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

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St. Luke's and Roosevelt Hospitals
Columbia University College of Physicians and Surgeons
New York City, New York


Disclosures: None for all authors


# ACAP Program at SLR


St. Luke’s Hospital
HARLEM
BROADWAY
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SOUTH STREET
BROAD ST
WALL ST
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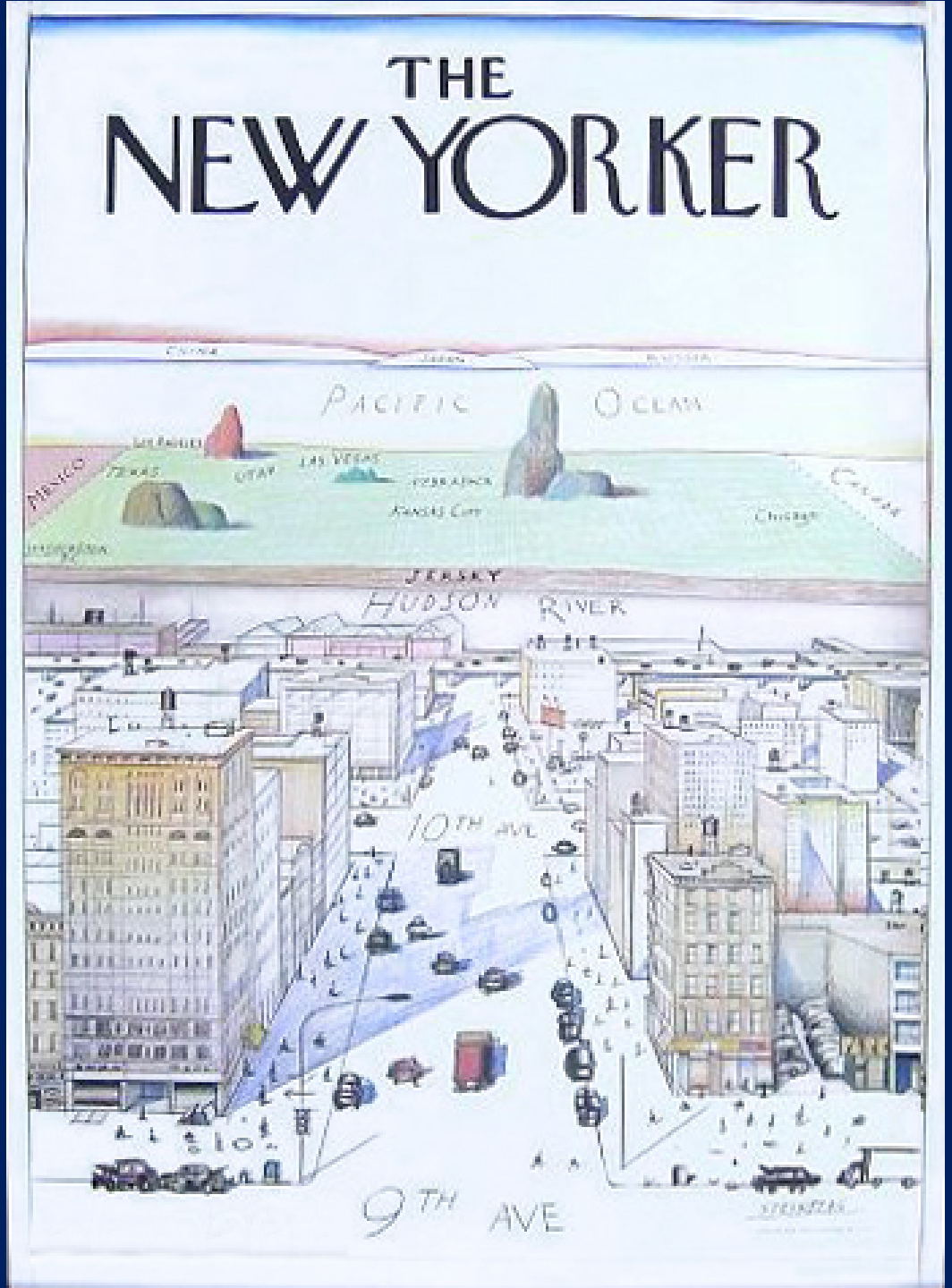
ogram at SLR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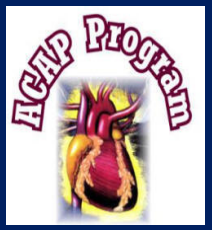

