

Sessione pratica: indicazioni, metodologie e risultati dei test diagnostici

Loop Recorder

Dr Matteo Scapinelli

Syncope Unit Nuovo Ospedale di Sassuolo (Mo)



Il Loop Recorder impiantabile (ILR - Implantable Loop Recorder) è un dispositivo miniaturizzato per il monitoraggio elettrocardiografico a lungo termine, indicato nello studio delle aritmie cardiache intermittenti e di difficile documentazione con metodiche tradizionali.

La sua utilità clinica risiede nella capacità di registrare eventi aritmici rari e imprevedibili, spesso responsabili di sincope, presincope o ictus criptogenetico.

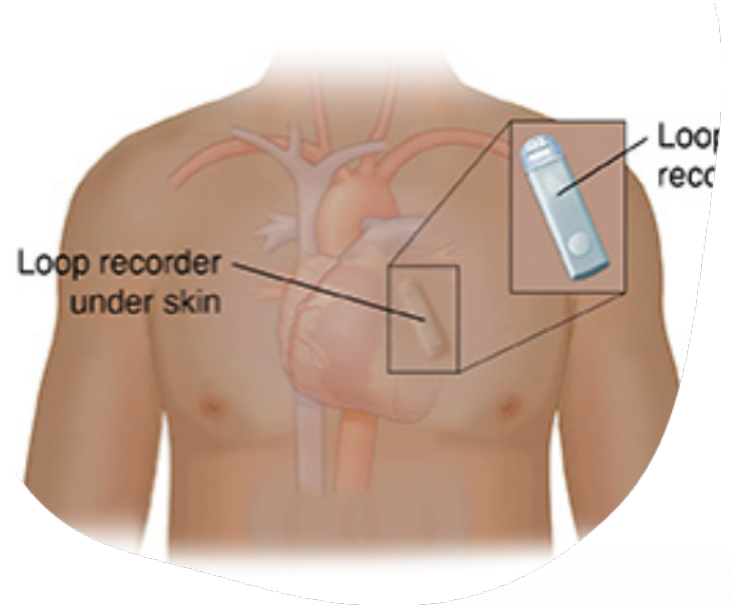


CONGRESSO ROMA, 25 - 27 Giugno 2026



Implantable Loop Recorder

- **Benefici legati al tipo di dispositivo:**
- *ridotte dimensioni del dispositivo;*
- *semplificazione della procedura di inserimento;*
- *riduzione delle dimensioni della ferita;*
- *non necessità di restrizione a letto o limitazione nei movimenti e quindi riduzione della degenza in ospedale;*
- *follow-up da remoto, che quindi aumenta comfort e sicurezza del paziente)*
- **Benefici legati alla strategia:**
- *Riduzione dei tempi e delle liste d'attesa grazie all'incremento del numero di procedure sostenibile delegando l'impianto a tecnici di cardiologia e infermieri*

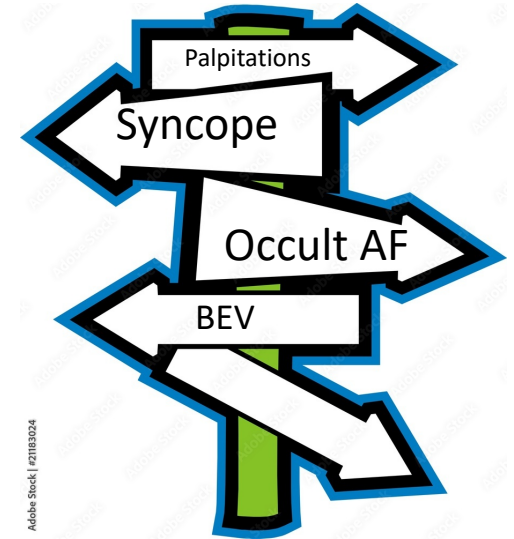


- **Indications**

- An implantable loop recorder is most commonly used for the evaluation of recurrent palpitations, syncope of unknown etiology or when other ambulatory monitoring devices of shorter duration are unrevealing. It may also be useful for the following:
- Identifying asymptomatic occult episodes of atrial fibrillation following a stroke
- Assessing the average heart rate and adequacy of rate control in a patient with atrial fibrillation
- Assessing bradycardic episodes before implanting a permanent pacemaker
- Screening for asymptomatic ventricular premature beats or nonsustained ventricular tachycardia in patients with congenital or acquired cardiac syndromes
- Evaluating prognosis following an acute coronary event

- **Contraindications**

- An absolute contraindication to implanting a loop recorder is when there is no indication for its use. Relative contraindications include active infection or a bleeding diathesis which may preclude its implantation for a certain period.

