SYNCOPE
THERAPY
AWARENESS
PRESENTATION

Reveal LINQ™
Insertable Cardiac Monitoring System

Medtronic
Further, Together
• Epidemiology
• Diagnosis
• Guidelines and Evidence to Support Reveal LINQ™ ICM in Syncope Patients
• Syncope Care Pathway
SYNCOPE OVERVIEW
**TLoC Definition**

A loss of consciousness with complete recover, usually spontaneous in onset

1. **TLoC**
   - **Non-traumatic**
   - **Traumatic (concussion)**

**Syncope**
- Temporary loss of consciousness with rapid recovery
- Usually related to temporary insufficient blood flow to the brain

**Epileptic seizure**
- Neurological disorder in which nerve cell activity in the brain becomes disrupted

**Substance abuse**
- Alcohol or drug induced loss of consciousness

**Psychogenic**
- Often an involuntary reaction of the brain to pressure or distress

A **leading cause of undiagnosed syncope is heart-related.**

**Arrhythmias** are most common cause of cardiac syncope.

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UNEXPLAINED SYNCOPE + CARDIAC SYNCOPE
OVER 50% OF PATIENTS

Syncope remains unexplained in approximately 1/3 of cases

- Neurologic: Seizure, stroke, TIA etc. 10%
- Unknown: 34%
- Neurally Mediated: vasovagal, carotid sinus, situational 24%
- Cardiac: abnormal rhythms, structural damage 18%
- Orthostatic/Drug-induced: ANS failure, medication 11%

## THE SYNCOPE CHALLENGE

<table>
<thead>
<tr>
<th>Magnitude</th>
<th>40% of the population will have at least one syncope event.¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Challenge</td>
<td>Approximately half of patients admitted to hospital leave without a diagnosis.²</td>
</tr>
<tr>
<td>Patient’s Frustration</td>
<td>In reaching a diagnosis patients see 3 different specialists, undergo 13 tests, and 1/3 have significant associated trauma.³</td>
</tr>
<tr>
<td>Cardiac Causes</td>
<td>Cardiac syncope is common, doubles the risk of death, and is associated with a 6-month mortality rate greater than 10%.⁴</td>
</tr>
</tbody>
</table>

Syncope
The Cause Matters

Cardiac syncope:\n\- Carries a 6-month mortality rate of greater than 10%\n\- Doubles the risk of death

Overall Survival of Participants with Syncope According to Cause

SYNCOPE
A GROWING CHALLENGE FOR THE SYSTEM

- 50% of patients admitted to hospital for syncope-related events are >75 years of age\(^1\)
- 10% of falls by elderly are attributed to syncope\(^1\)
- With an aging population, the prevalence of syncope is likely to increase\(^2\)

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DIAGNOSING SYNCOPE
## SYNCOPE DIAGNOSIS
### TESTING OPTIONS AND THEIR DIAGNOSTIC YIELDS

<table>
<thead>
<tr>
<th>Test/Procedure</th>
<th>Yield</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECG</td>
<td>2–11%¹</td>
</tr>
<tr>
<td>Holter Monitoring</td>
<td>2%²</td>
</tr>
<tr>
<td>External Loop Recorder</td>
<td>20%³</td>
</tr>
<tr>
<td>Tilt Table</td>
<td>11–87%⁴,⁵</td>
</tr>
<tr>
<td>EP Study without structural heart disease</td>
<td>11%⁶</td>
</tr>
<tr>
<td>Neurological (CT scan, carotid doppler)</td>
<td>0–4%⁵</td>
</tr>
<tr>
<td>Reveal ICM</td>
<td>43–88%³,⁷,⁸</td>
</tr>
</tbody>
</table>

PICTURE STUDY\(^1\): OVERVIEW

- **PICTURE** was a prospective, multi-center, observational study conducted from November 2006 to October 2009

- **PICTURE** aimed to:
  - Collect information on the use of the Reveal™ ICM in the syncope patient care pathway
  - Investigate Reveal ICM’s effectiveness in the diagnosis of unexplained recurrent syncope in everyday clinical practice