AGAP Program

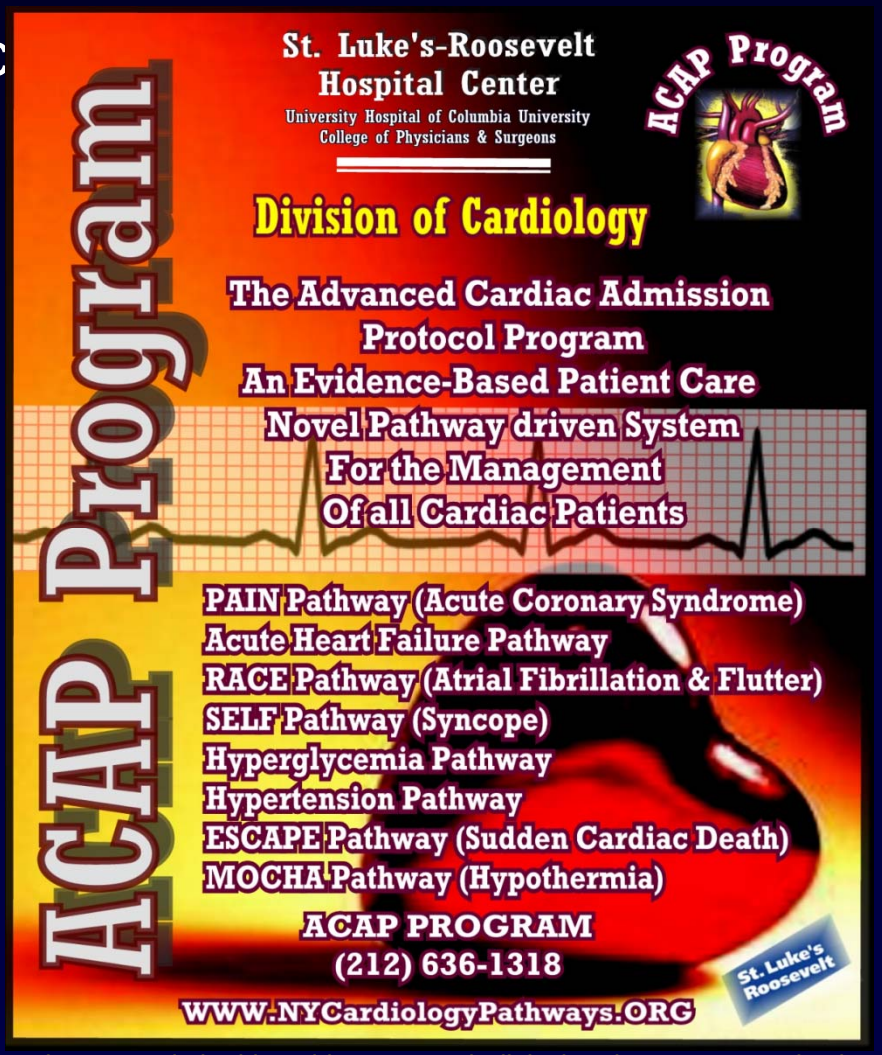
# Introduction

- 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[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[3].


1. Bendit DG., MD, Van Dijk G J, MD, PhD, Sutton R, et. al. Syncope: Curr Probl Cardiol, April 2004; 152-229.
2. Brignole M. Alboni P, Benitt DG, Bergfeldt L, Blanc JJ, Bloch PE, et al. Guidelines on management (diagnosis and treatment) of syncope. Eur Heart J 2001; 22:1256-1306.
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.

# Advanced Cardiac Admission Program (ACAP)

- 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.

# The SELF
## Pathway for the Management of Syncope

St. Luke's Roosevelt — University Hospital of Columbia University College of Physicians & Surgeons
Continuum Health Partners, Inc.
Arrhythmia Service

**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:**
- **S**hort period, **S**elf limited, **S**pontaneous recovery
- **E**arly - Rapid onset
- **L**oss of consciousness-LOC (transient)
- **F**ull recovery,**F**ail

**Not True Syncope**
- Psychogenic
- Somitization disorder
- TIA of Carotid origin
- Cataplexy

**No LOC**

**Prolonged LOC**

Is there evidence of trauma?
- YES → Concussion with variable duration of unconsciousness
- NO

**Consider:**
- Intoxication
- Metabolic disorder- *hypoglycemia, hypoxia, hyperventilation with hypocapnia*
- Intracranial/intracerebral hemorrhage
- Epilepsy, Seizure
- Vertebrobasilar transient ischemic attack

Evaluate and treat individually

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- Orthostatic hypotension (syncope with assumption of upright position)
  - Volume depletion
  - Medication
  - Age related
  - Autonomic insuffiency including diabetes
- Cerebrovascular → Consult neurology
- Cardiovascular Disease
  - Cardiac Arrhythmia or abnormal EKG
  - Structural Heart Disease

**Consider:**
- Behavioral Modification
- Medical Treatment
- Fluid Management
- Permanent Pacemaker (Rare)

- NO

**Unexplained syncope**

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

**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 ?**
- Structural Heart Disease
- Abnormal EKG
- Abnormal Telemetry

Medical Therapy
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His Bundle Study
Electrophysiology Study
ICD
Ablation
Pacemaker

**Structural Heart Disease**
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- Other Etiologies (Congenital,Infiltrative, etc)