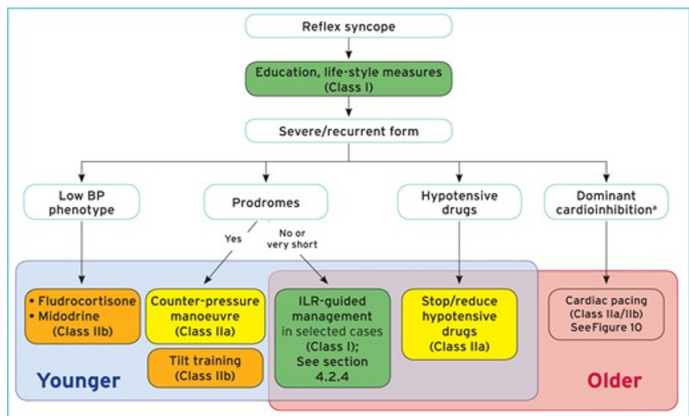


Adela Stock | #1183024



LG Syncope 2018

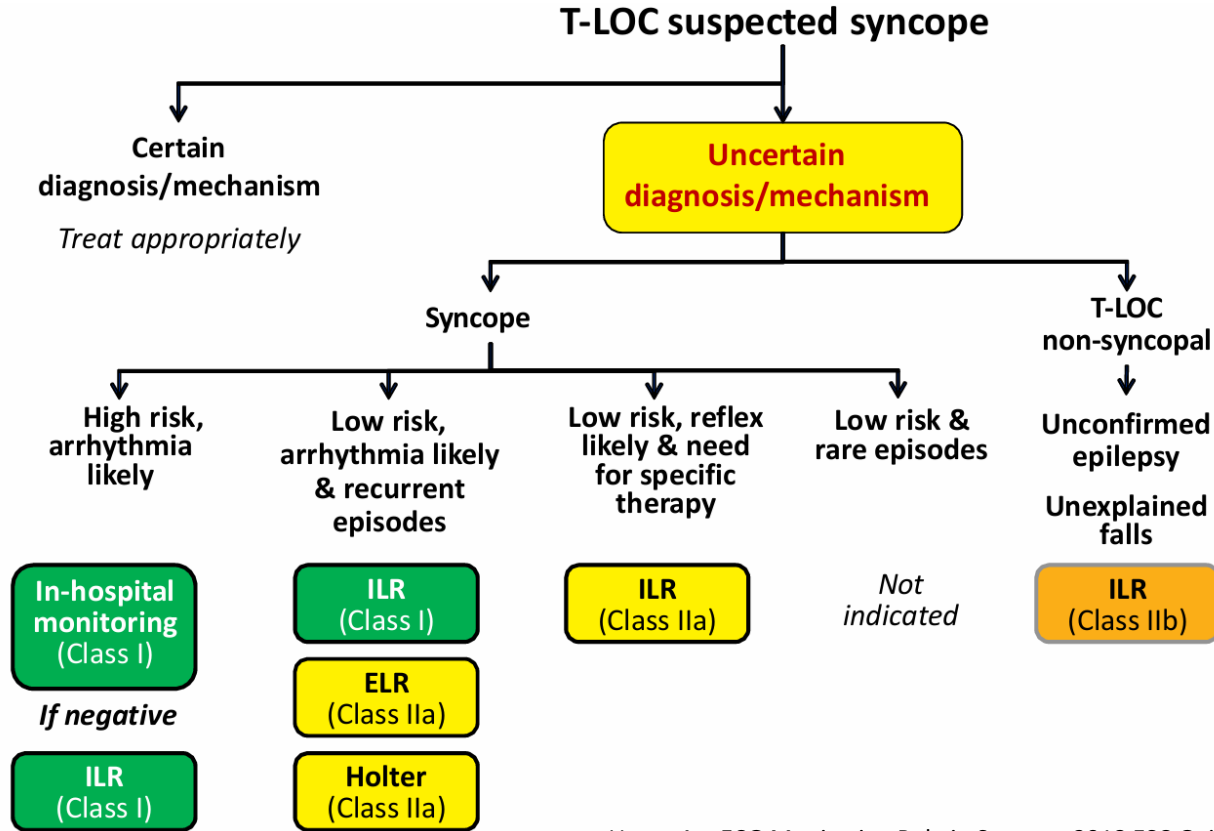
• Loop Recorder



Recommendations	Class ^a	Level ^b
Indications		
Immediate in-hospital monitoring (in bed or by telemetry) is indicated in high-risk patients (defined in Table 6).	I	C
Holter monitoring should be considered in patients who have frequent syncope or presyncope (≥ 1 episode per week). ¹⁶¹	IIa	B
External loop recorders should be considered, early after the index event, in patients who have an inter-symptom interval ≤ 4 weeks. ^{162,166,168,201}	IIa	B
ILR is indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria (listed in Table 6), and a high likelihood of recurrence within the battery life of the device. ^{175,176,181–184,202} Supplementary Data Table 5	I	A
ILR is indicated in patients with high-risk criteria (listed in Table 6) in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment, and who do not have conventional indications for primary prevention ICD or pacemaker indication. ^{174,180,187,188,195} , Supplementary Data Tables 5 and 6	I	A
ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes. ^{184–186}	IIa	B
ILR may be considered in patients in whom epilepsy was suspected but the treatment has proven ineffective. ^{137,189–191} , Supplementary Data Table 7	IIb	B
ILR may be considered in patients with unexplained falls. ^{191–194} , Supplementary Data Table 8	IIb	B
Diagnostic criteria		
Arrhythmic syncope is confirmed when a correlation between syncope and an arrhythmia (bradyarrhythmia or tachyarrhythmia) is detected. ^{172,184–186,188,200}	I	B
In the absence of syncope, arrhythmic syncope should be considered likely when periods of Mobitz II second- or third-degree AV block or a ventricular pause >3 s (with the possible exception of young trained persons, during sleep or rate-controlled atrial fibrillation), or rapid prolonged paroxysmal SVT or VT are detected. ^{185,188,197–199}	IIa	C
Additional advice and clinical perspectives		
- Be aware that the pre-test selection of the patients influences the subsequent findings. Include patients with a high likelihood of arrhythmic events. The duration (and technology) of monitoring should be selected according to the risk and the predicted recurrence rate of syncope.^{158–160,183} - Exclude patients with a clear indication for ICD, pacemaker, or other treatments independent of a definite diagnosis of the cause of syncope. - Include patients with a high probability of recurrence of syncope in a reasonable time. Owing to the unpredictability of syncope recurrence, be prepared to wait up to 4 years or more before obtaining such a correlation.²⁰³ - In the absence of a documented arrhythmia, presyncope cannot be considered a surrogate for syncope, whereas the documentation of a significant arrhythmia at the time of presyncope can be considered a diagnostic finding.¹⁹⁹ - The absence of arrhythmia during syncope excludes arrhythmic syncope.		



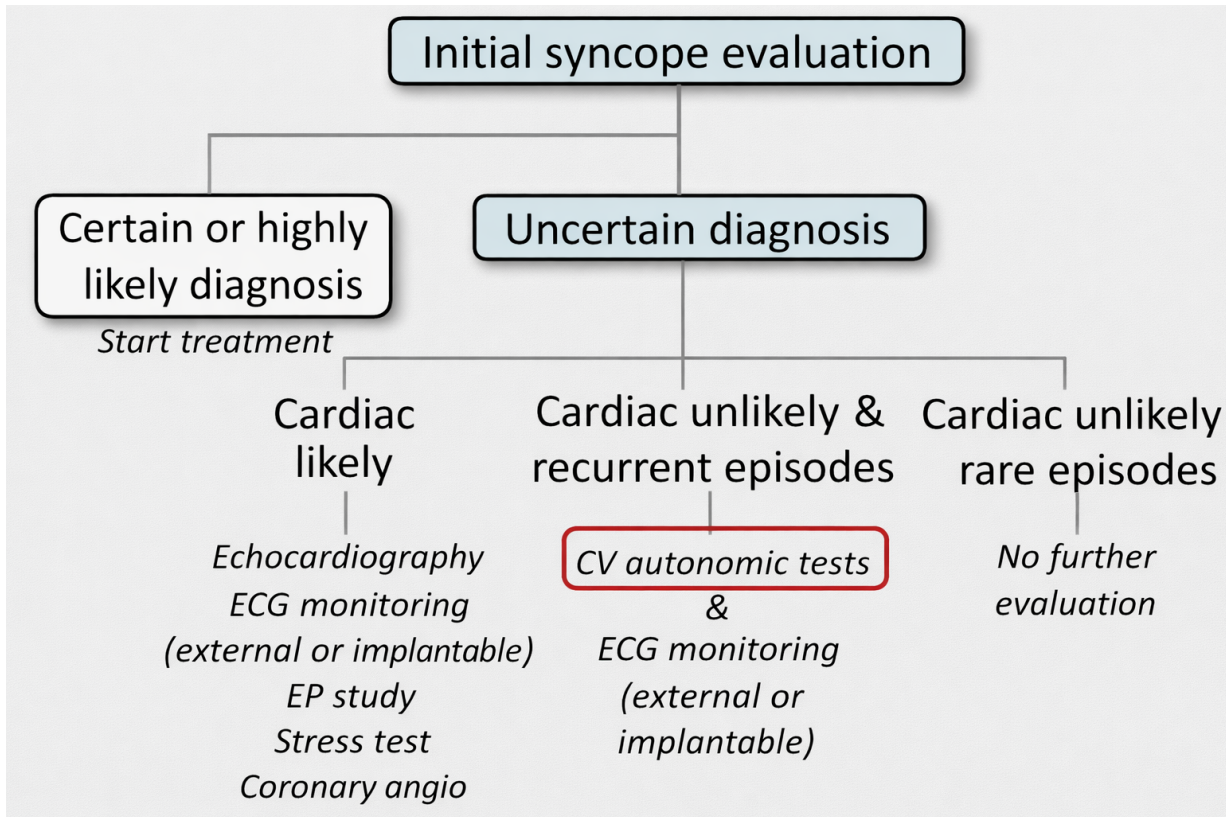
Indicazioni al monitoraggio ECG prolungato



Ungar A – ECG Monitoring Role in Syncope 2018 ESC Guidelines



Diagnosis



Definizione di sincope

- Perdita di coscienza transitoria
- Insorgenza rapida, durata breve
- Recupero spontaneo e completo
- Causata da ipoperfusione cerebrale globale



Sincope riflessa (o neuromediata)

- È la forma più frequente. Include:
- **Vasovagale** (classica, emotiva, ortostatica prolungata)
- **Situazionale** (tosse, minzione, defecazione, deglutizione, dolore, post-esercizio)
- **Sindrome del seno carotideo**
- **Forme atipiche** senza prodromi, senza un chiaro trigger, presentazione atipica)

Sincope da ipotensione ortostatica

- Dovuta a incapacità del sistema autonomico di mantenere la pressione in ortostatismo. Cause:
- **Disautonomia neurogena primaria** (Parkinson, neuropatie) o **secondaria** (diabete, amiloidosi, paraneoplastica, insufficienza renale)
- **Ipotensione ortostatica non neurogena** (farmaci, ipovolemia)

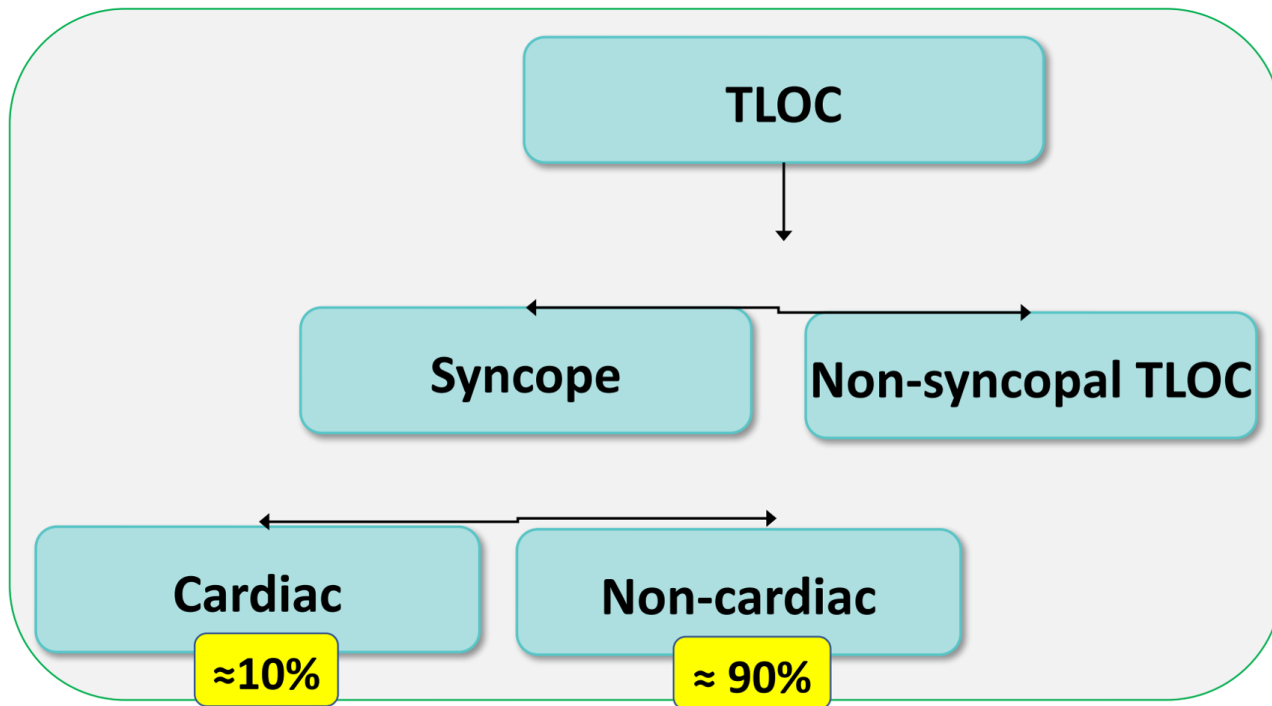
Sincope cardiogena

- La più pericolosa per prognosi. Origine:
- **Aritmie** (bradiaritmie, tachiaritmie)
- **Cause strutturali** (stenosi aortica, cardiomiopatia ipertrofica, ischemia)
- **Cause vascolari** (embolia polmonare, dissezione aortica)

