When to Consider an Implantable Loop Recorder (More Than Syncope)

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Evaluation of syncope

72 y/o nurse with recurrent syncope
- 2008 – syncope preceded by nausea and vomiting, associated with incontinence
  - Echo, stress test, EEG, MRA and carotid U/S negative
- 3/2009 – syncope preceded by nausea and lightheadedness, followed by transient Afib
  - Tilt showed mild hypotension (SBP 81), normal HR
- Easter dinner 2010
- Church supper 12/2010
  - Repeat tilt- LH and dizzy but no change in BP or HR
- ILR implanted 10/2011
2/2014 syncope while sitting in chair
Devices for arrhythmia detection

- EKG
- Holter monitor
- EKG event monitor
  - Intermittent or continuous
  - Symptom activated or automatic
- Mobile Cardiac Outpatient Telemetry
- Implantable Loop Recorder

Implantable loop recorder
Indications for ILR

Excellus Medical Policy as of 9/18/14

Based upon our criteria and assessment of peer-reviewed literature, use of implanted ambulatory event monitors, either patient activated or auto-activated, have been proven to be medically effective and therefore medically appropriate only in patients who experience recurrent symptoms so infrequently that a prior trial of Holter monitor and external AEMs has been unsuccessful.
Evaluation of syncope

68 y/o man with chronic Afib, HTN, diabetes, recurrent presyncope with one episode while driving. Holter normal. Unable to use external event recorder. ILR implanted.
Evaluation of syncope

RAST – Randomized Assessment of Syncope trial
- Early use of ILR for unexplained syncope. ECG diagnosis achieved in 52% of ILR pts vs 20% of conventional group

ISSUE 1, 2, & 3 – International Study on Syncope of Uncertain Etiology
- Early use of ILR in pts with suspected neurally mediated syncope. ILR-directed therapy for severe bradycardia led to lower recurrence rate of syncope.

EaSyAs I and II – Eastbourne Syncope Assessment
- Randomized trial of ILR vs conventional management in unexplained syncope. Time to ECG diagnosis and therapy were significantly faster in the ILR group. Fewer days in hospital and fewer post-randomization investigations, lower overall cost.

ISSUE3 study

Patients' flow:

Screening phase
511 met inclusion criteria and received an ILR

Study phase
89 had ECG documentation of:
- syncopeal recurrence with asystole ≥ 3 s (R72)
- non-syncopeal asystole ≥ 6 s (R17)

77 randomized
38 assigned and received PPM ON
39 assigned and received PPM OFF
8 had PPM reprogrammed due to abnormal absence of primary endpoint
8 refused randomization
12 lost to follow-up
9 followed-up (registry):
- no therapy
- implanted PPM

38 analyzed
89 analyzed

Time to first recurrence of syncope according to the intention-to-treat analysis:

Number at risk
Pre OFF: 36 31 25 21 18 14 13 11
Pre ON: 38 32 27 22 18 14 13 11

Log rank: p<0.009
Evaluation of syncope

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Early use of ILR in unexplained syncope should be considered, and may reduce cost.

Evaluation of infrequent arrhythmias

58 y/o woman with h/o MAT ablated by JD in 2001. Cardiomyopathy resolved. Notes palpitations once a month which feel rapid and irregular, with neck tightness, fatigue and lightheadedness.

External EKG event recorder (-) during 2 separate 4-week periods. Stress echo normal.

ILR implanted.
Evaluation of infrequent arrhythmias

Recurrent Unexplained Palpitations (RUP) study

- Pts with infrequent, sustained palpitations, and negative initial workup
- Randomized to ILR vs conventional evaluation
- Diagnosis was obtained in 73% of ILR pts vs 21% of conventional
- Cost per diagnosis lower in ILR group

68 y/o man with h/o diabetes, HTN, TIA, admitted with stroke
Head MRI showed multiple foci of restricted diffusion within mid and posterior aspect of left MCA distribution. CTA showed no stenosis of major arteries of head and neck
TEE mild MR, no PFO
EKG and telemetry normal.
Implantable loop recorder implanted.

68 y/o male with recent stroke
Afib confirmed, anticoagulation started
Detection of atrial fibrillation in patients with stroke

Most strokes are due to atherosclerotic disease and thrombosis in the arteries of the head and neck.

Some strokes are thromboembolic, due to clots launched from the heart.

Most cardiac emboli come from the LA appendage, in pts with Afib.

SO, we should probably look for Afib in pts who have stroke without obvious source

EMBRACE trial
CRystal AF trial

Detection of Afib in pts with stroke

ILR’s have algorithms designed to detect Afib

Accuracy is good, but false positives are a problem

Does the presence of Afib prove that it caused the stroke??

Does the duration of the Afib episode make a difference?
Evaluation of Arrhythmias after MI

CARISMA – Cardiac Arrhythmias and Risk Stratification After Acute MI Study
- Acute MI and LVEF <40%
- ILR in all patients
- 297 pts, followed up to 2 years
- 46% of pts had at least one arrhythmia documented by ILR
- 27% had Afib
  - 88% of AF episodes were asymptomatic
- High-degree AV block and bradycardia were independent predictors of mortality

Kaplan-Meier graphs showing time to first bradyarrhythmia or tachyarrhythmia.


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CARISMA - conclusions

After MI with LV dysfunction (EF<40%), high grade AV block, severe bradycardia, and non-sustained VT are associated with increased mortality

ILR’s may provide recognition of significant arrhythmias after MI
Evaluation of Afib after ablation

DISCERN AF — Discerning the Incidence of Symptomatic and Asymptomatic Episodes of AF Before and After Catheter Ablation

- Patients undergoing AF ablation had ILR implanted 3 months prior to ablation, followed for at least 18 months
- Total AF burden reduced by 86% after ablation
- Ablation “successful” in 58% of pts based on symptoms, 46% based on ILR-detected AF
- 12% of patients with recurrent AF after ablation were asymptomatic
- Ratio of asymptomatic to symptomatic AF episodes increased after ablation from 1.1 to 3.7 (p=0.002)

ILR may be useful in determining the efficacy of therapy and perhaps the need for anticoagulation


Concerns, issues, areas for improvement

- Knowing when to implant
- Technical issues of implant
- Technical issues of remote monitoring
- Whose turf is it?
- Who follows the patient?
- Diagnostic accuracy
- Implications for treatment
- Oh, the data
Conclusions

• ILR technology has advanced
  • Devices are smaller, easy to implant
  • Detection algorithms have improved

• Remote monitoring allows fast recognition of asymptomatic arrhythmias

• Use in evaluation of syncope is well established

• Helpful for patients with infrequent arrhythmia symptoms

• Valuable tool in diagnosis of asymptomatic Afib in stroke patients

• May have a role in detecting arrhythmias in situations where early recognition could lead to change in treatment and outcome