**Abnormal EKG**
- Sinus Bradycardia
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- Other

**SELF Cardiac Syncope**

**EP Consult**

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# SELF-1 Criteria requirements

- Initial assessment of a patient with syncope
- Definition of true syncope (SELF-1 Criteria)


- 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

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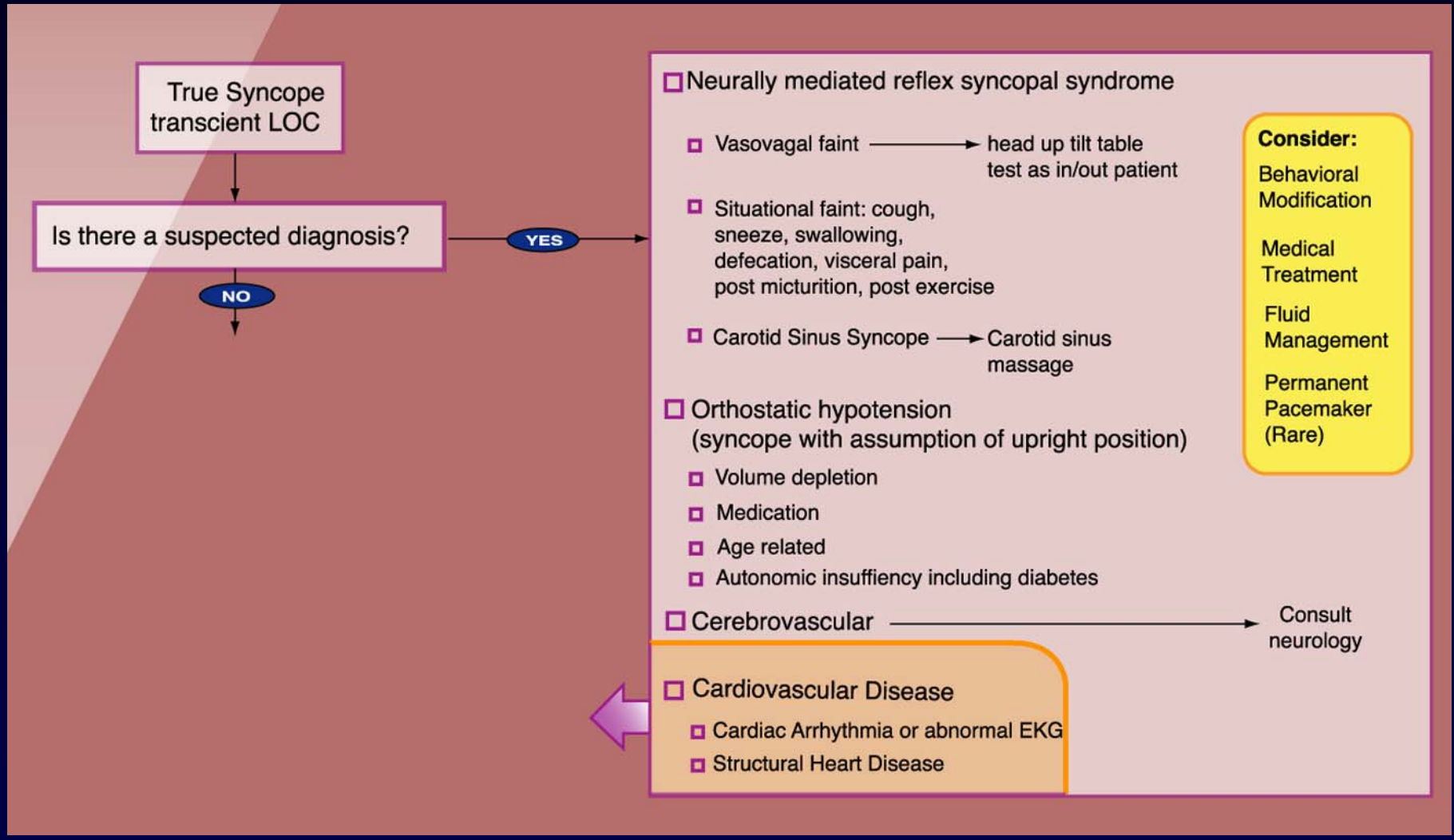
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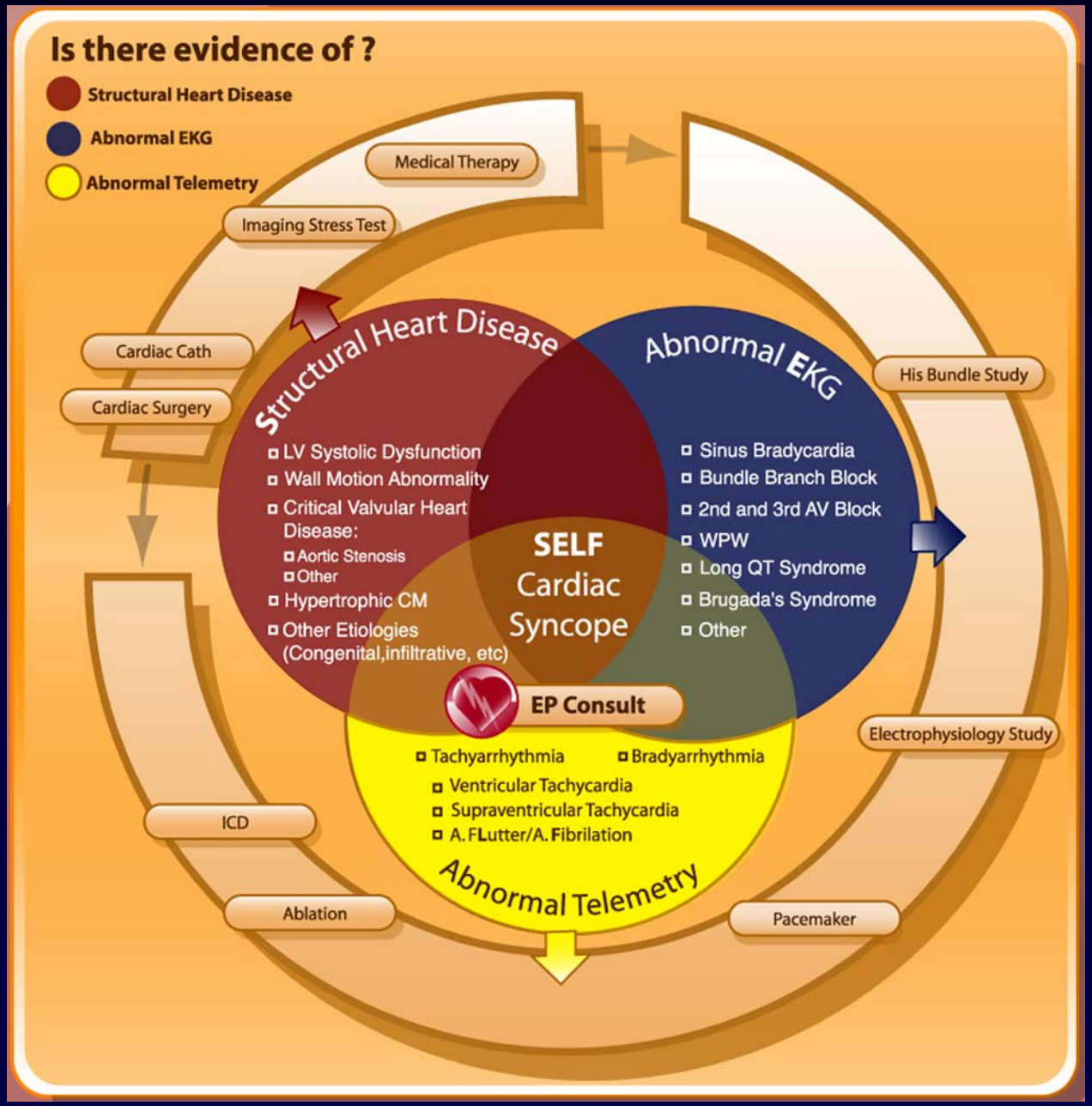
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Supraventricular Tachycardia
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Abnormal Telemetry

