



# Implantable loop recorder for unexplained syncope

## When to implant?

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# Syncope Reported Frequency

- Individuals <18 yrs 15%
- Military Population 17- 46 yrs 20-25%
- Individuals 40-59 yrs\* 16-19%
- Individuals >70 yrs\* 23%

\*during a 10-year period

## **Syncope recurrence rate in young patients (< 40 years) without structural heart disease**

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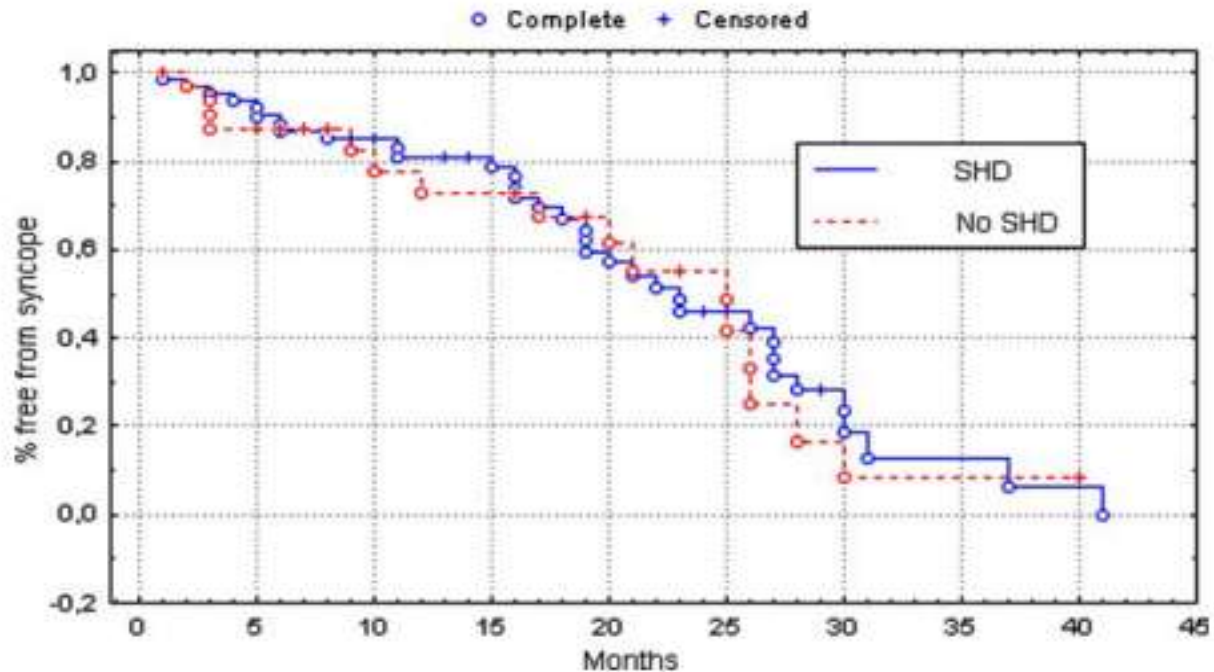
<b>Number of syncopes during life</b>	<b>Risk of recurrence of syncope after the index episode</b>	
	<b>Actuarial risk 1 year (%)</b>	<b>Actuarial risk 2 years (%)</b>
1	10	10
2	19	29
≥3	40	54
≥6	43	60

## Prognosis of patients with uncertain diagnosis and low risk >40 years according the number of syncopes during life

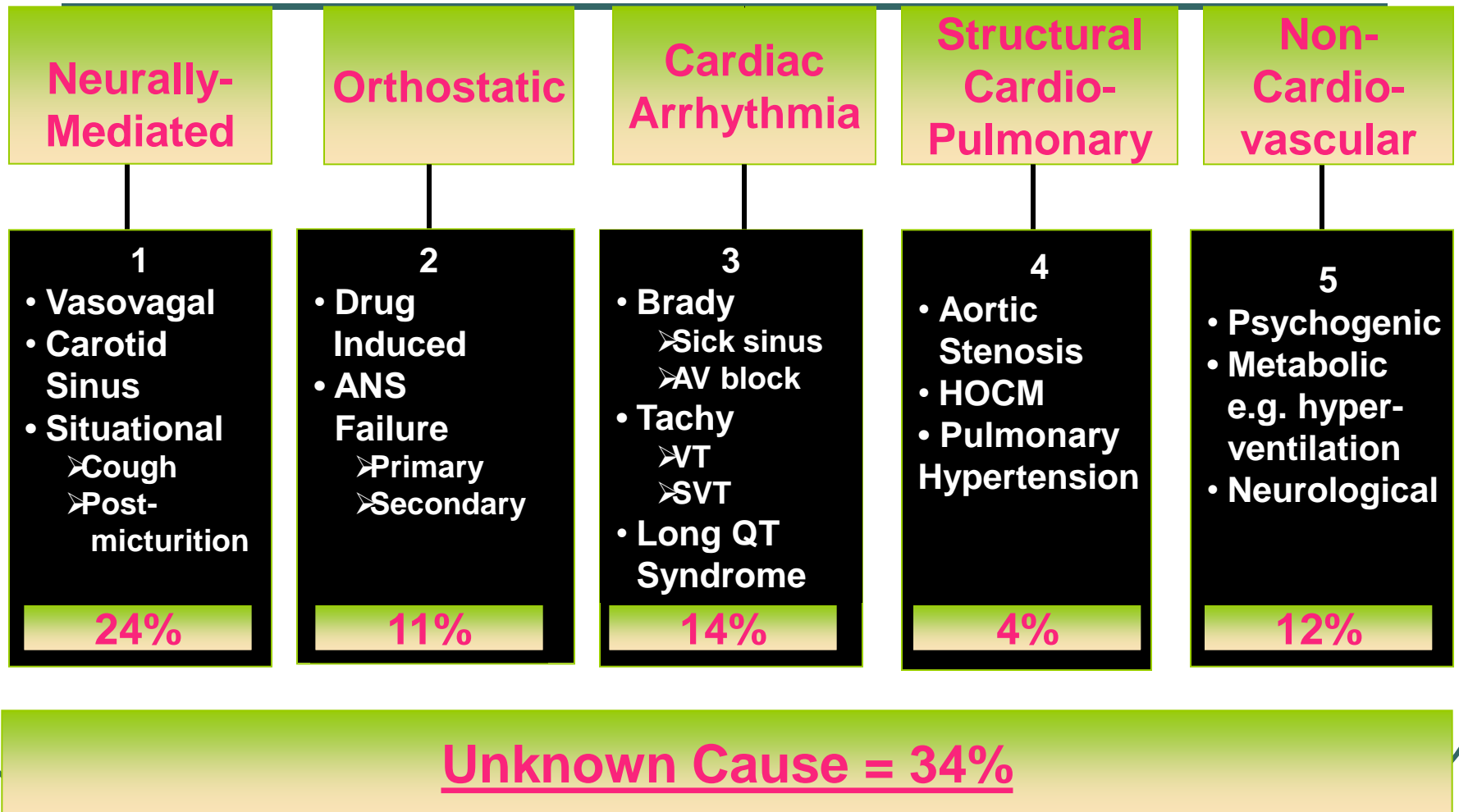
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Number of syncopes during life	Risk of recurrence of syncope after the index episode		
	Actuarial risk 1 year (%)	Actuarial risk 2 years (%)	Estimated risk 4 years <sup>a</sup> (%)
1–2	15.4	19.7	28.2
3	36.5	41.7	52.2
4–6	37.0	43.8	57.4
7–10	37.5	43.7	56.2
>10	44.3	56.4	80.7