- 71 sites from 11 European and Middle Eastern countries
PICTURE STUDY RESULTS

PATIENT EXPERIENCE

- 70% of patients had been hospitalized at least once for syncope
- 36% of patients had experienced significant trauma in association with a syncopal episode
- Overall, patients had seen an average of 3 different specialists for their syncope

1. Edvardsson N, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry Europace 2011;13:262-269
The median number of tests performed per patient was 13 (inter-quartile range 9 - 20)

<table>
<thead>
<tr>
<th>Total recruitment</th>
<th>570 (100%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard ECG</td>
<td>556 (98%)</td>
</tr>
<tr>
<td>Echocardiography</td>
<td>490 (86%)</td>
</tr>
<tr>
<td>Basic laboratory tests</td>
<td>488 (86%)</td>
</tr>
<tr>
<td>Ambulatory ECG monitoring</td>
<td>382 (67%)</td>
</tr>
<tr>
<td>In-hospital ECG monitoring</td>
<td>311 (55%)</td>
</tr>
<tr>
<td>Exercise testing</td>
<td>297 (52%)</td>
</tr>
<tr>
<td>Orthostatic blood pressure measurements</td>
<td>275 (48%)</td>
</tr>
<tr>
<td>MRI/CT scan</td>
<td>267 (47%)</td>
</tr>
<tr>
<td>Neurological or psychiatric evaluation</td>
<td>270 (47%)</td>
</tr>
<tr>
<td>EEG</td>
<td>222 (39%)</td>
</tr>
<tr>
<td>Carotid sinus massage</td>
<td>205 (36%)</td>
</tr>
<tr>
<td>Tilt test</td>
<td>201 (35%)</td>
</tr>
<tr>
<td>Electrophysiology testing</td>
<td>144 (25%)</td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>133 (23%)</td>
</tr>
<tr>
<td>External loop recording</td>
<td>67 (12%)</td>
</tr>
<tr>
<td>ATP test</td>
<td>15 (3%)</td>
</tr>
<tr>
<td>Other tests</td>
<td>52 (9%)</td>
</tr>
<tr>
<td>No tests performed</td>
<td>1 (0%)</td>
</tr>
</tbody>
</table>

1. Edvardsson N, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry Europace 2011;13:262-269
During follow-up, **38% of patients** had a recurrence of syncope within 1 year.

**Reveal™ ICMs** guided diagnosis in **78%** of patients with recurrence.
Of the 170 Reveal ICM-guided diagnoses, 75% were cardiac-related
Patients with unexplained syncope and without a pacing indication following basic clinical work-up, tilt-test and 24-h Holter

Randomized to Reveal (n=103) or conventional testing (n=98)

Median follow-up: 17 months

More ICM patients received an ECG diagnosis than by conventional testing (43% vs 6%; HR 6.53 [95% CI 3.73-11.4]; p<0.001)

Time to ECG directed therapy was 6.5x quicker for ILR group (P<0.001)

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When a strategy of prolonging monitoring is chosen, monitoring should be maintained even for several years until a diagnosis is established.¹

ICMs ARE A COST-EFFECTIVE DIAGNOSTIC TOOL

PICTURE: EDVARDSSON, EUROPACE 2011 AND 2015

- Average spending amount to €2,000 (£1,613) for diagnostic tests per patient, without establishing a diagnosis.
- Prior to ICM implant, only 12% of patients had tests within current guideline recommendations; up to 10% of patients had tests exceeding £3540.
- The early use of specialized tests and the repetition of tests can be reduced.

ICMs are a cost-effective strategy for patients with infrequent episodes of unexplained syncope.

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“The gold standard for the diagnosis of syncope is when a correlation between the symptoms and a documented arrhythmia is recorded.”

Class I ICM Guidelines

• Indicated in early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high risk criteria and a high likelihood of recurrence within battery longevity of the device.