# SELF-2 Criteria requirements

- SELF 2 includes cardiac etiology for syncope
- SELF-2 Criteria : any Structural heart disease, Abnormal EKG, or Abnormal telemetry.

**S** Structural Heart Disease: includes LV systolic dysfunction, wall motion abnormality, Valvular heart disease, HOCM, others

**E** Abnormal EKG: includes S. Bradycardia, BBB, 2nd and 3rd AVB, WPW, Long QT & Brugada's Syndromes and others

**L** Atrial fLutter

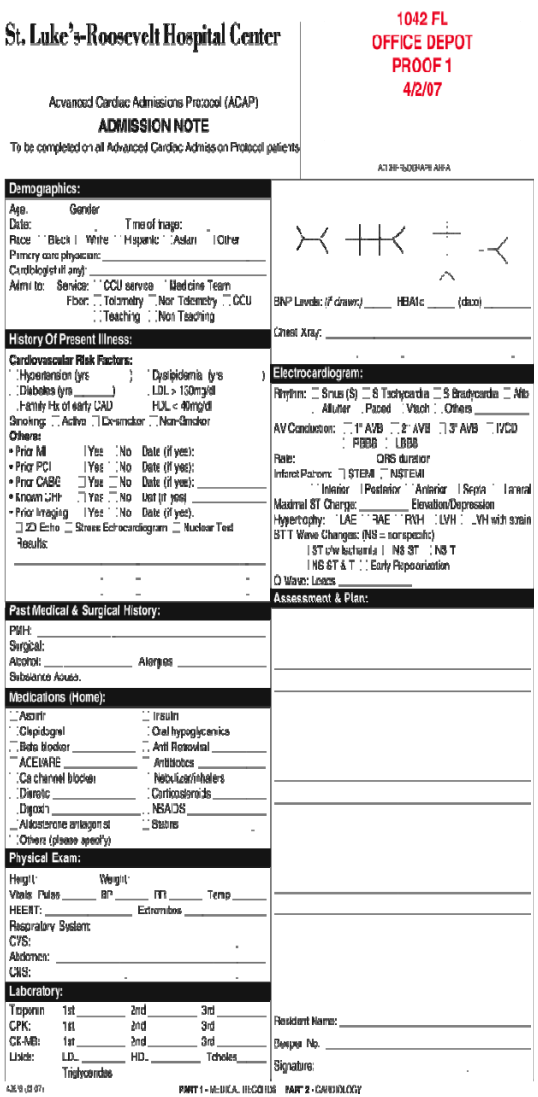
**F** Atrial Fibrillation: any of the tachy and bradyarrhythmia including Ventricular tachycardia and Supraventricular tachycardia.

