My Patient Has Palpitations, Passed Out or had a Stroke: Should I Refer for an Implantable Monitor?

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Disclosures

None
Syncope

Facts

• ~40% of the population will have at least one syncopal event in their lifetime¹
• 20% with multiple events
• 10% of falls by elderly are believed due to syncope²
• Major morbidity reported in 6%¹ (e.g., fractures, motor vehicle accident)
• Minor injury reported in 29%¹ (e.g., lacerations, bruises)
• $2.4 billion in health care expenditures


*Syncope and collapse (ICD-9 Code: 780.2) listed as primary reason for visit. NAMCS 2006.
Syncope remains unexplained in approximately 1/3 of cases.

Supporting Clinical Evidence
“...cardiac syncope can be a harbinger of sudden death.” NEJM

- Study of survival rates with and without syncope
- Cardiac syncope carried a 6-month mortality rate of greater than 10%
- Cardiac syncope doubled the risk of death

• 570 patients with unexplained recurrent syncope were followed observationally for 12-36 months:
  - Patients had seen an average of 3 specialists and undergone an average of 13 tests
  - 70% had been hospitalized and 36% had significant trauma with syncope

• ILR/Reveal guided the diagnosis in 78% of the 218 patients with recurrent syncope at 12 months
The Challenge of Cryptogenic Stroke

Types of Ischemic Stroke

- **Atherothrombotic (25-30%)**
  Stenotic artery feeding area of infarction

- **Cardioembolic (20%)**
  A thrombus or other material dislodges from the heart or aortic arch

- **Lacunar/Small Vessel (15-20%)**
  Small, deep infarct

- **Other/Uncommon (5-10%)**

- **Cryptogenic (25-40%)**
  Unknown cause

Stroke etiologies

**Vessel Rupture (15%)**

**Artery Occlusion (85%)**

Adams HP Jr, Stroke. Jan 1993; 24; 35-41
Cryptogenic Stroke

Why Atrial Fibrillation (AF) Matters

• 25% of ischemic strokes are considered cryptogenic, despite intense work-up\(^1\)

• Patients may have underlying undiagnosed AF

• Detection of AF in these patients changes treatment
  – Guidelines state change from antiplatelets to OAC\(^2\)

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\(^1\) Adams HP Jr, *Stroke*. Jan 1993; 24; 35-41;
\(^2\) Camm et al, *European Heart Journal*. 2012; 33, 2719-2747
How AF is Detected in Cryptogenic Stroke Patients

The more you look, the more AF you find

- **N = 149**
- Acute stroke or TIA and no history of AF
- ECG monitoring in Hospital
- 24-hour Holter recording if normal ECG
- 7-day event monitor if normal Holter

**Incremental % AF Detection**

<table>
<thead>
<tr>
<th>Workup</th>
<th>Acute Workup</th>
<th>After CS Diagnosis</th>
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<tbody>
<tr>
<td>1 ECG</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td>Multi...</td>
<td>4.1%</td>
<td></td>
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<tr>
<td>24...</td>
<td>5.0%</td>
<td></td>
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<tr>
<td>7 day...</td>
<td>5.7%</td>
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**Cotter / Ritter Data**

Occult Atrial Fibrillation in Cryptogenic Stroke Detection by 7-day ECG vs. ICM

Methods:
• 60 patients with cryptogenic stroke implanted
• Compared ICM to 7-day Holter monitor
• Patient workup included Cerebral imaging, ECG, 72 hour telemetry, 24-hour Holter, TEE

Results:
• AF detected in 17% (10 pts)
• Average time to detection 64 days post-stroke
• Yield of ICM (17%) vs. 7-day ECG (1.7%) significantly higher p=0.0077

Atrial Fibrillation: Epidemiology

• Most common arrhythmia in clinical practice
• 20% lifetime risk of developing afib
• 8% prevalence in 80-90 y/o
Prevalence of Afib - Projected to Double by 2050

Olmsted County study

NVAF Is Associated With Significant Morbidity and Mortality

Morbidity
- The risk of stroke is increased ~5-fold in NVAF patients vs those without NVAF\(^1,2\)

Incidence of Stroke According to Presence of NVAF (Framingham Heart Study)

- Risk Ratio: 4.8\(^*\)

<table>
<thead>
<tr>
<th>2-Year Age-Adjusted Incidence of Stroke/1000</th>
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<tbody>
<tr>
<td>Patients Without NVAF</td>
</tr>
<tr>
<td>50</td>
</tr>
<tr>
<td>40</td>
</tr>
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<td>30</td>
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<td>20</td>
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Mortality
- Stroke patients with NVAF are at increased risk of death vs those without AF\(^3\)

Rate of Death

- 30-Day Mortality
  - Without AF (n=2661): 16.2%
  - With NVAF (n=674): 34.7%

- 1-Year Mortality
  - Without AF: 27.1%
  - With NVAF: 52.4%

AF=atrial fibrillation
* P<0.001.
Tools for Diagnosis

**ECGs** No asymptomatic arrhythmias; limited duration

**24-48 hour Holter monitoring** Short duration

**Event recorders**
- Non-looping require frequent manual activations and/or symptoms
- Limited sensitivity/specificity of auto trigger algorithms

**Outpatient cardiovascular telemetry monitoring**
- Requires continuous wearing (patient compliance)
- Limited monitoring time

**Implantable loop recorders**
Why Not Trust Patient Symptoms?
Poor Correlate When Monitoring for AF

- N=48
- 95% of AT episodes were asymptomatic
- AF symptoms accurate only 15% of time
- 45% of patients reported symptoms without recorded AT event
- Other studies show 12:1 ratio asymptomatic:symptomatic AT

TRENDS Study Subgroup Analysis
Newly Detected AF (“NDAF”) in Patients with Thromboembolic Events

• 163 patients with previous ischemic stroke/TIA, no known AF, were continuous monitored via pacemaker or ICD

• NDAF ≥ 5 minute duration were found in 28% patients.