# Recurrence of syncope in patients with or without SHD



# Syncope: Etiology

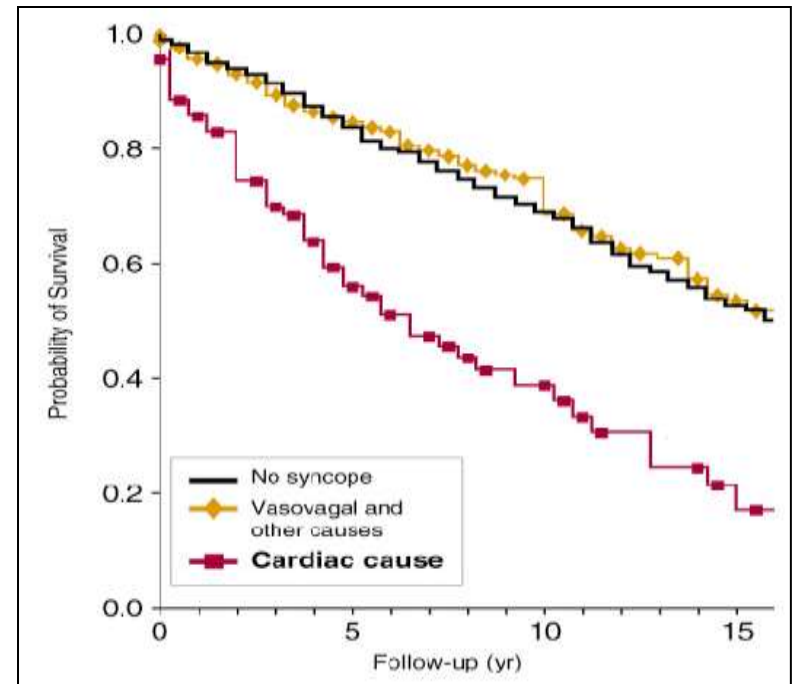
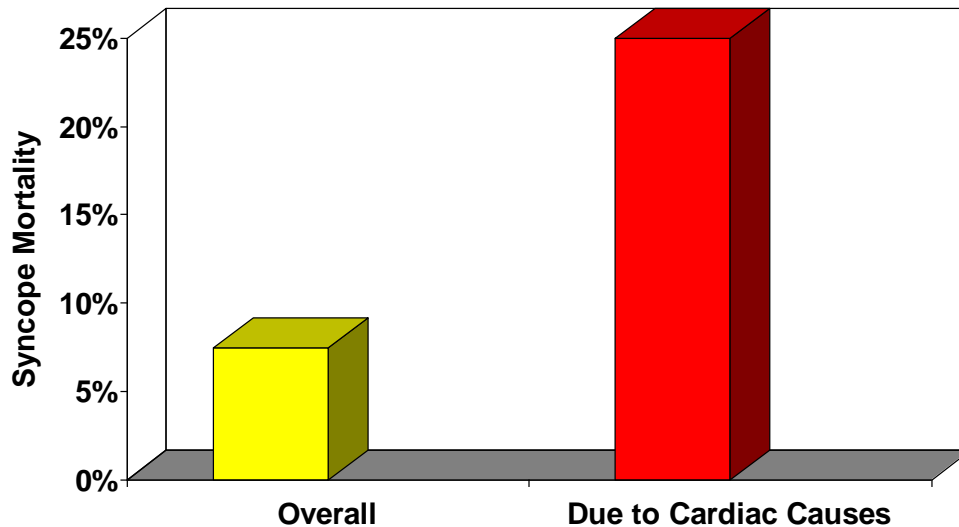


# An Implantable Loop Recorder Study of Highly Symptomatic Vasovagal Patients

The Heart Rhythm Observed During a Spontaneous Syncope Is Identical to the Recurrent Syncope But Not Correlated With the Head-Up Tilt Test or Adenosine Triphosphate Test

- OBJECTIVES** The aim of this study was to analyze the heart rhythm during spontaneous vasovagal syncope (VVS) in highly symptomatic patients with implantable loop recorders (ILR) and to correlate this rhythm with the heart rhythm observed during head-up tilt test (HUT).
- BACKGROUND** Heart rhythm obtained during provocative condition is often used to guide therapy in VVS. To date there is no conclusive evidence that the heart rhythm observed during a positive HUT can predict heart rhythm during VVS or that the heart rhythm observed during a spontaneous syncope will be identical to the recurrent syncope.
- METHODS** Twenty-five consecutive VVS patients (age  $60.2 \pm 17.1$  years; 14 women,) presenting with frequent syncopes ( $6.9 \pm 4.6$  episodes/year) and a positive HUT (cardioinhibitory in 8 patients) were implanted with an ILR. Seven of them also had a positive adenosine triphosphate (ATP) test.
- RESULTS** Follow-up was  $17.0 \pm 3.6$  months. Thirty VVS were observed in 12 patients. Nine episodes showed bradycardia of  $<40$  beats/min or asystole; progressive sinus bradycardia preceding sinus arrest was the most frequent electrocardiographic finding. Twenty-one syncopes occurred without severe bradycardia. The heart rhythm observed during the first syncope was identical to the recurrence. No correlation was found between slow heart rate at the ILR interrogation and a cardioinhibitory HUT response ( $p = 1.0$ ) or a positive ATP test ( $p = 1.0$ ).
- CONCLUSIONS** In highly symptomatic patients with VVS, the heart rhythm observed during spontaneous syncope does not correlate with the HUT. The heart rhythm during the first spontaneous syncope is identical to the recurrent syncope. (J Am Coll Cardiol 2006;47:587-93) © 2006 by the American College of Cardiology Foundation

# The Significance of Syncope



- Some causes of syncope are potentially fatal
- Cardiac causes of syncope have the highest mortality rates

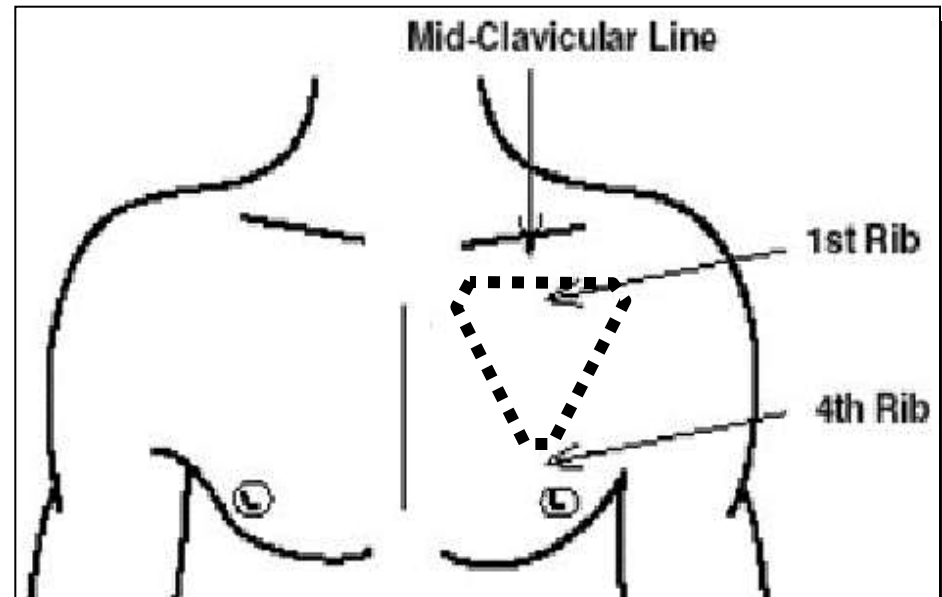
# Insertable Loop Recorder (ILR)



17 gr

61mm


19 mm



Typical Location of the  
Reveal® Plus ILR

# Always on watch, always informed



- 
- Query button:  
Check for stored cardiac event data
- 'OK' indication if no pre-defined episodes are found. No need to contact the physician
- Arrhythmic episodes recorded:  
Physician should be alerted
- Record ECG during symptoms
- Successful memory storage
- Medtronic  
REVEAL<sup>®</sup> XT
- The image shows a blue and grey Medtronic REVEAL XT device. It has a question mark icon, a heart with an ECG line icon, a green 'OK' indicator, a checkmark icon, and a telephone handset icon. Lines connect these icons to their respective descriptions in the text.

