOC

Is there a suspected diagnosis?

NO

YES

- Neurally mediated reflex syncopal syndrome
  - Vasovagal faint: head up tilt table test as in/out patient
  - Situational faint: cough, sneeze, swallowing, defecation, visceral pain, post micturition, post exercise
  - Carotid Sinus Syncope: Carotid sinus massage

- Orthostatic hypotension (syncope with assumption of upright position)
  - Volume depletion
  - Medication
  - Age related
  - Autonomic insufficiency including diabetes

- Cerebrovascular

- Cardiovascular Disease
  - Cardiac Arrhythmia or abnormal EKG
  - Structural Heart Disease

Consult neurology

Consider:
Behavioral Modification
Medical Treatment
Fluid Management
Permanent Pacemaker (Rare)
SELF-2 Criteria requirements

- SELF 2 includes cardiac etiology for syncope
- SELF-2 Criteria: any Structural heart disease, Abnormal EKG, or Abnormal telemetry.
  - **Structural Heart Disease**: includes LV systolic dysfunction, wall motion abnormality, Valvular heart disease, HOCM, others
  - **Abnormal EKG**: includes S. Bradycardia, BBB, 2nd and 3rd AVB, WPW, Long QT & Brugada's Syndromes and others
  - **Atrial Fibrillation**: any of the tachy and bradyarrhythmia including Ventricular tachycardia and Supraventricular tachycardia.
- To be SELF-2 Positive, Subjects have to meet at least **ONE** of the criteria
Methods-Implementation of the SELF Pathway

- The SELF pathway was implemented using focused novel easy to understand pathway, printed color-coded standardized admission and discharge orders, educational lectures and materials which are supplemented to all house staff including emergency department physicians.

- Residents admission notes are collected and entered into an integrated database including all admission labs, admission and discharge medications.
According to our study design, subjects are risk stratified twice in the SELF pathway.

Group A defined as those who are both SELF 1 (true syncope) and SELF 2 (any one of the cardiac etiologies) positive.

Group B defined as those who are both SELF 1 and 2 negative, i.e., who do not have a true syncope and do not have any one of the cardiac etiologies.
Study Aim

- The objective of our study was to assess the short and long-term outcomes in patients presenting to the emergency department with unexplained syncope using the SELF criteria.
- The primary endpoint was a composite of all-cause mortality, STEMI, NSTEMI/UA, syncope and stroke.
- Follow-up period was $394 \pm 140$ days
Patient Population

- According to our standardized care under the ACAP program, all patients presenting with the diagnosis of unexplained syncope to the hospital are included in a prospective institutional registry and consented for follow-up.

- **2920** consecutive patients admitted with unexplained syncope between September 2007 and August 2012 are included in this analysis *(Current enrollment is 3050).*

- Patients therapeutics, diagnostic tools, and Outcomes were reviewed and analyzed.
Statistical Analysis

- Statistical analysis performed using a standard statistical software package (SPSS for Windows, version 17; SPSS, Inc., Chicago, Illinois).
- Patient groups were compared using student $t$-test for continuous variables, chi-square test for categorical variables and Analysis of Variance for independent groups.
- Cox proportional hazard model was used to assess the effect of the implementation of the pathway on the patient outcomes.
- $P < 0.05$ was used to denote statistical significance.
### Baseline Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, Yrs.</td>
<td>73 ± 16</td>
<td>59 ± 22</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Sex, Female, %</td>
<td>373 (50)</td>
<td>539 (56)</td>
<td>0.016</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>547 (73)</td>
<td>449 (47)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Diabetes Mellitus, %</td>
<td>190 (26)</td>
<td>170 (18)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Dyslipidemia, %</td>
<td>254 (34)</td>
<td>170 (18)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>272 (37)</td>
<td>226 (24)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>PMHx MI, %</td>
<td>90 (12)</td>
<td>51 (5)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Heart Failure, %</td>
<td>116 (16)</td>
<td>56 (6)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Arrhythmia History, %</td>
<td>120 (16)</td>
<td>57 (6)</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>
## Baseline Home Medications

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SELF +/+</td>
<td>SELF -/-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N = 726 (26)</td>
<td>N = 960 (33)</td>
<td></td>
</tr>
<tr>
<td>Aspirin, %</td>
<td>331 (44)</td>
<td>192 (20)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>BB, %</td>
<td>291 (39)</td>
<td>205 (21)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>CCB, %</td>
<td>182 (25)</td>
<td>136 (14)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Diuretic, %</td>
<td>185 (25)</td>
<td>120 (13)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>ACEi / ARB, %</td>
<td>285 (38)</td>
<td>217 (23)</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Statin, %</td>
<td>285 (38)</td>
<td>189 (20)</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