Pseudosincope



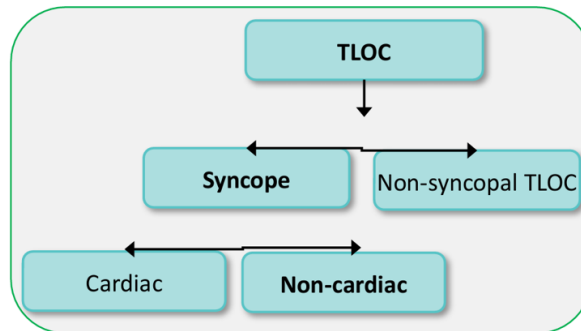
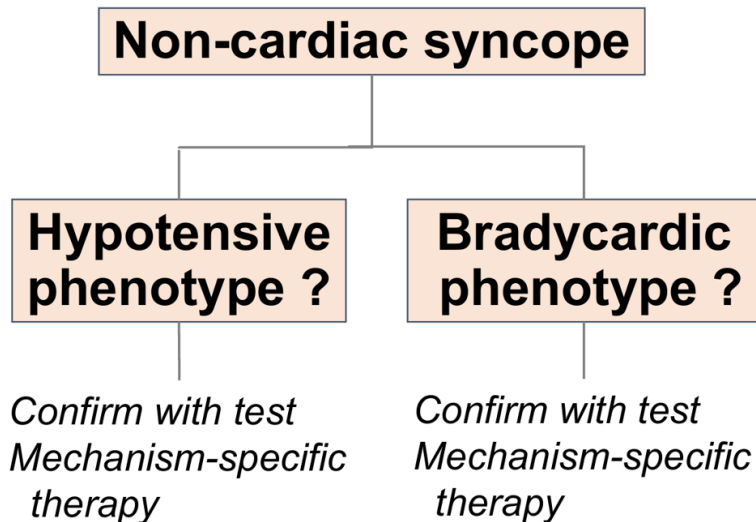
Nuova classificazione della sincope



Brignole M, Rivasi G. New insights in diagnostics and therapies in syncope: a novel approach to non-cardiac syncope. *Heart* 2021;107:864–873



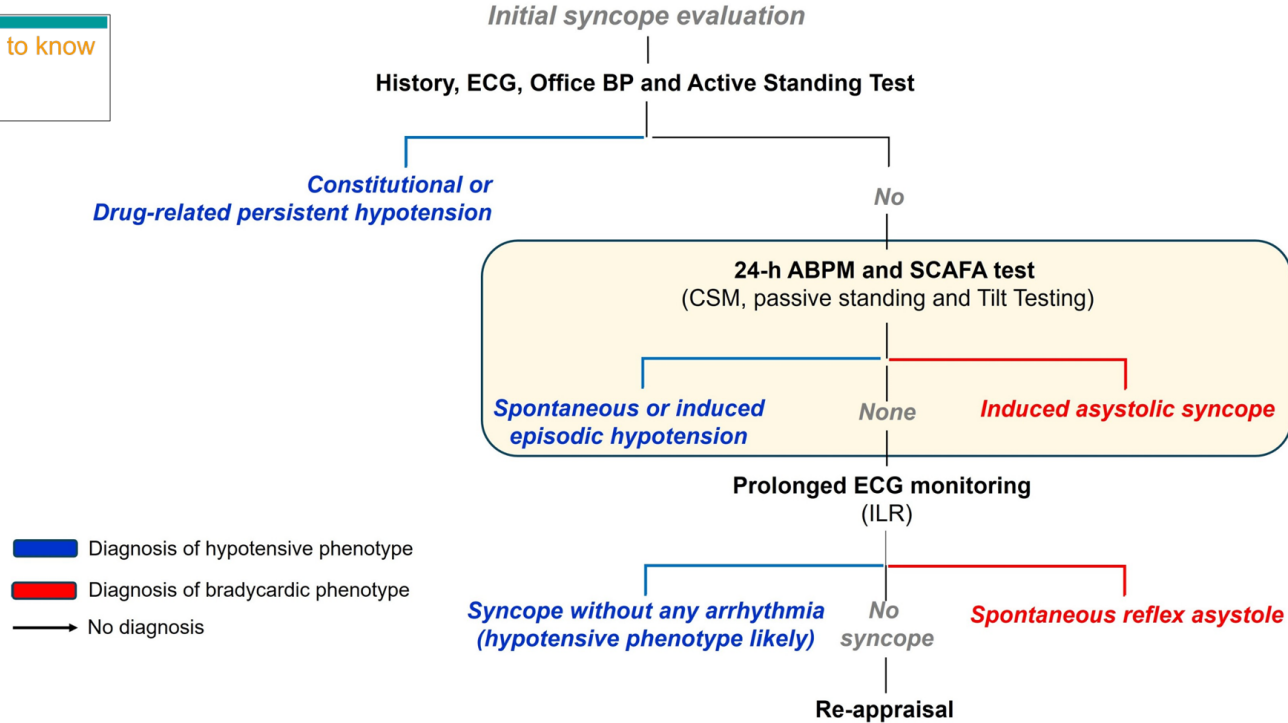
Mechanisms of non-cardiac syncope



Brignole M, Rivasi G. New insights in diagnostics and therapies in syncope: a novel approach to non-cardiac syncope. *Heart* 2021;107:864–873



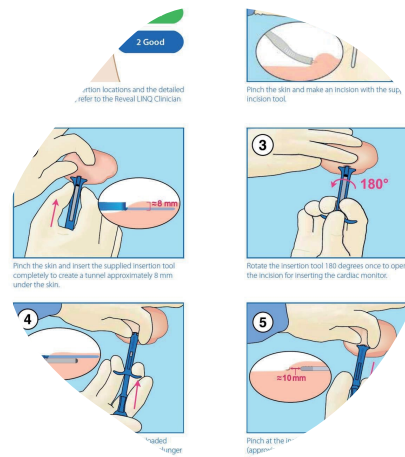
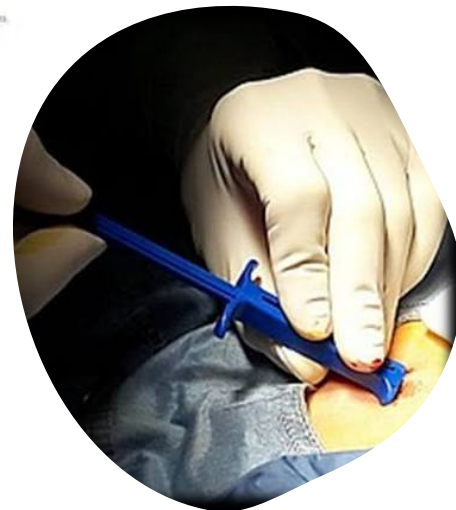
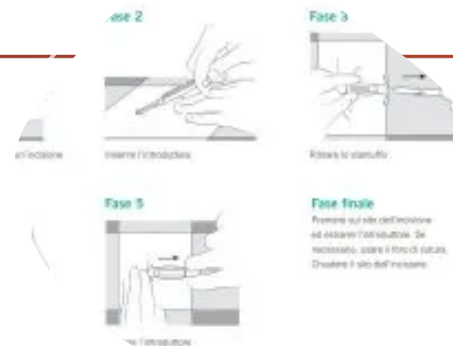
Diagnosi Sincope non cardiaca



Brignole M, et al. *Mechanism-based therapy of non-cardiac syncope: a practical guide*. Europace 2024



Ma come si fa?



Procedura di impianto

The placement of an implantable loop recorder (ILR) is a minimally invasive outpatient procedure.

Preparation: The area on the upper left chest is cleaned and numbed with a local anesthetic. Conscious sedation may be used but is rarely required.