# Conventional Diagnostic Methods/Yield

Test/Procedure	Yield (based on mean time to diagnosis of 5.1 months <sup>7</sup> )
History and Physical (including carotid sinus massage)	49-85% <sup>1,2</sup>
ECG	2-11% <sup>2</sup>
Electrophysiology Study without SHD*	11% <sup>3</sup>
Electrophysiology Study with SHD	49% <sup>3</sup>
Tilt Table Test (without SHD)	11-87% <sup>4,5</sup>
Ambulatory ECG Monitors:	
● Holter	2% <sup>7</sup>
● External Loop Recorder (2-3 weeks duration)	20% <sup>7</sup>
● Insertable Loop Recorder (up to 4 years duration)	50-80% <sup>6,7,8,9</sup>
Neurological † (Head CT Scan, Carotid Doppler)	0-4% <sup>4,5,8,10</sup>

<sup>1</sup> Kapoor, et al *N Eng J Med*, 1983.

<sup>3</sup> Linzer, et al. *Ann Int. Med*, 1997.

<sup>6</sup> Farwell D, *Eur Heart J* 2006;27:351-356

<sup>2</sup> Kapoor, *Am J Med*, 1991.

<sup>4</sup> Kapoor, *Medicine*, 1990.

<sup>7</sup> Menozzi C *Circulation* 2002;105:2741-2745.

<sup>5</sup> Kapoor, *JAMA*, 1992

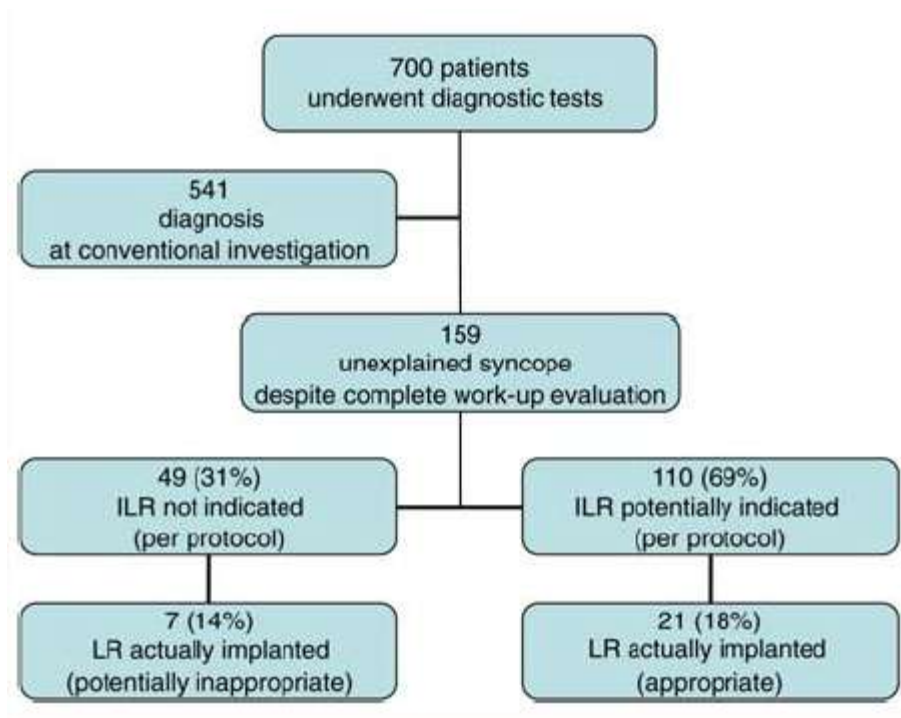
<sup>8</sup> Edvardsson N *Europace* 2011;13:262-269

<sup>9</sup> FURUKAWA T. *J Cardiovasc Electrophysiol* 2011

<sup>10</sup> Stetson P, et al. *PACE*. 1999; 22 (part II): 782.

# Discrepancy between clinical practice and standardized indications for an implantable loop recorder in patients with unexplained syncope<sup>†</sup>

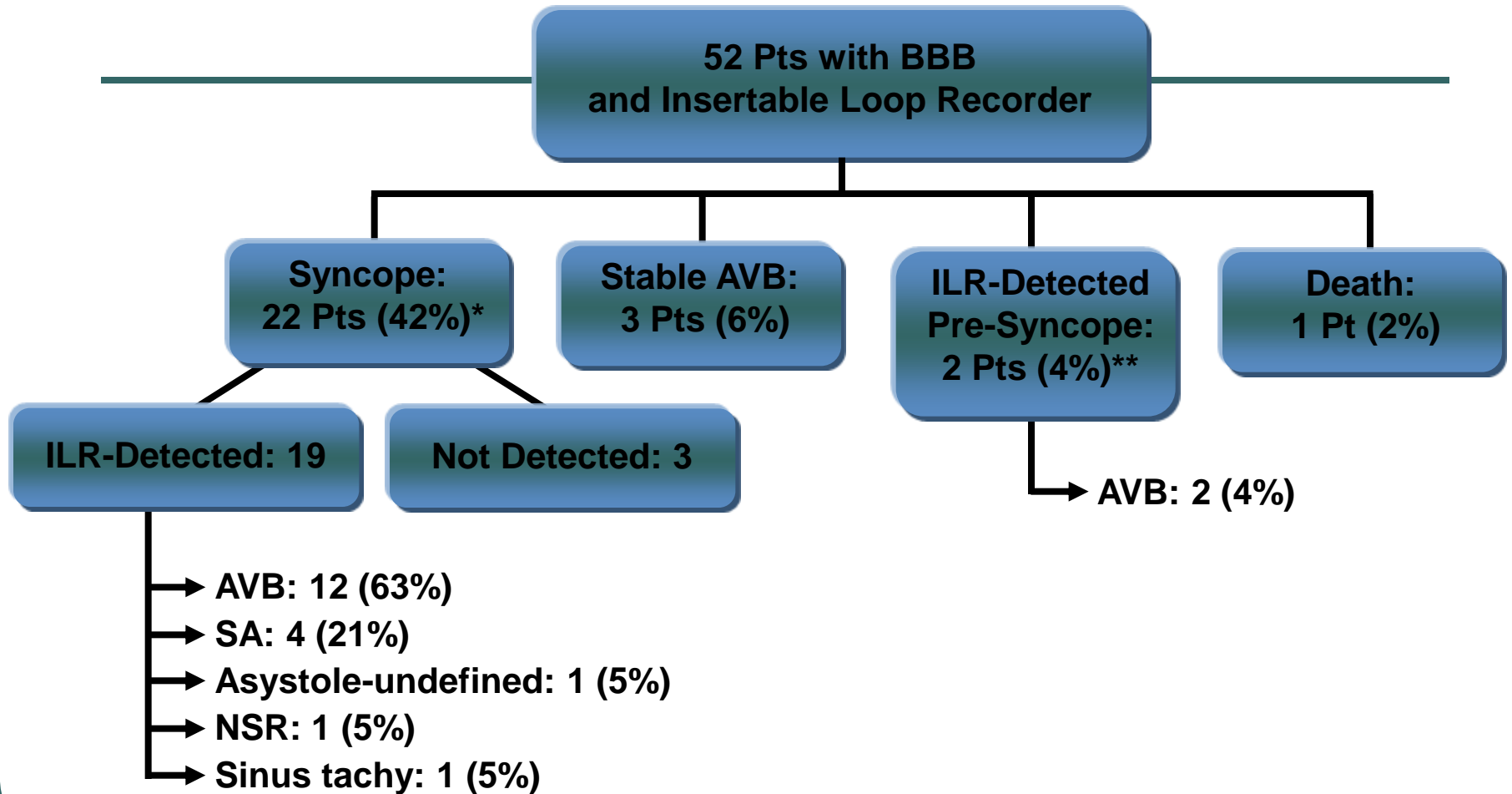
Elena Vitale<sup>1\*</sup>, Andrea Ungar<sup>2</sup>, Roberto Maggi<sup>3</sup>, Maura Francese<sup>4</sup>, Maurizio Lunati<sup>5</sup>, Roberto Colaceci<sup>6</sup>, Attilio Del Rosso<sup>7</sup>, Antonio Castro<sup>8</sup>, Massimo Santini<sup>9</sup>, Silvia Giuli<sup>10</sup>, Lara Belgini<sup>10</sup>, Ivo Casagrande<sup>1</sup>, and Michele Brignole<sup>3</sup>