BB = Beta Blockers, CCB = Calcium Channel Blockers, ACEi = angiotensin-converting enzyme inhibitors, ARB = Angiotensin II Receptor Blockers
# EKG & Echo Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Group A (%)</th>
<th>Group B (%)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SELF +/+</td>
<td>SELF -/-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>( N = 726 (26) )</td>
<td>( N = 960 (33) )</td>
<td></td>
</tr>
<tr>
<td><strong>EKG</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart Rate, bpm</td>
<td>75 ± 21</td>
<td>76 ± 15</td>
<td>0.57</td>
</tr>
<tr>
<td>PR Interval, msec</td>
<td>171 ± 37</td>
<td>159 ± 30</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>QRS Interval, msec</td>
<td>105 ± 37</td>
<td>91 ± 21</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>QT Interval, msec</td>
<td>413 ± 59</td>
<td>394 ± 45</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>QTc Interval, msec</td>
<td>452 ± 41</td>
<td>437 ± 35</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td><strong>Echocardiography</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean LVEF, %</td>
<td>57 ± 15</td>
<td>61 ± 10</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>LVEF &lt; 35%, n, %</td>
<td>63 (8)</td>
<td>22 (2)</td>
<td>0.0004</td>
</tr>
</tbody>
</table>
Events free Survival Curve

Composite End-Point
(All Cause Mortality, STEMI, NSTEMI, Recurrent Syncope & Stroke)

Log Rank $X^2=67$, $P<0.0001$
$HR=2.2$, 95% CI: 1.7 - 2.5

After Adjusting for Age, Medication, Risk Factors, & Device Therapy
Short & Long-term Outcomes (%) of the SELF Groups
<table>
<thead>
<tr>
<th>Variable</th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>1.02</td>
<td>1.02 – 1.03</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>CHF</td>
<td>2.1</td>
<td>1.66 – 2.69</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>1.32</td>
<td>1.07 – 1.63</td>
<td>0.007</td>
</tr>
<tr>
<td>CAD</td>
<td>1.45</td>
<td>1.13 – 1.84</td>
<td>0.0033</td>
</tr>
<tr>
<td>SELF Criteria</td>
<td>1.31</td>
<td>1.07 – 1.60</td>
<td>0.008</td>
</tr>
</tbody>
</table>

* Over all Model Chi-square Fit= 174; p < 0.0001

CAD = Coronary Artery Disease, CHF = Congestive Heart Failure
Although several guidelines have been published for the diagnostic approach to patients with syncope, none has been validated prospectively and none applies to every clinical situation encountered.

Most guidelines do not specify the level of detail needed to create a structural evaluation tool for these patients, thus, providing only a framework to approach the diagnostic evaluation of this difficult problem.

The novel SELF pathway is comprehensive, yet simple, and provides guidelines for the management of all patients presenting to emergency departments with a complaint of syncope.
Conclusion

- Routine utilization of a standardized clinical pathway for patients presenting with unexplained syncope effectively identifies patients who merit hospitalization for further work-up.

- This has important implications for the evaluation and the management of a common disease that poses a significant economic burden on healthcare utilization.
Thank You
The ACAP Cardiac Research Group
www.NYCardiologyPathways.Org
Acute coronary syndrome (ACS) is among the most common causes of emergency hospital admission and a major cause of morbidity and mortality worldwide. There is approximately 1.8 million hospitalizations for ACS in the United States; out of the eight million presenting with chest pain in the emergency departments, which suggests an ischemic origin. The large numbers of coronary artery disease (CAD) hospitalization resulted in large-scale clinical trials and registries which have provided abundant data on hundreds of thousands of patients which resulted in defining guidelines through evaluation of the quality of care and outcomes for patients with ACS. These guidelines are dedicated to the assessment of patients with ACS, have existed in the United States since 1994.

Despite considerable investment in the development and nationwide distribution of guidelines, the Center for Medicare and Medicaid Services Cooperative Cardiovascular Project reported the quality of care for Medicaid beneficiaries with acute myocardial infarction (AMI) was far from optimal. Many subsequent studies have also shown similar disappointing adherence to the therapeutic recommended in published guidelines.