Why Continuous AF Monitoring Is Important

• AF may be asymptomatic
• AF may be intermittent
• AF duration may be important
• Intermittent asymptomatic AF of “short” duration can lead to....
  • Stroke
  • Heart failure
Landmark CRYSTAL AF Study:

**CRYptogenic STroke And underLying Atrial Fibrillation**

**Objectives:**

- Assess ICM vs. Standard Care for detection of AF in cryptogenic stroke patients
  - 6 month endpoint (primary)
  - 12 month endpoint (secondary)
- Determine proportion of patients with underlying AF
- Record actions taken after AF diagnosis

CRYSTAL AF Study Overview

- Patient had Cryptogenic stroke/TIA
- Randomized to SoC or ICM
- AF defined as ≥ 30 seconds
- Primary endpoint
  - AF detection at 6 months
- Secondary endpoints
  - AF detection at 12 months
  - AF duration
  - Symptom correlation
  - Physician actions
CRYSTAL AF: At 36 months, 30% of patients in the ICM arm found to have AF\(^1\)

8.8x more than standard follow-up arm

CRYSTAL AF Study Results

Reveal ICM superior to SoC for finding AF in patients with a cryptogenic stroke\(^1\)

- Over \textbf{7x more} patients with AF at 12-months
- At 36 months, \textbf{30\%} of patients in the Reveal ICM arm found to have AF
- Short-term monitoring not sufficient: median time to AF detection over 12 months was \textbf{84 days}
- At 12 months, \textbf{97\%} of patients with AF prescribed OAC

As published in the \textit{New England Journal of Medicine}

Patients We Can Help with Long Term Monitoring

- SYNCOPE
- PRE SYNCOPE/DIZZINESS
- PALPITATIONS
- EPILEPSY
- NEGATIVE EP
- CRYPTOGENIC STROKE or TIA
- AF MANAGEMENT
The Reveal LINQ ICM System

The Complete Monitoring Solution

Simplified Insertion Procedure

Reveal LINQ ICM

Wireless
Miniaturized Reveal LINQ ICM
The Smallest ICM to Provide Continuous and Wireless Data Collection and Trending

- No wires or leads
- Proven AF algorithm accurately detects AF in 98.5% of patients¹
- Three-year longevity for long-term monitoring²
- MR Conditional at 1.5 and the only ICM at 3.0 Tesla with no post-insertion waiting required‡

Reveal LINQ ICM is 1/3 the width of an AAA battery

† Reveal LINQ ICM has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Please see Reveal LINQ ICM clinician manual or MRI Technical Manual for more details.
2. See the Reveal LINQ ICM clinician manual for usage parameters.
Minimally Invasive Outpatient Insertion Procedure - No Leads or Fluoroscopy

Best location: 45 degrees to sternum over 4th intercostal space, 2 cm from left edge of sternum
• Indications for ILRs and ELRs in patients with syncope ILRs

Class I. ILR is indicated: † In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have: –absence of high-risk criteria that require immediate hospitalization or intensive evaluation, and –a likely recurrence within battery longevity of the device (Level of evidence A) † In high-risk patients in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to specific treatment (Level of evidence B)

Class II A. ILR may be indicated: † To assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes (Level of evidence B)

Class II B. ILR may be indicated: † In patients with T-LOC of uncertain syncopal origin in order to definitely exclude an arrhythmic mechanism (Level of evidence C)

ELRs Class II A. ELRs may be indicated in patients with recurrent (pre)syncopes who have: –inter-symptom interval of 4 weeks, and –suspicion of arrhythmic origin and –absence of high-risk criteria that require immediate hospitalization or intensive evaluation, (Level of evidence B)

Interpretation of ILR and ELR findings in patients with syncope Class I † ILR and ELR findings are diagnostic when: –a correlation between syncope and an arrhythmia (brady- or tachyarrhythmia) is detected (Level of evidence B) –in the absence of such correlation, periods of Mobitz II or III degree AV block or a ventricular pause .3 s (with possible exceptions for young trained persons, during sleep, medicated patients or rate-controlled atrial fibrillation), or rapid prolonged (i.e. 160 bpm for .32 bpm) paroxysmal atrial or ventricular tachyarrhythmias are detected (Level of evidence C) † ILR and ELR findings exclude an arrhythmic cause when there is no correlation between syncope and rhythm variation (Level of evidence B).

Class III. ILR and ELR findings are not diagnostic and monitoring should be continued in case of: † Pre-syncope without any relevant arrhythmias as those listed above (Level of evidence C). † Asymptomatic arrhythmias (other than those listed above) (Level of evidence C). † Sinus bradycardia (in absence of syncope) (Level of evidence C) Note: This task force recognizes that, in real world practice, there is occasionally the need to make a therapeutic decision with weaker diagnostic criteria. Physicians should be aware that effectiveness of therapy is not well documented in such cases.
• Indications for ILRs and ELRs in patients with undocumented palpitations

• Class I: ELRs are indicated in patients with recurrent palpitations, undocumented by conventional ECG techniques, who have: inter-symptom interval ≤ 4 weeks and absence of high-risk criteria, which require immediate hospitalization or intensive evaluation (Level of evidence B)

• Class IIA: ILRs may be indicated in selected cases with severe infrequent symptoms when ELRs and other ECG monitoring systems fail to document the underlying cause (Level of evidence B).
Thank You
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