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**VALUE OF ILR IN THE PRESENCE  
OF DETECTABLE CARDIAC  
ABNORMALITIES**

# ISSUE: Patients with Bundle Branch Block and Negative EP Test



# ISSUE

## Patients with Bundle Branch Block and Negative EP Test

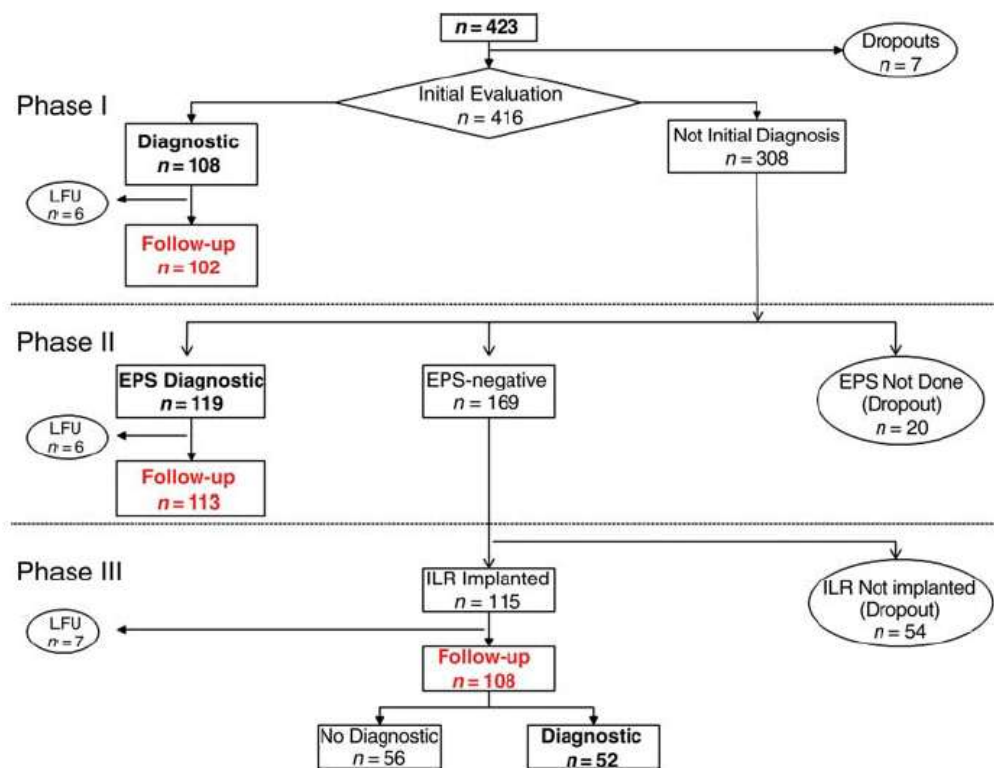
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### Conclusion:

- In patients with BBB and negative EP study, most syncopal recurrences have a homogeneous mechanism that is characterized by prolonged asystolic pauses mainly attributable to sudden-onset paroxysmal AV block

# Diagnosis, management, and outcomes of patients with syncope and bundle branch block

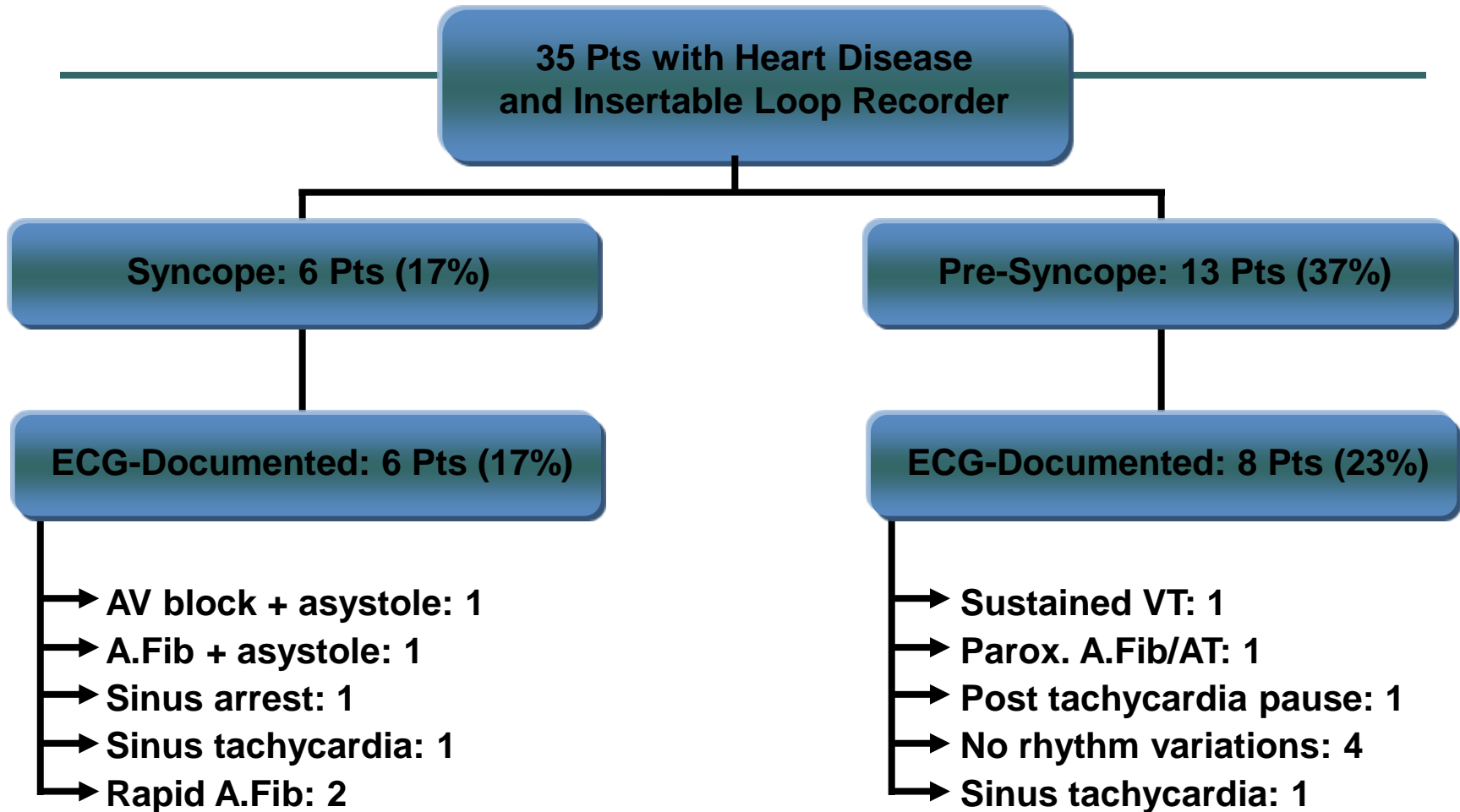
Angel Moya<sup>1\*</sup>, Roberto García-Civera<sup>2</sup>, Francesco Croci<sup>3</sup>, Carlo Menozzi<sup>4</sup>, Josep Brugada<sup>5</sup>, Fabrizio Ammirati<sup>6</sup>, Attilio Del Rosso<sup>7</sup>, Alejandro Bellver-Navarro<sup>8</sup>, Jesús Garcia-Sacristán<sup>9</sup>, Miriam Bortnik<sup>10</sup>, Lluís Mont<sup>11</sup>, Ricardo Ruiz-Granell<sup>12</sup>, and Xavier Navarro<sup>13</sup> on behalf of the Bradycardia detection in Bundle Branch Block (B4) study