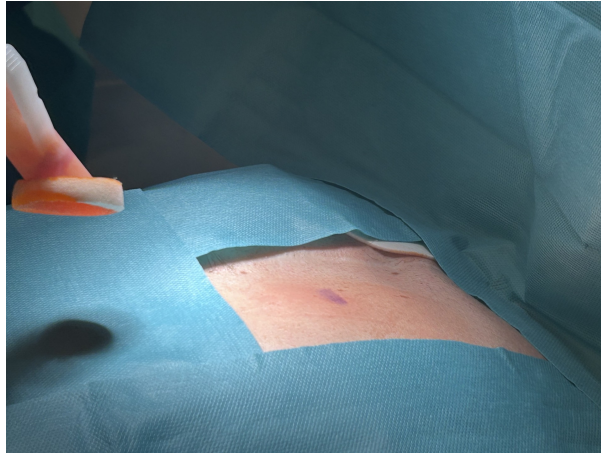
Insertion: The cardiologist or electrophysiologist makes a tiny incision (usually less than an inch). Using a specialized insertion tool, the device—which is roughly the size of a USB flash drive or a large paperclip—is slipped just under the skin to form a small pocket. No wires or leads are threaded into the heart.

Closure: The incision is closed with surgical glue or a few stitches and covered with a sterile dressing. The entire process generally takes 15 to 30 minutes.

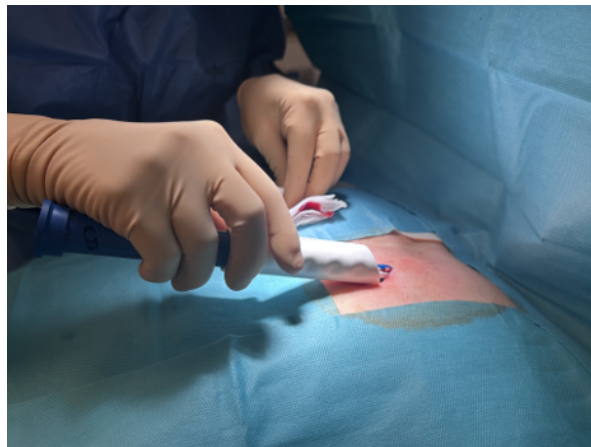
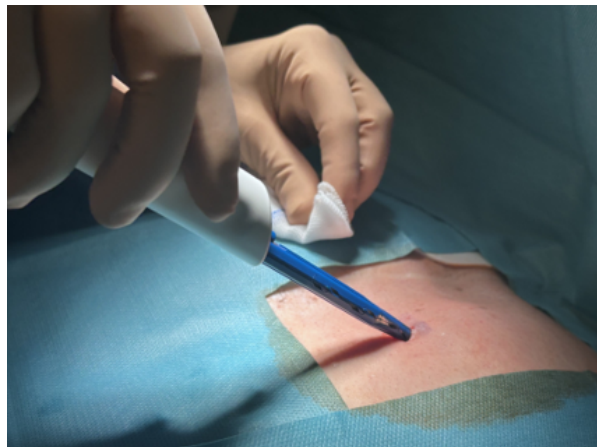




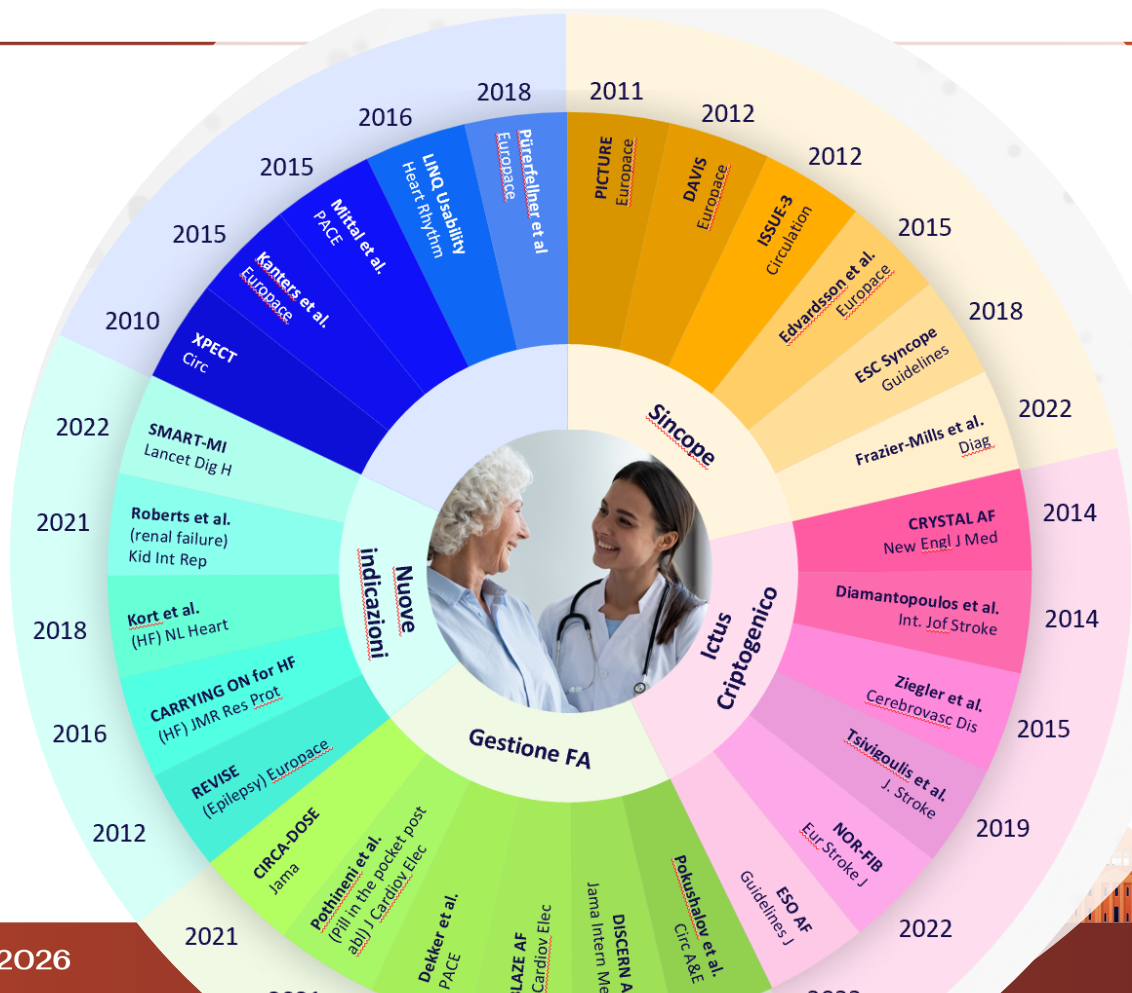
Procedura impianto



Procedura impianto



Quali evidenze abbiamo?



PICTURE STUDY¹: 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



Europace
doi:10.1093/europace/euq418

CLINICAL INVESTIGATION

Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry

Nils Edvardsson^{1*}, Viveka Frykman², Rob van Mechelen³, Peter Mitro⁴, Afshaneh Mohi-Oskarsen⁵, Jean-Luc Pasquie⁶, Hemanth Ramanna⁷, Frank Schwertfeger⁸, Rodolfo Ventura⁹, Despina Voulgaraki¹⁰, Claudio Garutti¹⁰, Pelle Stolt¹¹, and Nicholas J. Linker¹² on behalf of the PICTURE Study Investigators[†]

¹Division of Cardiology, Sahlgrenska University Hospital, S-413 45, Gothenburg, Sweden; ²Department of Cardiology, Karolinska Institute Danderyd Hospital, Stockholm, Sweden; ³Division of Cardiology, St Vincent's Centre, Rotterdam, The Netherlands; ⁴Leuven University Hospital, Leuven, School of Medicine, Department of Medicine, Campus St. Luke's Hospital, Brussels, Belgium; ⁵Cardiology Department, CHU Arnaud de Villeneuve, Montpellier, France; ⁶Medical Center Haaglanden, The Hague, Netherlands; ⁷Marburg Diakonissenanstalt GmbH, Synthesedistrikt Lütten Lütten, Germany; ⁸Electrophysiology Clinic, St. Anne's Hospital, Lüneburg, Germany; ⁹Thames Valley Research Centre, Plymouth, The Netherlands; ¹⁰Thames Valley Research Centre, Plymouth, The Netherlands; ¹¹Thames Valley Research Centre, Plymouth, The Netherlands; ¹²Thames Valley Research Centre, Plymouth, The Netherlands