- 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.

# ACAP Program Admission and Discharge Forms



St. Luke's-Roosevelt Hospital Center

1042 FL
OFFICE DEPOT
PROOF 1
4/2/07

Advanced Cardiac Admissions Protocol (ACAP)

**ADMISSION NOTE**

To be completed on all Advanced Cardiac Admission Protocol patients

Demographics:

History Of Present Illness:

Past Medical & Surgical History:

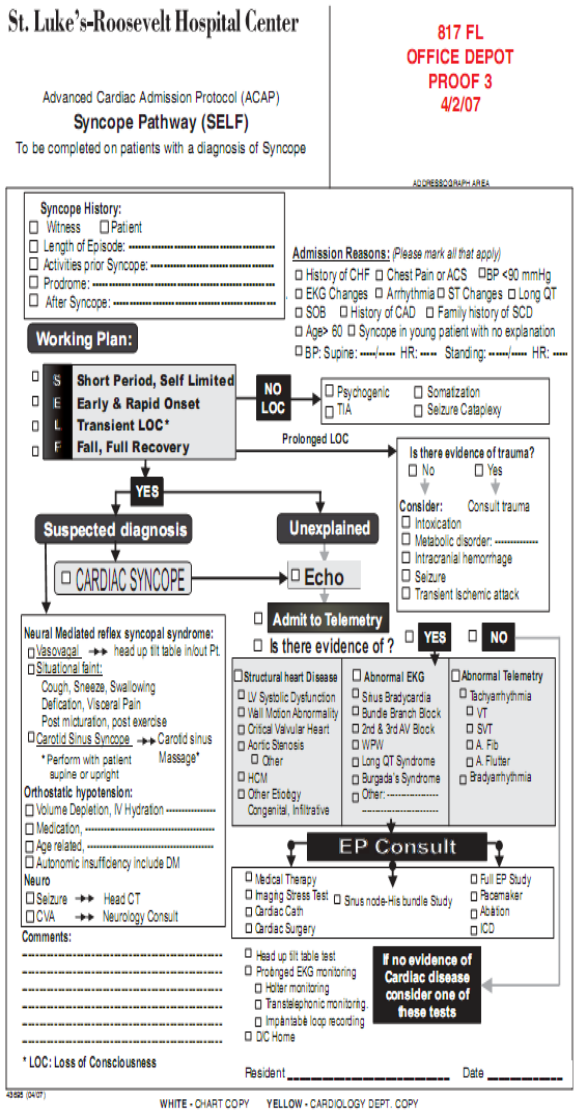
Medications (Home):

Physical Exam:

Laboratory:

Electrocardiogram:

Assessment & Plan:



St. Luke's-Roosevelt Hospital Center

817 FL
OFFICE DEPOT
PROOF 3
4/2/07

Advanced Cardiac Admission Protocol (ACAP)

**Syncope Pathway (SELF)**

To be completed on patients with a diagnosis of Syncope

Syncope History:

Admission Reasons: *(Please mark all that apply)*

Working Plan:

S Short Period, Self Limited
E Early & Rapid Onset
L Transient LOC*
F Fall, Full Recovery

NO LOC

Prolonged LOC

YES

Suspected diagnosis

Unexplained

CARDIAC SYNCOPE

Echo

Admit to Telemetry

Is there evidence of ?