ILR implantation (Phase III), n = 52

Bradyarrhythmia	A-VB	36
	SA	5
Non-arrhythmic		7
VT/VF		3
Brady/tachy		1

# ISSUE: Patients with Heart Disease and a Negative EP Test



## ISSUE

# Patients with Heart Disease and a Negative EP Test

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## Conclusions

- Patients with unexplained syncope, overt heart disease, and negative EP study had a favorable medium-term outcome
- Mechanism of syncope was heterogeneous
- Ventricular tachyarrhythmia was unlikely
- “ILR-guided strategy seems reasonable, with specific therapy safely delayed until a definite diagnosis is made.”

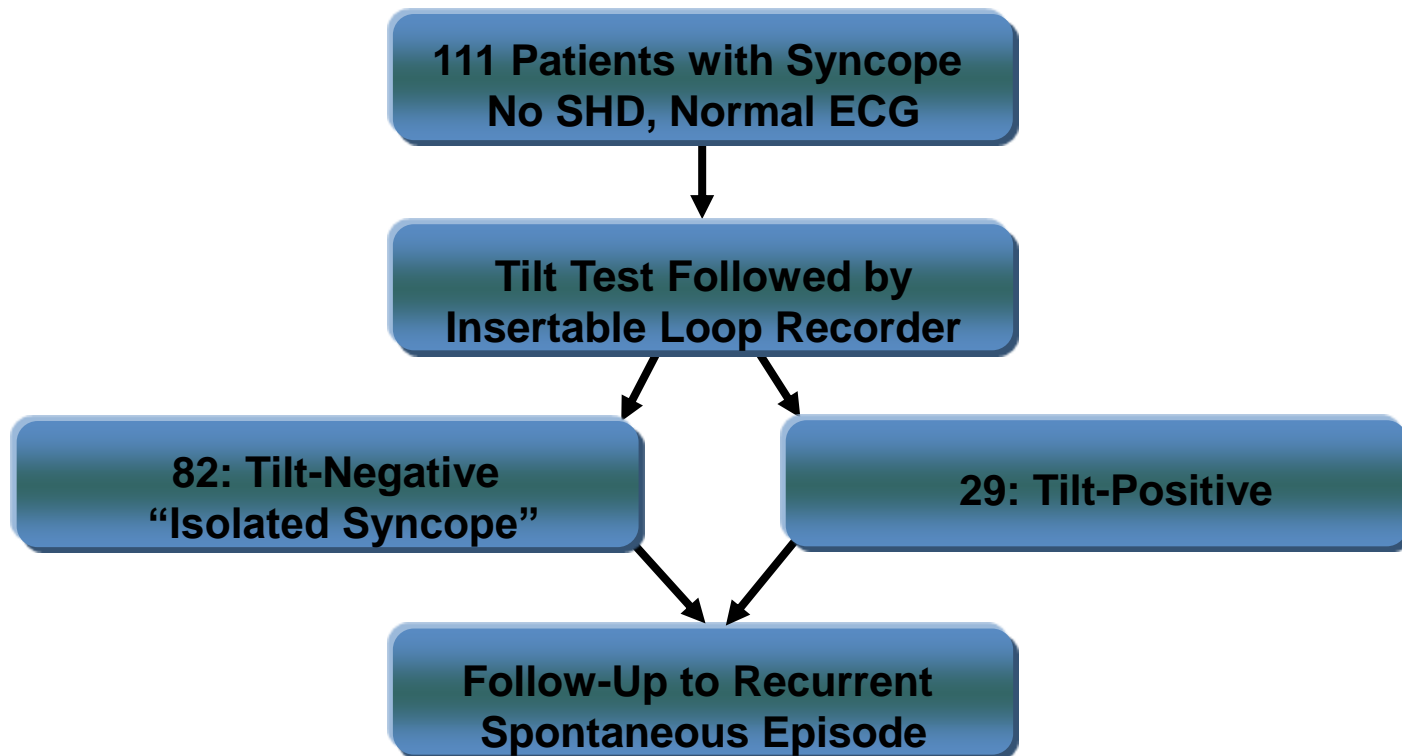
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**VALUE OF ILR IN THE ABSENCE OF  
DETECTABLE CARDIAC  
ABNORMALITIES**

# ISSUE

## Patients with Isolated Syncope and Tilt-Positive Syncope

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# ISSUE

## Isolated Syncope vs. Tilt-Positive Syncope

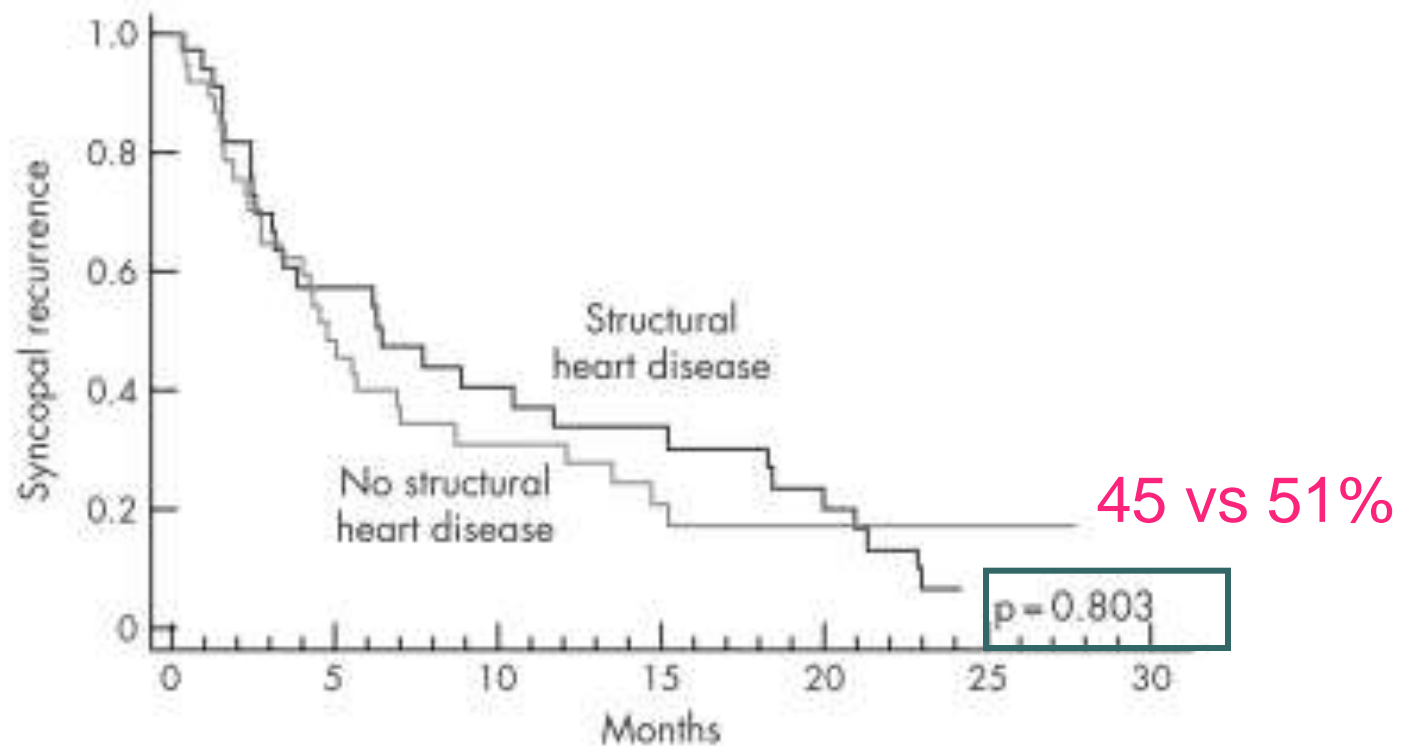
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### Conclusions