Received 30 April 2010; accepted after revision 14 October 2010

Aims	To collect information on the use of the Reveal implantable loop recorder (ILR) in the patient care pathway and to investigate its effectiveness in the diagnosis of unexplained recurrent syncope in everyday clinical practice.
Methods and results	Prospective, multicentre, observational study conducted in 2006–2009 in 10 European countries and Israel. Eligible patients had recurrent unexplained syncope or presyncope. Subjects received a Reveal Plus, DX or XT. Follow up was until the first recurrence of a syncope event leading to a diagnosis or for ≥ 1 year. In the course of the study patients were evaluated by an average of three different specialists for management of their syncope and underwent a median of 13 tests (range 9–20). Significant physical trauma had been experienced in association with a syncope episode by 36% of patients. Average follow up time after ILR implant was 10 $\pm$ 6 months. Follow up visit data were available for 570 subjects. The percentages of patients with recurrence of syncope were 19.2% and 36.3% after 3.6 and 12 months, respectively. Of 218 events within the study, ILR guided diagnosis was obtained in 170 cases (78%), of which 128 (75%) were cardiac.
Conclusion	A large number of diagnostic tests were undertaken in patients with unexplained syncope without providing conclusive data. In contrast, the ILR revealed or contributed to establishing the mechanism of syncope in the vast majority of patients. The findings support the recommendation in current guidelines that an ILR should be implanted early rather than late in the evaluation of unexplained syncope.
Keywords	Reveal • Guidelines • Implantable loop recorder • Trauma • Injuries • Cardiac syncope

Introduction

Syncope is common in the general population^{1,2} and is perceived as an important clinical problem with adverse outcomes from associated physical trauma, negative impact on quality of life, and an increased cardiovascular risk in many patients.^{3,4}

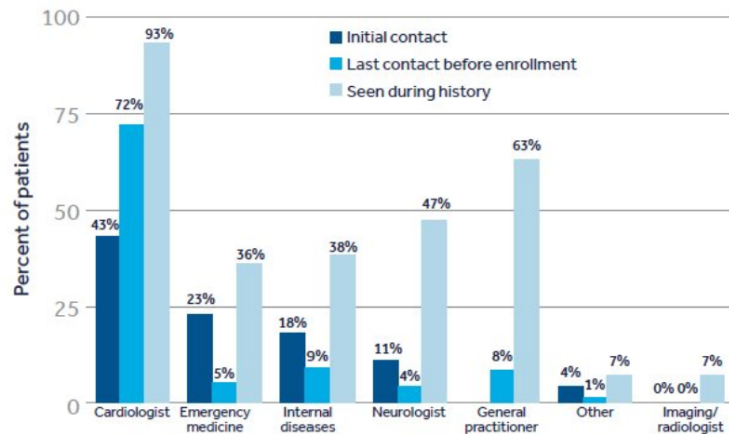
The first European Society of Cardiology (ESC) guidelines for diagnosis and treatment of syncope were published in 2001⁵ and were revised in 2004⁶ and 2009.⁷ The 2009 guidelines differ from earlier versions not only in their specific recommendations but also in their transcatheter endorsement: the guidelines were developed in collaboration with the Heart Failure Association

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



PICTURE STUDY RESULTS PATIENT EXPERIENCE¹

- 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



PICTURE STUDY RESULTS

DIAGNOSTIC TESTS PERFORMED¹

The median number of tests performed per patient was 13

(inter-quartile range 9 - 20)

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

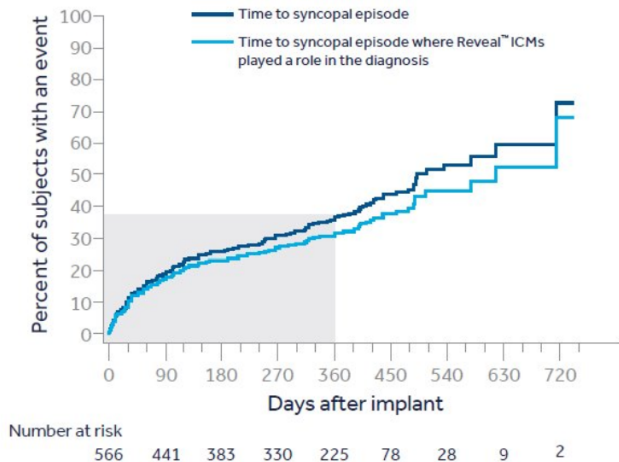
1. Edvardsson N, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry *Europace* 2011;13:262-269



PICTURE STUDY RESULTS

SYNCOPE RECURRENCE AND DIAGNOSTIC YIELD¹

- During follow-up, **38% of patients had a recurrence of syncope within 1 year**
- Reveal™ ICMs guided diagnosis in 78% of patients with recurrence**



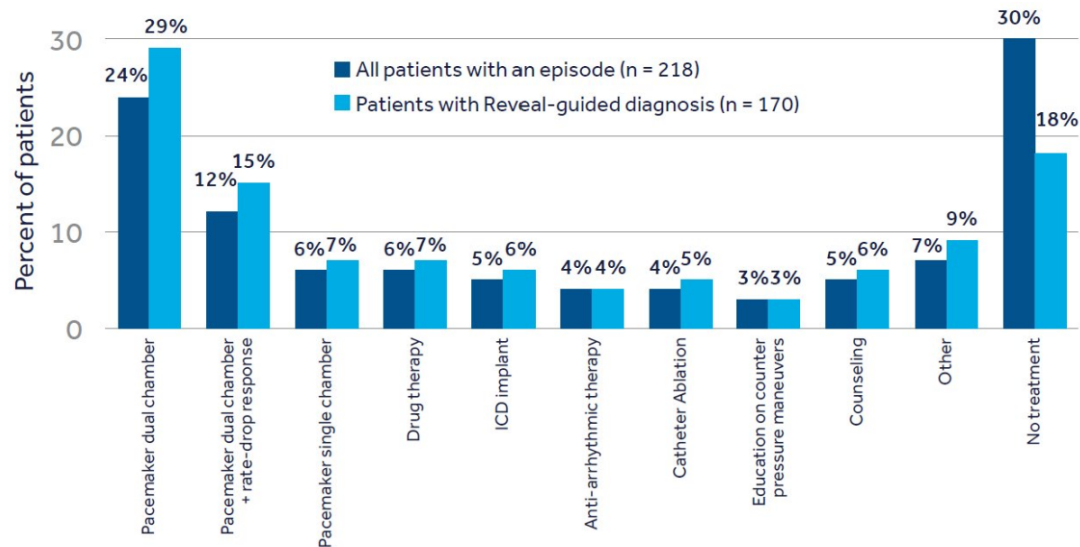
1. Edvardsson N, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry *Europace* 2011;13:262-269



PICTURE STUDY RESULTS

TREATMENT DECISIONS MADE IN RELATION TO SYNCOPE DIAGNOSIS¹

Of the 170 Reveal ICM-guided diagnoses, 75% were cardiac-related



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



Implantable Loop Recorders–Syncope, Cryptogenic Stroke, Atrial Fibrillation

Suneet Mittal ¹

Affiliations + expand

PMID: 34330371 DOI: 10.1016/j.ccep.2021.04.006

Table 1 Indications for an implantable loop recorder in patients with unexplained syncope: summary of the European Society of Cardiology guidelines		
ESC Recommendation	Class	Level
ILR is indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria, and a high likelihood of recurrence within the battery life of the device.	I	A
ILR is indicated in patients with high-risk criteria in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment and who do not have conventional indications for primary prevention.	I	A
ICD or pacemaker indication.		
ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes.	II	B

Trial	Study Population/Design	Patients, n	Key Findings
ISSUE-1	Patients without structural heart disease or with minor cardiac abnormalities that were considered to be without clinical relevance and not suggestive of a cardiac cause of syncope, absence of intraventricular conduction defects, and a negative complete workup including tilt-testing. ⁷	82	An ILR-documented syncopal episode occurred in 24 (29%) patients after a median of 105 d (range, 47–226 d). The most frequent finding, which was observed in 11 (46%) of these 24 patients, was ≥1 asystolic pauses (median 31 s; range, 20–44 s).
	Same population as aforementioned but with a positive response to tilt-testing. ⁷	29	An ILR-documented syncopal episode occurred in 8 (28%) patients after a median of 59 d (range, 22–98 d). The most frequent finding, which was observed in 5 (62%) of these 8 patients was ≥1 asystolic pauses (median 33 s; range, 23–41 s). No difference in baseline characteristics or follow-up outcomes between patients with and without a positive response to tilt-testing.
	Patients with bundle branch block and a negative electrophysiological test. ⁸	52	Syncope recurred in 22 (42%) patients. The most frequent findings, recorded in 17 (77%) patients, was ≥1 prolonged asystolic pause mainly attributable to AV block. AV block not observed in patients with isolated right bundle branch block.
	Patients with overt heart disease who were at risk of ventricular arrhythmia, because these were patients with depressed ejection fraction or nonsustained ventricular tachycardia in whom an electrophysiological study did not induce sustained ventricular arrhythmias. ⁹	35	Syncope recurred in 6 (17%) patients after a mean of 6 ± 5 mo. Recurrent syncope was never attributable to a ventricular arrhythmia and never resulted in death.
ISSUE-2	Prospective, multicenter, observational study to assess the efficacy of specific therapy based on ILR diagnostic observations in patients with recurrent suspected neurally mediated syncope. ¹⁰	103	The 1-y recurrence rate in patients assigned to ILR-guided specific therapy was 10%, compared with 41% in the patients without specific therapy. The 1-y recurrence in patients with a pacemaker was 5%.
ISSUE-3	Multicenter, prospective, randomized, double-blind study to evaluate the effectiveness of pacing therapy to prevent recurrent syncope in patients with documented spontaneous asystole during neurally mediated syncope. ¹¹	77	In patients ≥40 y of age with recurrent asystole (≥3 s + syncope or ≥6 s without syncope) during an episode of neurally mediated syncope, there was a 32% absolute and 57% relative reduction in syncope recurrence. Even with pacing, 25% of patients had recurrent syncope.