Neural Mediated reflex syncopal syndrome:

Orthostatic hypotension:

Neuro

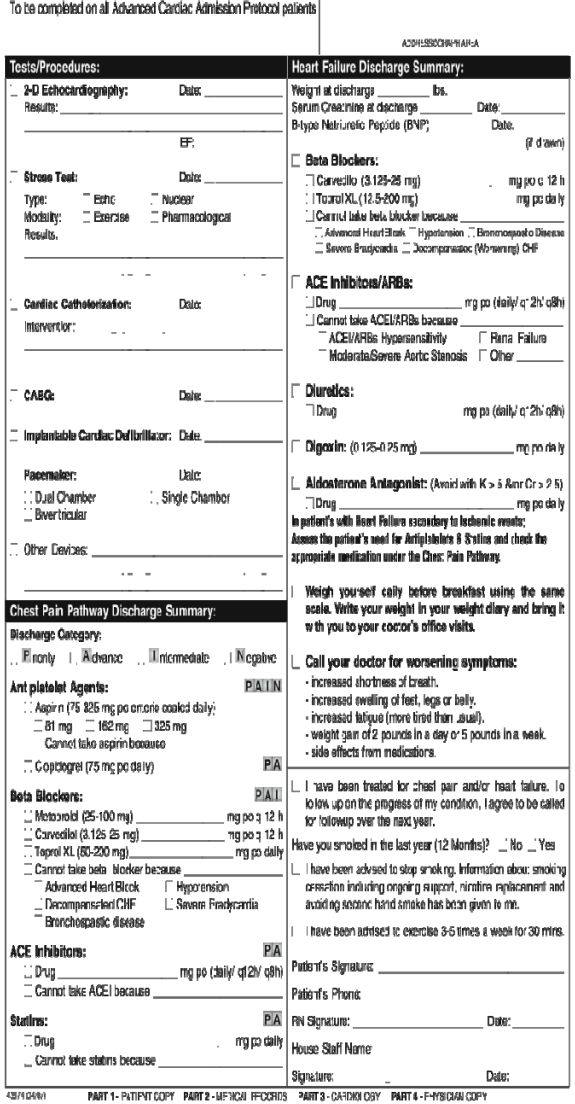
Comments:

EP Consult

If no evidence of Cardiac disease consider one of these tests

* LOC: Loss of Consciousness

WHITE - CHART COPY YELLOW - CARDIOLOGY DEPT. COPY



St. Luke's-Roosevelt Hospital Center

1046 FL
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PROOF 1
4/2/07

Advanced Cardiac Admissions Protocol (ACAP)

**Cardiac Discharge Summary**

To be completed on all Advanced Cardiac Admission Protocol patients

Tests/Procedures:

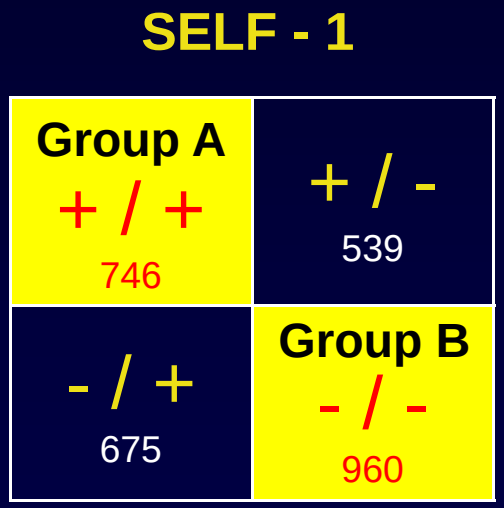
Heart Failure Discharge Summary:

Chest Pain Pathway Discharge Summary:

PART 1 - PATIENT COPY PART 2 - MEDICAL RECORDS PART 3 - CARDIOLOGY PART 4 - PHYSICIAN COPY

# Study Design

- 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 ± 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

| Variable | Group A (%) SELF +/+ N = 726 (26) | Group B (%) SELF -/- N = 960 (33) | *p* |
|---|---|---|---|
| Age, Yrs. | 73 ± 16 | 59 ± 22 | *< 0.0001* |
| Sex, Female, % | 373 (50) | 539 (56) | *0.016* |
| Hypertension, % | 547 (73) | 449 (47) | *< 0.0001* |
| Diabetes Mellitus, % | 190 (26) | 170 (18) | *< 0.0001* |
| Dyslipidemia, % | 254 (34) | 170 (18) | *< 0.0001* |
| Smoking, % | 272 (37) | 226 (24) | *< 0.0001* |
| PMHx MI, % | 90 (12) | 51 (5) | *< 0.0001* |
| Heart Failure, % | 116 (16) | 56 (6) | *< 0.0001* |
| Arrhythmia History, % | 120 (16) | 57 (6) | *< 0.0001* |