- Results similar in the two arms, including syncope recurrence and ECG correlation
- Tilt-negative patients had as many bradycardias (18%) as tilt-positive patients (21%)
- Most frequent finding was asystole secondary to progressive sinus bradycardia, suggesting a neuro-mediated origin
- Homogeneous findings from tilt-negative and tilt-positive infer low sensitivity of tilt-testing

# Value of implantable loop recorder in diagnosis of syncope with and without structural heart diseases

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# Value of implantable loop recorder in diagnosis of syncope with and without structural heart diseases

	SHD (n = 38)	No SHD (n = 65)	P value
Total diagnosis	22 (58%)	33 (51%)*	0.50
Primary cardiac arrhythmia likely	18 (47%)	10 (15%)	0.0001
Neurally mediated syncope likely	4 (10%)	20 (31%)	0.02
Hysteria	0 (0%)	2 (2%)	0.40
Epilepsy	0 (0%)	1 (1%)	0.63



# ***ILR in syncope with normal heart***

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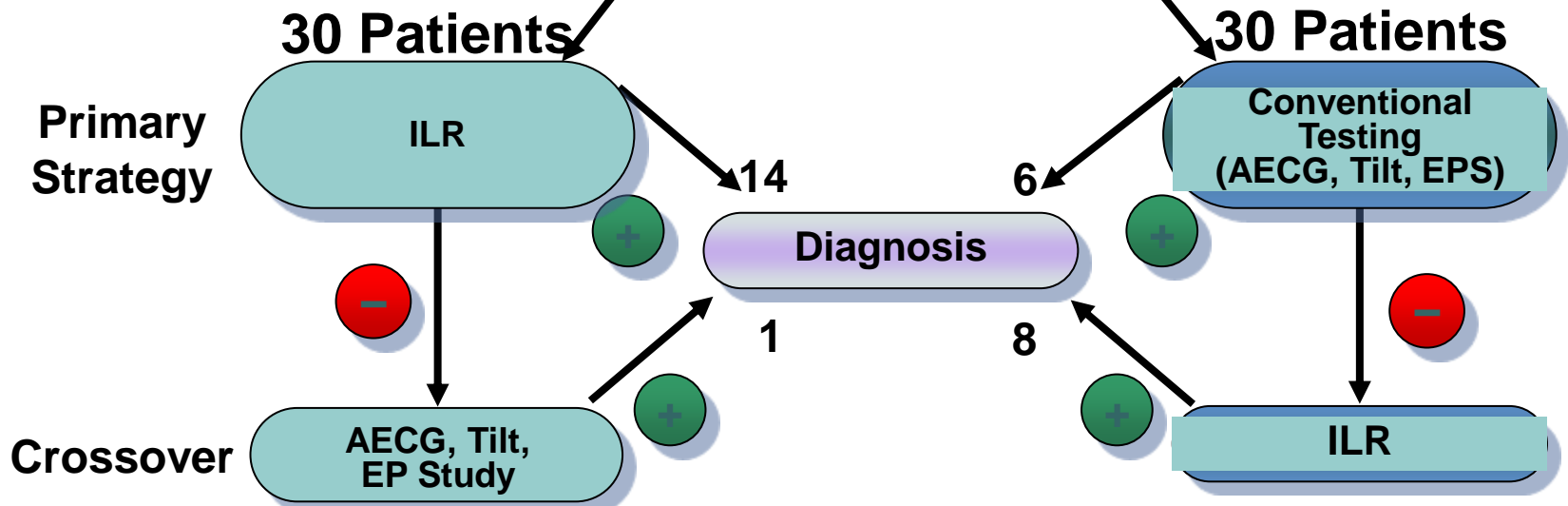
***Where in the workup?***



# Randomized Assessment of Syncope Trial (RAST)

60 Patients

Unexplained Syncope  
EF > 35%



## Results:

- Combining primary strategy with crossover, the diagnostic yield is 43% ILR only vs. 20% conventional only<sup>1</sup>
- Cost/diagnosis is 26% less than conventional testing<sup>2</sup>

<sup>1</sup>Krahn AD, et al. *Circ.* 2001;104:46-51.

<sup>2</sup>Krahn AD, et al. *JACC.* 2003;42:495-501.

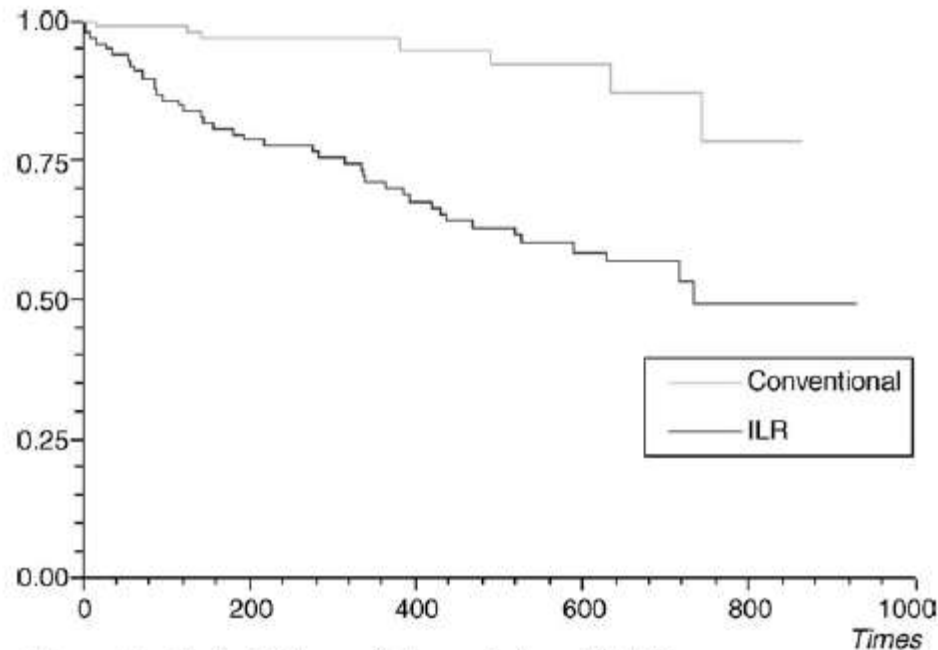
# The clinical impact of implantable loop recorders in patients with syncope

EaSyAS

David J. Farwell<sup>1,2</sup>, Nick Freemantle<sup>1,2</sup>, and Neil Sulke<sup>1,2\*</sup>

<sup>1</sup>Department of Cardiology, Eastbourne District General Hospital, King's Drive, Eastbourne, East Sussex, UK; and