Clinical Trial > Eur Heart J. 2006 May;27(9):1085-92. doi: 10.1093/eurheartj/ehi842.

Epub 2006 Mar 28.

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

Michele Brignole¹, Richard Sutton, Carlo Menozzi, Roberto Garcia-Civera, Angel Moya, Wouter Wieling, Dietrich Andresen, David G Benditt, Panos Vardas; International Study on Syncope of Uncertain Etiology 2 (ISSUE 2) Group

Patients with three or more clinically severe syncopal episodes in the last 2 years without significant electrocardiographic and cardiac abnormalities were included. Orthostatic hypotension and carotid sinus syncope were excluded. After ILR implantation, patients were followed until the first documented syncope (Phase I). The ILR documentation of this episode determined the subsequent therapy and commenced Phase II follow-up. Among 392 patients, the 1-year recurrence rate of syncope during Phase I was 33%. One hundred and three patients had a documented episode and entered Phase II: 53 patients received specific therapy [47 a pacemaker because of asystole of a median 11.5 s duration and six anti-tachyarrhythmia therapy (catheter ablation: four, implantable defibrillator: one, anti-arrhythmic drug: one)] and the remaining 50 patients did not receive specific therapy. The 1-year recurrence rate in 53 patients assigned to a specific therapy was 10% (burden 0.07 +/- 0.2 episodes per patient/year) compared with 41% (burden 0.83 +/- 1.57 episodes per patient/year) in the patients without specific therapy (80% relative risk reduction for patients, $P = 0.002$, and 92% for burden, $P = 0.002$). The 1-year recurrence rate in patients with pacemakers was 5% (burden 0.05 +/- 0.15 episodes per patient/year). Severe trauma secondary to syncope relapse occurred in 2% and mild trauma in 4% of the patients.

This prospective multicentre observational study assessed the efficacy of specific therapy based on implantable loop recorder (ILR) diagnostic observations in patients with recurrent suspected neurally mediated syncope (NMS).

A strategy based on early diagnostic ILR application, with therapy delayed until documentation of syncope allows a safe, specific, and effective therapy in patients with NMS.



Randomized Controlled Trial > [Circulation](#). 2012 May 29;125(21):2566-71.

doi: 10.1161/CIRCULATIONAHA.111.082313. Epub 2012 May 7.

Pacemaker therapy in patients with neurally mediated syncope and documented asystole: Third International Study on Syncope of Uncertain Etiology (ISSUE-3): a randomized trial

Michele Brignole¹, Carlo Menozzi, Angel Moya, Dietrich Andresen, Jean Jacques Blanc, Andrew D Krahn, Wouter Wieling, Xulio Beiras, Jean Claude Deharo, Vitantonio Russo, Marco Tomaino, Richard Sutton;
[International Study on Syncope of Uncertain Etiology 3 \(ISSUE-3\) Investigators](#)

Methods and results: Double-blind, randomized placebo-controlled study conducted in 29 centers in the Third International Study on Syncope of Uncertain Etiology (ISSUE-3) trial. Patients were ≥ 40 years, had experienced ≥ 3 syncopal episodes in the previous 2 years. Initially, 511 patients, received an implantable loop recorder; 89 of these had documentation of syncope with ≥ 3 s asystole or ≥ 6 s asystole without syncope within 12 ± 10 months and met criteria for pacemaker implantation; 77 of 89 patients were randomly assigned to dual-chamber pacing with rate drop response or to sensing only. The data were analyzed on intention-to-treat principle. There was syncope recurrence during follow-up in 27 patients, 19 of whom had been assigned to pacemaker OFF and 8 to pacemaker ON. The 2-year estimated syncope recurrence rate was 57% (95% CI, 40-74) with pacemaker OFF and 25% (95% CI, 13-45) with pacemaker ON (log rank: $P=0.039$ at the threshold of statistical significance of 0.04). The risk of recurrence was reduced by 57% (95% CI, 4-81). Five patients had procedural complications: lead dislodgment in 4 requiring correction and subclavian vein thrombosis in 1 patient.

Conclusions: Dual-chamber permanent pacing is effective in reducing recurrence of syncope in patients ≥ 40 years with severe asystolic neurally mediated syncope. The observed 32% absolute and 57% relative reduction in syncope recurrence support this invasive treatment for the relatively benign neurally mediated syncope.



Diagnostic yield of implantable loop recorders: results from the hellenic registry

Konstantinos P. Letsas,¹ Athanasios Saplaouras,¹ Panagiotis Mililis,¹ Ourania Kariki,¹ George Bazoukis,¹ Stefanos Archontakis,² Ioannis Anagnostopoulos,³ Sokratis Triantafyllou,⁴ Lina Palaiodimou,⁴ Anastasios Chatziantoniou,¹ Anastasios Lykoudis,⁵ Athena Mpatsoi,⁵ Georgia Katsa,¹ Olga Kadda,¹ Stylianos Dragasis,¹ Vasileios Cheilas,¹ Eleftheria Garyfalia Tsetika,¹ Dimitrios Asvestas,⁶ Panagiotis Korantzopoulos,⁷ George Poulos,¹ Themistocles Maounis,¹ Anna Kostopoulou,¹ Charalambos Kossyvakis,³ Sotirios Xydonas,⁵ Georgios Giannopoulos,⁸ John Papagiannis,¹ Alexandros Tsoutsinos,¹ George Sidiropoulos,⁸ Vassilios Vassilikos,⁸ Nikolaos Fragakis,⁸ Stylianos Tzeis,⁶ Spyridon Deftereos,⁹ Polychronis Dilaveris,² Skevos Sideris,² Michael Efremidis,¹ Georgios Tsvigoulis⁴



871 Patients
8 Implantation centers
3 ILR indications

Median follow-up
28.8 ± 12.9 months

26.8% received a diagnosis with subsequent
new therapeutic management

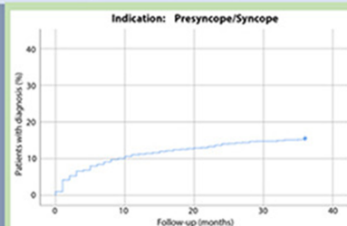
Established Diagnosis Kaplan-Meier estimates

Findings

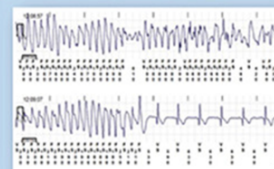
Recordings

Presyncope/Syncope
539 (61.9%)

167 (31%)

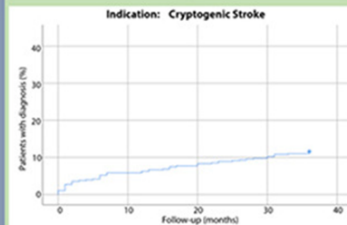


Sick sinus syndrome (18.6%)
Atrioventricular block (5%)
Supraventricular tachycardia (3%)
Ventricular tachycardia (2.4%)
Atrial fibrillation (2%)



Cryptogenic stroke
241 (27.7%)

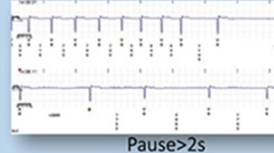
47 (19.5%)



Atrial fibrillation (19.5%)
Initiation of anticoagulants

Non-atrial fibrillation diagnoses

- Atrioventricular block
- Sick sinus syndrome
- Supraventricular tachycardia

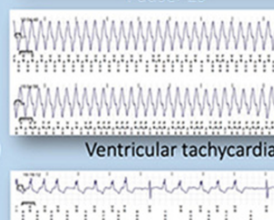


Palpitations
91 (10.4%)

20 (22%)



Supraventricular tachycardia (9.9%)
Atrial fibrillation (8.8%)
Ventricular tachycardia (3.3%)



RESEARCH

Open Access

Diagnostic usefulness of implantable loop recorder in patients with unexplained syncope or palpitation

Yun Young Choi, Jong-Il Choi¹, Yun Gi Kim, Kyongjin Min, Seung-Young Roh, Jaemin Shim, Jin Seok Choi and Young-Hoon Kim

Table 1 Baseline characteristics of patients with documented arrhythmia by implantable loop recorder (ILR) and not documented arrhythmia