# Baseline Home Medications

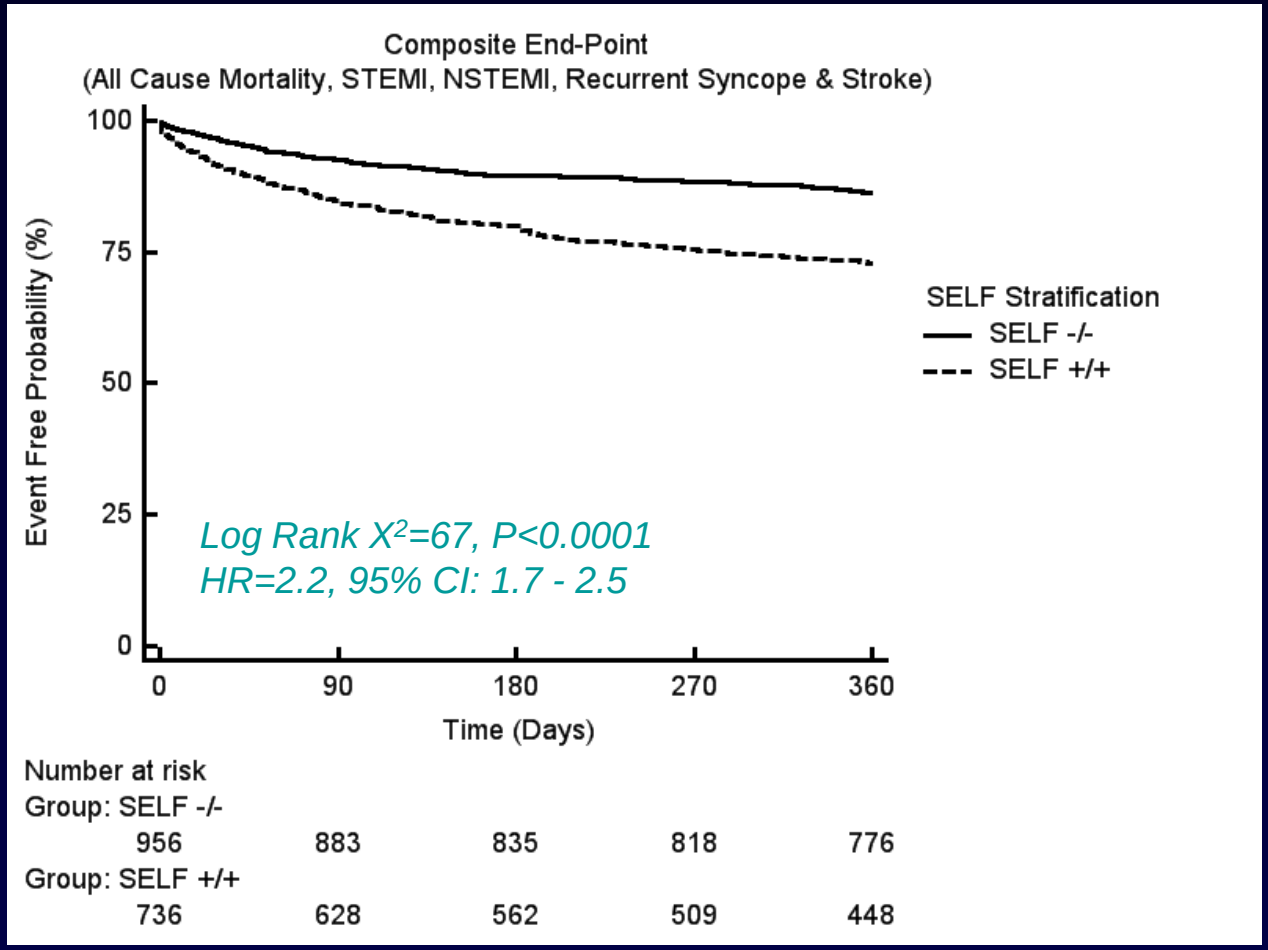
| Variable | Group A (%) SELF +/+ N = 726 (26) | Group B (%) SELF -/- N = 960 (33) | *p* |
|---|---|---|---|
| Aspirin, % | 331 (44) | 192 (20) | *< 0.0001* |
| BB, % | 291 (39) | 205 (21) | *< 0.0001* |
| CCB, % | 182 (25) | 136 (14) | *< 0.0001* |
| Diuretic, % | 185 (25) | 120 (13) | *< 0.0001* |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

BB = Beta Blockers, CCB = Calcium Channel Blockers, ACEi = angiotensin-converting enzyme inhibitors, ARB = Angiotensin II Receptor Blockers