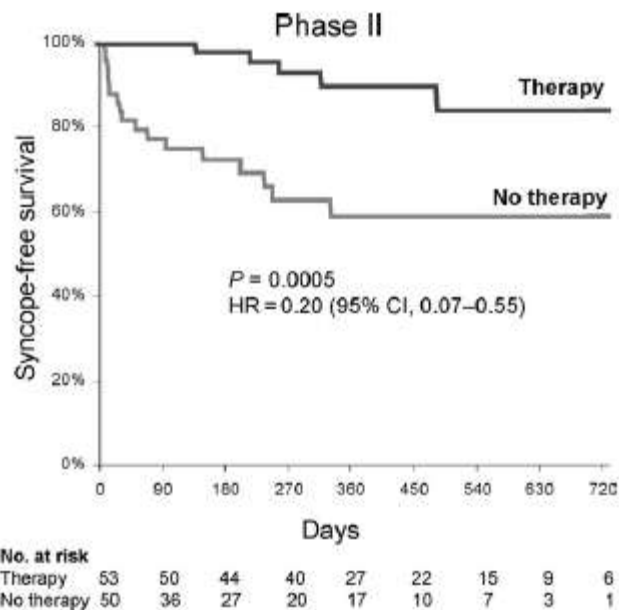
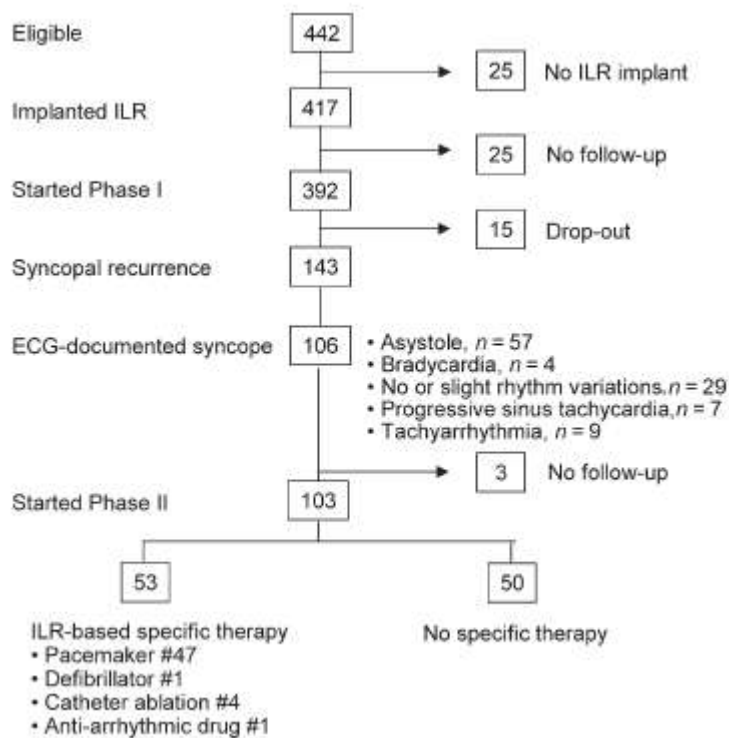
<sup>2</sup>Department of Primary Care and General Practice, University of Birmingham, UK



Hazard ratio (~95% confidence interval), ILR vs. conventional = 6.53 (3.73–11.4),  $P < 0.001$ .

## Early application of an implantable loop recorder allows effective specific therapy in patients with recurrent suspected neurally mediated syncope

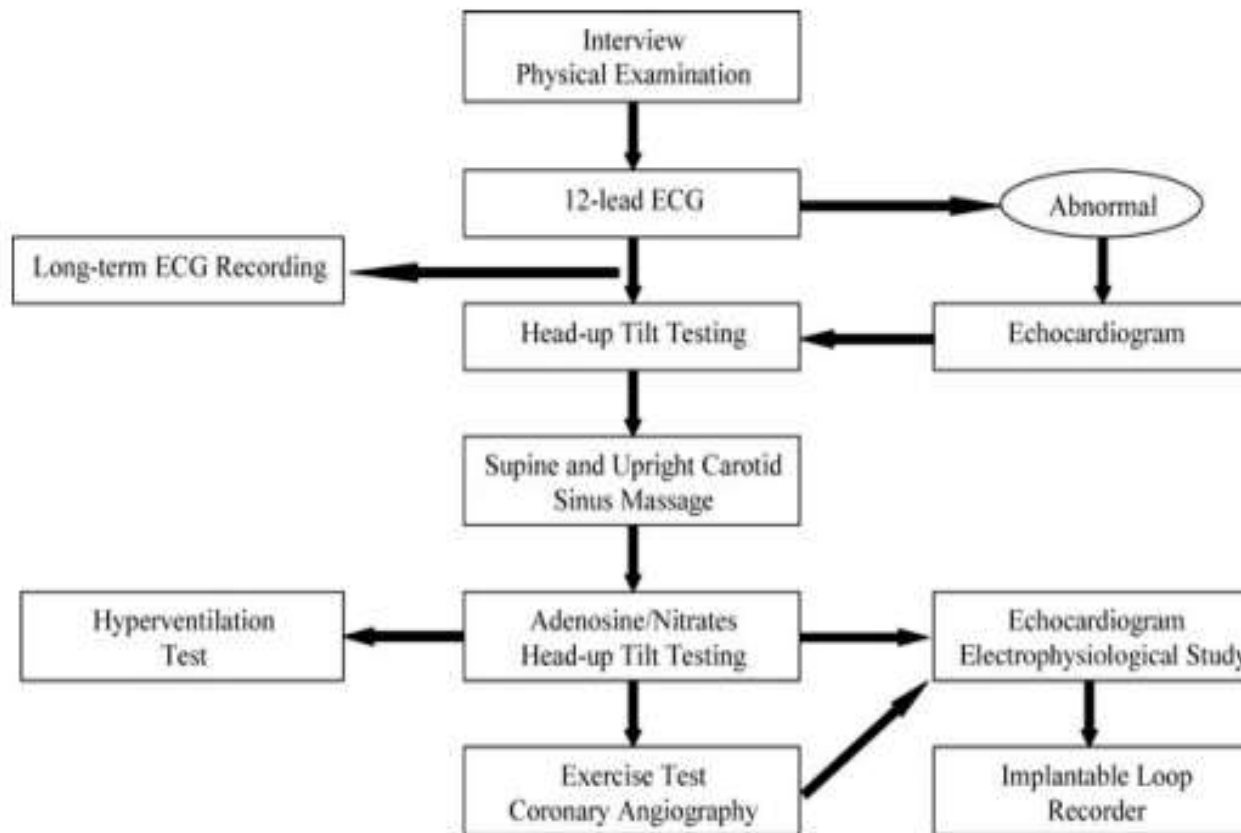
Michele Brignole<sup>1\*</sup>, Richard Sutton<sup>2</sup>, Carlo Menozzi<sup>3</sup>, Roberto Garcia-Civera<sup>4</sup>, Angel Moya<sup>5</sup>, Wouter Wieling<sup>6</sup>, Dietrich Andresen<sup>7</sup>, David G. Benditt<sup>8</sup>, and Panos Vardas<sup>9</sup> for the International Study on Syncope of Uncertain Etiology 2 (ISSUE 2) Group