• Indicated in high risk individuals in whom comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment.

# ESC GUIDELINES ON CARDIAC PACING AND CRT

## DIAGNOSTIC TESTING ACCORDING TO FREQUENCY OF SYMPTOMS

<table>
<thead>
<tr>
<th>Frequency of symptoms</th>
<th>Suggested ECG monitoring technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>24 h Holter, in-hospital telemetric monitoring</td>
</tr>
<tr>
<td>Every 2-3 days</td>
<td>48-72 h Holter, in-hospital telemetric monitoring</td>
</tr>
<tr>
<td>Every week</td>
<td>7 day Holter or external loop recorder</td>
</tr>
<tr>
<td>Every month</td>
<td>14-30 days external loop recorder</td>
</tr>
<tr>
<td>Less than once per month</td>
<td>Implantable loop recorder</td>
</tr>
</tbody>
</table>

ECG = electrocardiogram

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USE OF ICM IN SYNCOPE PATHWAY REMAINS INEFFICIENT
EHRA SURVEY, EUROPACE 2014

- 42 European centers evaluated use of ICM in clinical practice
- Less than 20% of patients with unexplained syncope received an ICM in accordance with guidelines

There is poor adherence to guidelines regarding use of ICM in unexplained syncope

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REVEAL LINQ™ SYSTEM
AN ADVANCED MONITORING SYSTEM

Solution Enablers

Insertion Tools
Patient Assistant
NEW App-based Reveal LINQ Mobile Manager
NEW FocusOn™ Monitoring Service
REVEAL LINQ SYSTEM
REVOLUTIONIZING CARDIAC MONITORING

The smallest, most powerful insertable cardiac monitor

- One-third the size of a AAA battery (1.2 cc)
- Up to a 3-year longevity for long-term monitoring\(^1\)
- MR Conditional at 1.5 and 3.0 Tesla
- Minimally invasive, simplified insertion procedure\(^2\)

\(^1\) Reference the Reveal LINQ ICM Clinician Manual for usage parameters.
REVEAL LINQ™ SYSTEM
SIMPLE INSERTION PROCEDURE

Best location:
45 degrees to sternum over 4th intercostal space,
2 cm from left edge of sternum

97%
Of physicians found the insertion tool simple and intuitive.¹

Requires minimal procedure time and clinical resources

PUTTING IT INTO PRACTICE
COLLABORATIVE RECOMMENDATION

Structured Care Pathway

- To maximize implementation of the guidelines “a cohesive, structured care pathway is recommended for the global assessment of patients with suspected syncope.”

A Multidisciplinary Approach

- “Experience and training in key components of cardiology, neurology, emergency and geriatric medicine are pertinent”

Syncope Unit Implementation

- “A structured care pathway – either delivered within a single syncope facility or as a more multi-faceted service – is the optimal for quality service delivery.”

Guidelines for the diagnosis and management of syncope (version 2009)

The Task Force for the Diagnosis and Management of Syncope of the European Society of Cardiology (ESC)

Endorsed by:
- European Society of Emergency Medicine
- European Federation of Internal Medicine
- European Union Geriatric Medicine Society
- European Neurological Society
- European Federation of Autonomic Societies
SYNCOPE TESTING PATHWAY

Flowchart adapted from:
CONCLUSIONS

- Syncope care pathway remains inefficient, despite guidelines.
- ICMs should be implanted earlier in evaluation as supported by guidelines.\(^1\)\(^-\)\(^4\)
- In unexplained syncope, ICMs provide superior diagnostic yield compared to conventional tests, increasing rate of guideline directed therapy.\(^5\)\(^-\)\(^8\)
- ICMs are cost-effective.\(^5\)\(^,\)\(^9\)\(^-\)\(^11\) Used sooner in a syncope care pathway, an ICM can reduce testing without losing diagnostic yield.
- A multidisciplinary approach is needed to improve syncope patient care.\(^1\)

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Brief statement
See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and / or consult the Medtronic website at www.medtronic.com.

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.