# EKG & Echo Characteristics

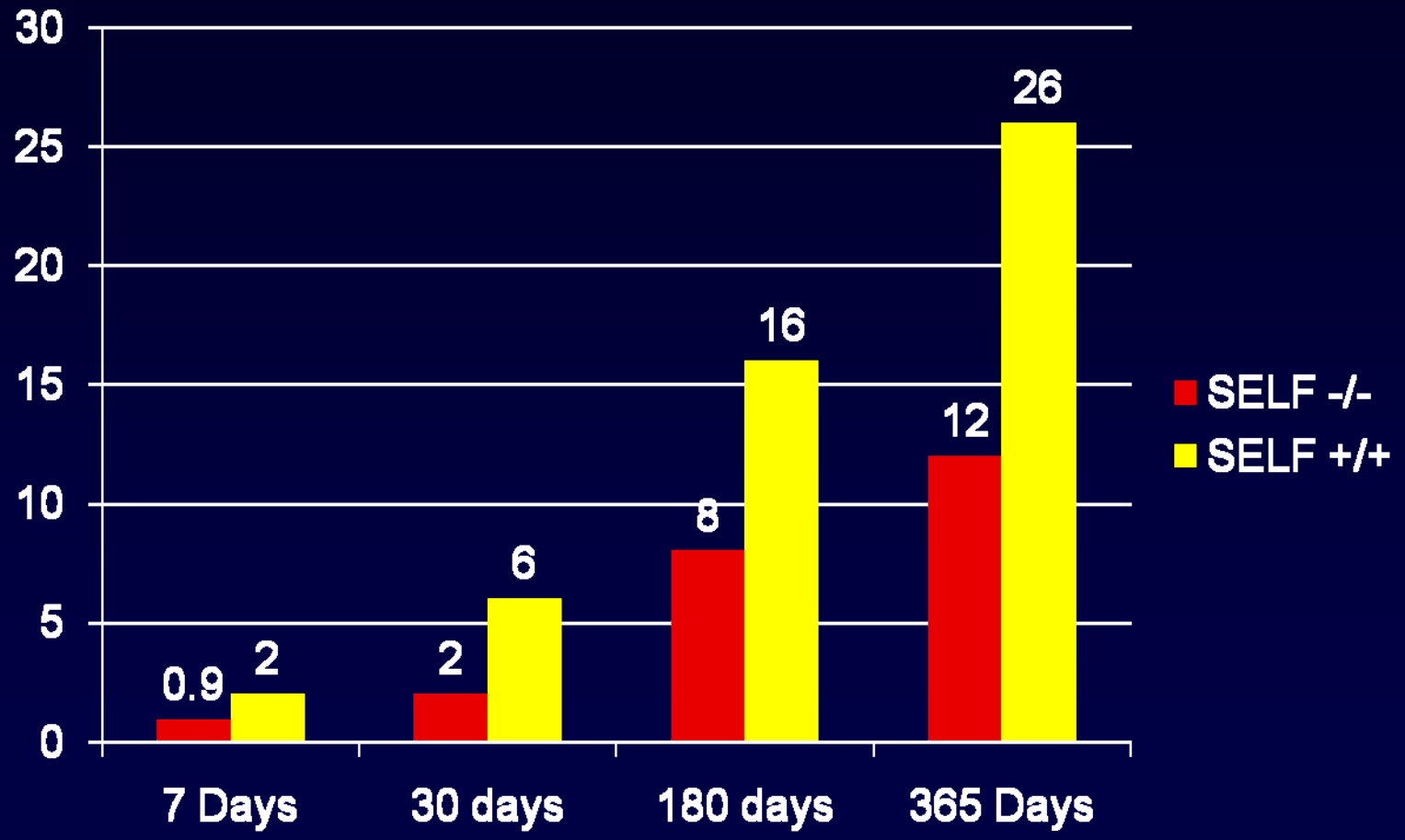
| Variable | Group A (%) SELF +/+ N = 726 (26) | Group B (%) SELF -/- N = 960 (33) | *p* |
|---|---|---|---|
| **EKG** | | | |
| Heart Rate, bpm | 75 ± 21 | 76 ± 15 | *0.57* |
| PR Interval, msec | 171 ± 37 | 159 ± 30 | *< 0.0001* |
| QRS Interval, msec | 105 ± 37 | 91 ± 21 | *< 0.0001* |
| QT Interval, msec | 413 ± 59 | 394 ± 45 | *< 0.0001* |
| QTc Interval, msec | 452 ± 41 | 437 ± 35 | *< 0.0001* |
| **Echocardiography** | | | |
| Mean LVEF, % | 57 ± 15 | 61 ± 10 | *< 0.0001* |
| LVEF < 35%, n, % | 63 (8) | 22 (2) | *0.0004* |

# Events free Survival Curve




*After Adjusting for Age, Medication, Risk Factors, & Device Therapy*

# Short & Long-term Outcomes (%) of the SELF Groups



# Multivariate Logistic Regression Predictors of Outcomes*

| Variable | OR | 95% CI | *p* |
|---|---|---|---|
| Age | 1.02 | 1.02 – 1.03 | *<0.0001* |
| CHF | 2.1 | 1.66 – 2.69 | *<0.0001* |
| Diabetes | 1.32 | 1.07 – 1.63 | *0.007* |
| CAD | 1.45 | 1.13 – 1.84 | *0.0033* |
| SELF Criteria | 1.31 | 1.07 – 1.60 | *0.008* |

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

CAD = Coronary Artery Disease, CHF = Congestive Heart Failure

# Summary

- 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

Herzog E, Frankenberger O, Pierce W, Steinberg JS. The SELF pathway for the management of syncope. Crit Pathw Cardiol. 2006 Sep;5(3):173-8.

# 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*

# NY Cardiology Critical Pathways

## St. Luke's and Roosevelt Hospitals

### University Hospital of Columbia University
### College of Physicians and Surgeons
### New York, New York

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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.

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