Variables	Arrhythmia detected (n = 26)	No arrhythmia detected (n = 44)	p-value
Age (years)	57.3 ± 18	46 ± 20.6	0.023
Men, n (%)	14 (53.8)	13 (29.5)	0.044
Body weight (kg)	63.7 ± 14.3	64.7 ± 12.8	0.746
Height (cm)	161.6 ± 11.9	168.1 ± 9.4	0.014
BMI (kg/m ²)	24.1 ± 3.2	22.9 ± 4.0	0.173
Hypertension, n (%)	6 (23.1)	7 (15.9)	0.456
Diabetes mellitus, n (%)	1 (3.8)	2 (4.5)	0.889
Previous stroke, n (%)	2 (7.7)	0 (0)	0.062
Other arrhythmias, n (%)	5 (33.8)	12 (27.3)	0.448
Structural heart disease, n (%)	4 (15.4)	3 (6.8)	0.248
Previous RFCA, n (%)	2 (7.7)	6 (13.6)	0.450
Left ventricular ejection fraction (%)	57.1 ± 1.5	56.1 ± 3.0	0.017
Left atrium diameter (mm)	37.2 ± 7.2	34.9 ± 5.7	0.142

BMI, body mass index; RFCA, radiofrequency catheter ablation

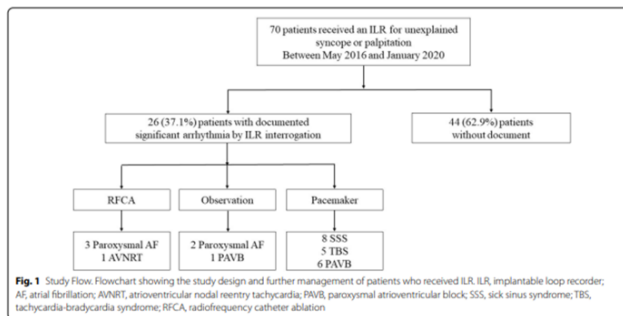


Fig. 1 Study Flow: Flowchart showing the study design and further management of patients who received ILR. ILR, implantable loop recorder; AF, atrial fibrillation; AVNRT, atrioventricular nodal reentry tachycardia; PAVB, paroxysmal atrioventricular block; SSS, sick sinus syndrome; TBS, tachycardia-bradycardia syndrome; RFCA, radiofrequency catheter ablation



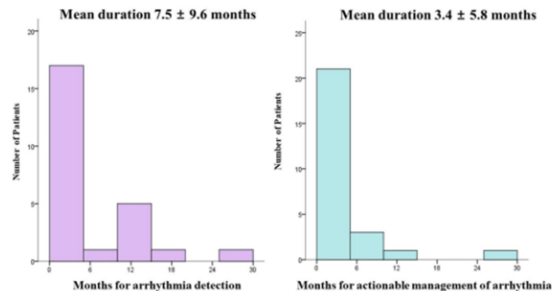


Fig. 3 Time duration for the detection and treatment of arrhythmia. The histograms show the mean duration of time from implantation of the loop recorder to the diagnosis of arrhythmias and the mean duration from arrhythmia detection to treatment initiation

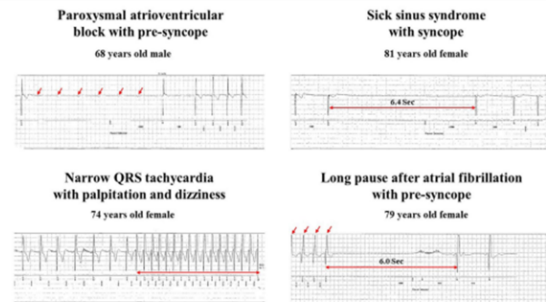


Fig. 2 Representative examples of arrhythmias that were detected in the tracings downloaded from the ILR at the time of symptoms

Table 3 Documented arrhythmia during follow-up

Patient	First event (days)	Finding on ILR	Management
1	572	SSS	Permanent pacemaker
2	34	SSS	Permanent pacemaker
3	193	TBS	Permanent pacemaker
4	104	PAVB	Permanent pacemaker
5	1188	SSS	Permanent pacemaker
6	78	High degree AVB	Permanent pacemaker
7	101	TBS	Permanent pacemaker
8	6	PAVB	Permanent pacemaker
9	340	TBS	Permanent pacemaker
10	21	PAVB	Permanent pacemaker
11	34	SSS	Permanent pacemaker
12	138	SSS	Permanent pacemaker
13	893	SSS	Permanent pacemaker
14	11	TBS	Permanent pacemaker
15	120	PAVB	Permanent pacemaker
16	323	SSS	Permanent pacemaker
17	92	PAVB	Permanent pacemaker
18	76	TBS	Permanent pacemaker
19	107	SSS	Permanent pacemaker
20	429	Paroxysmal AF	RFCA
21	15	AVNRT	RFCA
22	409	PAVB	Observation
23	337	Paroxysmal AF	Cryoballoon ablation
24	61	Paroxysmal AF	Observation
25	108	Paroxysmal AF	Observation
26	49	Paroxysmal AF	RFCA

SSS, sick sinus syndrome; TBS, tachycardia-bradycardia syndrome; PAVB, paroxysmal atrioventricular block; AF, atrial fibrillation; RFCA, radiofrequency catheter ablation; ILR, implantable loop recorder; AVNRT, atrioventricular nodal reentry tachycardia



Effectiveness and safety of implantable loop recorder and clinical utility of remote monitoring in patients with unexplained, recurrent, traumatic syncope

Pietro Palmisano  Federico Guerra, Vittorio Aspromonte, Gabriele Dell'Era, Pier Luigi Pellegrino, Mattia Laffi, [...show all](#)

Pages 45-54 | Received 29 May 2022, Accepted 10 Jan 2023, Accepted author version posted online: 11 Jan 2023, Published online: 21 Jan 2023

Prospective, multicentre registry enrolling consecutive patients undergoing ILR insertion for unexplained, recurrent, traumatic syncope. In a proportion of enrolled patients, remote monitoring (RM) was used for device follow-up. The risk of traumatic and non-traumatic syncopal recurrences during ILR observation were prospectively assessed.

A total of 483 consecutive patients (68 ± 14 years, 59% male) were enrolled. During a median follow-up of 18 months, a final diagnosis was reached in 270 patients (55.9%). The risk of syncopal and traumatic syncopal recurrence was of 26.5 and 9.3%, respectively. RM significantly reduced the time to diagnosis (19.7 ± 10.3 vs. 22.1 ± 10.8 months; $p=0.015$) and was associated with a significant reduction in the risk of syncope recurrence of 48% ($p<0.001$), and of traumatic syncope recurrence of 49% ($p=0.018$).

Conclusions

ILR monitoring is effective and safe in patients with unexplained, recurrent, traumatic syncope. RM reduces the time to diagnosis and significantly reduces the risk of traumatic and non-traumatic syncopal relapses.



Remote monitoring of implantable loop recorders reduces time to diagnosis in patients with unexplained syncope: a multicenter propensity score-matched study

Vincenzo Russo^{1*}, Anna Rago¹, Nicola Grimaldi², Raffaele Chianese³, Aniello Viggiano⁴, Giuliano D'Alterio⁵, Diego Colonna², Agostino Mattera Iacono³, Andrea Antonio Papa¹, Andrea Spadaro Guerra⁶, Alessio Gargaro⁶, Antonio Rapacciuolo⁴, Berardo Sarubbi², Antonio D'Onofrio⁵ and Gerardo Nigro¹

TABLE 1 Device programming and automatic remote monitoring alert setting.

Trigger type ms/bpm	Detection
AF	Low—12% RR variability
HVR	180 bpm
Bradycardia	40 bpm
SRD	40%
Asystole	3 s
Device	Type of alarm
Programmer triggered message received	Yellow warning
ERI	Red warning + notification
Backup mode active	Red warning + notification
Sensing	
Ventricular sensing amplitude (daily mean): <0.05 mV	Red warning + notification
Atr. and ven. arrhythmia	
Mean ventricular rate during AF > 150 bpm for >5% of day	Yellow warning
Number of asystole episodes: at least one	Red warning + notification
Number of high ventricular rate episodes (HVR): at least one	Red warning + notification
Number of bradycardia episodes: at least one	Yellow warning + notification
Number of sudden rate drop episodes: at least one	Yellow warning + notification
Episode	
Episode details received	Yellow warning
Remote monitoring	
First message received	Yellow warning
No messages received for 5 days	Yellow warning + notification
HM follow-up transmission has arrived	Yellow warning

AF, atrial fibrillation; HVR, high ventricular rate; SRD, sudden rate drop; ERI, elective replacement indicator; HM, home monitoring.

TABLE 2 Patient characteristics.