# Stepwise Evaluation of Unexplained Syncope

STEPWISE EVALUATION OF UNEXPLAINED SYNCOPE

n=939 pts



# Stepwise Evaluation of Unexplained Syncope

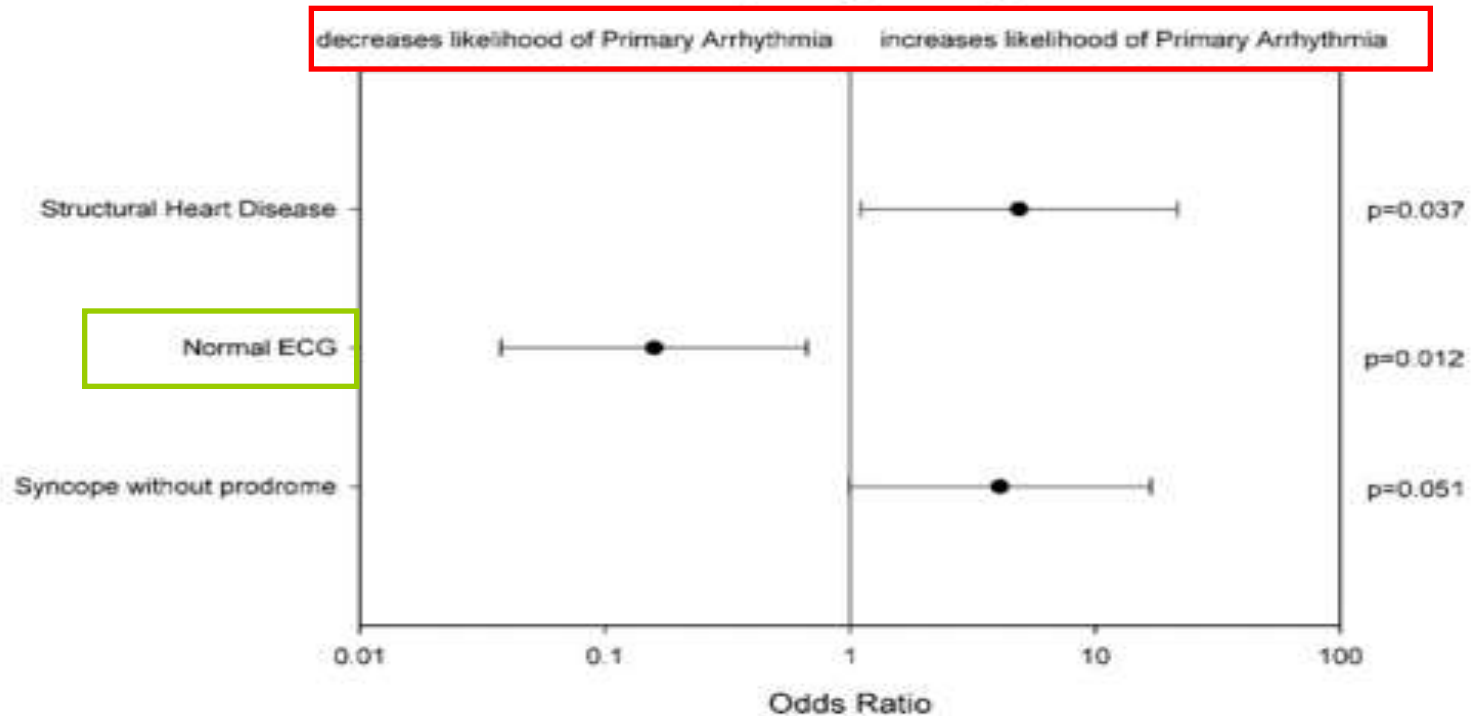
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- A standardized stepwise diagnostic evaluation establishes an etiology in 2/3 of patients referred for unexplained syncope and highlights the use of noninvasive tests for the investigation of unexplained recurrent syncope
- In selected patients however, ILR established a diagnosis in over 50% of recipients, confirming its incremental benefit in patients with unexplained syncope after a negative standardized diagnostic evaluation

# Predicting the cause of syncope from clinical history in patients undergoing prolonged monitoring

Variables Associated with Syncope due to Primary Arrhythmia after Multiple Logistic Regression



# In patients with syncope ILR for everybody?

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# Indications for the use of diagnostic implantable loop recorders



*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, i.e. those listed in the *Table 5*; and
  - a likely recurrence within battery longevity of the device (*Level of evidence A*)
- In high-risk patients in whom a comprehensive evaluation (that listed in *Table 5*) 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*)

# High Risk Criteria that require immediate hospitalization or early intensive investigation

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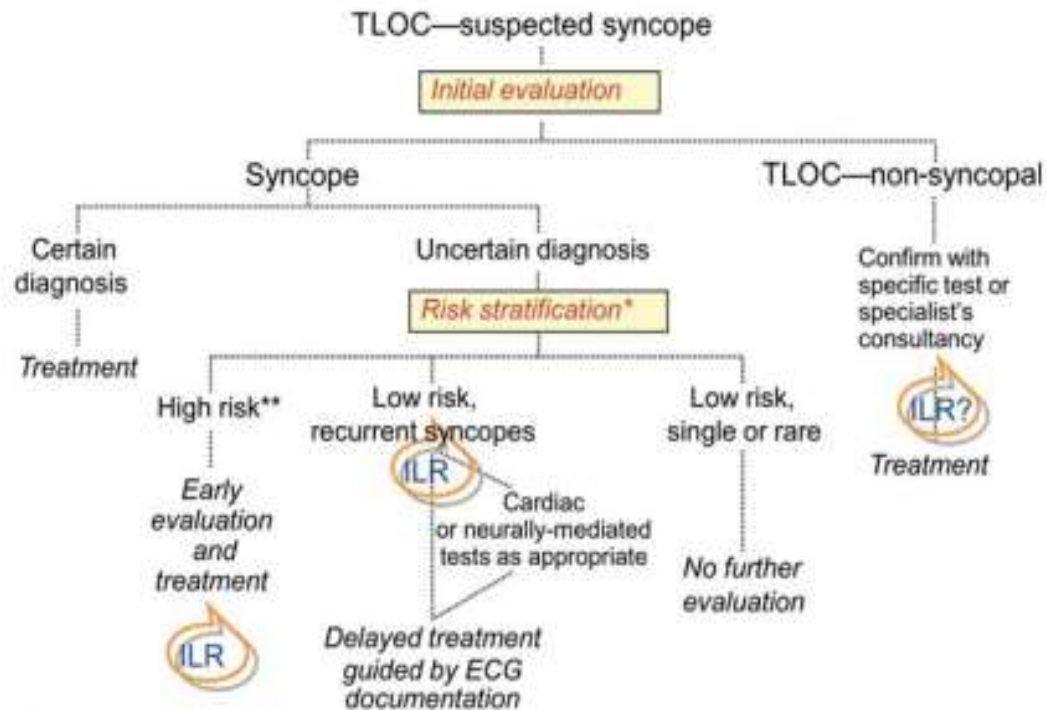
## High Risk

Unexplained syncope and...

- Severe structural or coronary heart disease
- Arrhythmic syncope likely
  - ✓ Syncope during exertion or supine
  - ✓ Palpitations at the time of syncope
  - ✓ Heart failure or low EF
  - ✓ Nonsustained VT
  - ✓ Bundle branch block
  - ✓ Sinus bradycardia <50 beats/min
  - ✓ AV block
  - ✓ WPW, long QT, ARVD, Brugada
- Important comorbidities (severe anemia)

Immediate in-hospital evaluation and treatment

# Implantable loop recorder in the work-up of transient loss of consciousness



\* May require laboratory investigations

\*\* Risk of short-term serious events

# Conclusions

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- An ILR strategy can safely be undertaken in patients, who have **a severe presentation of syncope** (because of high risk of trauma or high frequency of episodes), that can benefit of a mechanism specific therapy



# Conclusions

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- In **high-risk patients** in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to specific treatment



# Conclusions

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- In the less severe forms of syncope, clinical evaluation is sufficient to establish a **likely mechanism of syncope** in the majority of patients and no further investigation is usually necessary



# Conclusions

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- Patients at **low risk for arrhythmic syncope** are not candidates for ILR monitoring
- ILR is not indicated **when the probability of syncope recurrence during the longevity of the battery is low**

# ΕΥΧΑΡΙΣΤΩ ΠΟΛΥ

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