Characteristic	RM-ON, N = 133 ^a	RM-OFF, N = 108 ^a	p-value ^b
Age	54 (28, 71)	64 (48, 76)	0.007
Male	91 (68%)	65 (60%)	0.2
Smoke	33 (26%)	21 (23%)	0.6
Familiarity of sudden death	17 (13%)	12 (13%)	0.9
History of arrhythmia	19 (15%)	18 (19%)	0.4
Hypertension	58 (45%)	38 (41%)	0.5
Dyslipidemia	35 (27%)	20 (22%)	0.3
Coronary artery disease	16 (12%)	11 (12%)	0.9
Chronic obstructive pulmonary disease	12 (9.3%)	17 (18%)	0.05
Diabetes	10 (7.8%)	12 (13%)	0.2
Previous stroke or TIA	5 (3.9%)	5 (5.4%)	0.7
Atrial fibrillation	14 (11%)	14 (15%)	0.4
Chronic kidney disease	8 (6.2%)	8 (8.6%)	0.5
Palpitations	29 (22%)	22 (24%)	0.8
History of syncope	133 (100%)	108 (100%)	
Total number of syncope	2 (1, 4)	3 (2, 4)	0.06
Prodromes	57 (43%)	30 (33%)	0.14
Presyncope	39 (29%)	24 (26%)	0.6
Trauma	36 (27%)	23 (26%)	0.8
Resting heart rate	70 (62, 80)	70 (65, 75)	0.6
Systolic blood pressure	120 (111, 130)	120 (115, 128)	0.9
Left ventricle ejection fraction (%)	59 (55, 60)	55 (55, 60)	0.5
Medical therapy			
ACE inhibitors	32 (25%)	22 (22%)	0.6
Angiotensin receptor blockers	14 (11%)	10 (9.9%)	0.8
Beta blockers	35 (28%)	30 (30%)	0.7
Diuretics	15 (12%)	10 (9.9%)	0.6
Calcium antagonists	16 (13%)	8 (7.9%)	0.3
Antiplatelets	22 (17%)	20 (20%)	0.6
Anticoagulants	12 (9.4%)	2 (2.0%)	0.020
Antiarrhythmic class IC agents	6 (4.7%)	5 (5.0%)	0.9
Amiodarone	3 (2.4%)	1 (1.0%)	0.6
Sotalol	5 (3.9%)	2 (2.0%)	0.5
Insulin	19 (15%)	16 (16%)	0.9

ACE, angiotensin-converting enzyme; TIA, transient ischemic attack.

^aMedian (interquartile range) or n (%).

^bWilcoxon rank sum test, Pearson's Chi-squared test, or Fisher's exact test.



TABLE 3 ILR-detected events, symptoms, and medical interventions.

	RM-ON, N = 133	RM-OFF, N = 108
ILR-detected events		
Sinus arrest/bradycardia	13 (9.8%)	5 (4.6%)
AV block	19 (13.3%)	9 (8.3%)
Atrial fibrillation	4 (3.0%)	5 (4.6%)
PSVT	1 (0.75%)	3 (2.8%)
VT	1 (0.75%)	0 (0.0%)
Asymptomatic	24 (18.0%)	8 (7.4%)
Medical interventions		
Pacemaker implantation	25 (18.8%)	14 (13.0%)
PSVT ablation	1 (0.8%)	2 (1.8%)
AADs initiation	1 (0.7%)	1 (0.9%)
AADs adjustment	2 (1.5%)	3 (2.8%)
OACs initiation	0 (0%)	2 (1.8%)

AV: atrio-ventricular; ILR: implantable loop recorder; PSVT: paroxysmal supraventricular tachycardia; RM: remote monitoring; VT: ventricular tachycardia; AADs: antiarrhythmic drugs; OACs: oral anticoagulants

TABLE 4 Ratios of rate of event evaluations in the RM-ON group vs. the RM-OFF group, expressed in terms of PS-matched, adjusted/unadjusted hazard ratios between study groups.

Variable	PS-matched	Unmatched	
	Univariate HR (CI); p	Multivariate HR (CI); p	Multivariate HR (CI); p
All events			
Remote monitoring	2.22 (1.15–4.30); p = 0.017	2.53 (1.32–4.86); p = 0.005	2.57 (1.39–4.74); p = 0.002
Adjusting variables			
CAD		0.54 (0.21–1.41); p = 0.43	0.82 (0.38–1.76); p = 0.60
Hypertension		3.81 (2.09–6.94); p < 0.0001	2.89 (1.64–5.10); p = 0.0002
Asymptomatic events			
Remote monitoring	4.58 (1.64–12.76); p = 0.0003	4.28 (1.52–11.96); p = 0.006	4.58 (1.78–11.78); p = 0.002
Adjusting variables			
CAD		0.64 (0.19–2.12); p = 0.47	1.05 (0.39–2.86); p = 0.60
Hypertension		2.55 (1.15–5.64); p = 0.02	1.94 (0.93–4.22); p = 0.07
Events leading to pacemaker implantation			
Remote monitoring	2.18 (0.89–5.33); p = 0.08	2.82 (1.77–6.77); p = 0.02	2.31 (1.08–4.95); p = 0.03
Adjusting variables			
CAD		0.75 (0.29–1.98); p = 0.57	0.50 (0.16–1.57); p = 0.23
Hypertension		3.13 (1.51–6.46); p = 0.002	4.32 (1.99–9.38); p = 0.0002

CAD, coronary artery disease; CI, confidence interval; HR, hazard ratio; PS, propensity score; RM, remote monitoring

In our PS-matched comparison of remotely monitored patients who received an ILR for unexplained syncope with a historical cohort of non-remotely monitored patients, RM

(50% relative reduction). Our estimations were obtained by balancing the two groups with the PS-match method based on the inverse probability of treatment weighting (8). The method assigns PS-dependent weights to controls (rather than excluding individuals not fulfilling matching criteria). The method was effective in covariate balancing (Figure 1), despite retaining all individuals in the analysis reducing the loss of information.

(35 vs. 240 days). The chance of a diagnosis of events leading to the indication of pacemaker implantation was also 2.8-fold higher with RM-ON vs. RM-OFF.

Syncope is a common medical problem with a frequency between 15% and 39% in the general population and an annual number of episodes of 18.1 to 39.7 per 1,000 patients (10). Reflex syncope is by far the most common cause (11) but determining the cause of recurrent unexplained syncope remains a clinical challenge and a permanent quest. Immediate notification to clinician of events detected by VPM is a key feature for the step-by-step management and ECG recording.



ORIGINAL RESEARCH

Accuracy of Implantable Loop Recorders

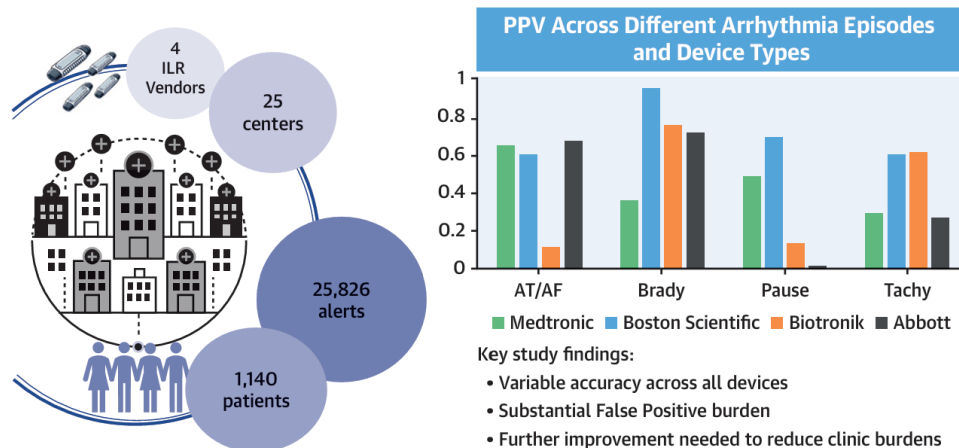
Multicenter, Multidevice Comparison

Suraya H. Kamsani, MBBS,^{a,b} Melissa E. Middeldorp, MPH, PhD,^a Shaun Evans, MBBS,^a Andrea M. Russo, MD,^c Mohanaraj Jayakumar, MBBS,^a Thomas F. Deering, MD,^d Elnaz Shahmohamadi, MBBS, MPH,^a Tina Baykaner, MD, MPH,^e John L. Fitzgerald, MBBS, PhD,^f Rakesh Gopinathannair, MD,^g Mohamed Abbas, MBBS,^a Niraj Varma, MD, PhD,^h James V. Freeman, MD, MPH, MS,^h Suneet Mittal, MD,ⁱ Prashanthan Sanders, MBBS, PhD^a

CONCLUSIONS

Currently available ILR devices have variable accuracy in detecting arrhythmia episodes, with a substantial burden of FP alerts across all vendors. This may have implications for device selection to improve clinic workloads. There is a need for further improvement of alert algorithms to reduce clinic burdens. Individualized device programming, use of AI and machine learning to further improve algorithm characterization and signal quality, and deployment by qualified cardiac device specialists are strategies that can be used to improve arrhythmia detection accuracy.

CENTRAL ILLUSTRATION Accuracy of Implantable Loop Recorders: A Multi-Center, Multi-Device Comparison



Kamsani SH, et al. JACC Clin Electrophysiol. 2026;■(■):■-■.

The figure depicts a multicenter comparison of diagnostic accuracy across four implantable loop recorder devices in 1,140 patients from 25 centers. Positive predictive value (PPV) for major arrhythmia categories is shown, demonstrating variable performance across devices and a substantial false-positive burden. AF = atrial fibrillation; AT = atrial tachycardia.





Contents lists available at ScienceDirect

Journal of Arrhythmia

journal homepage: www.elsevier.com/locate/joa



CrossMark

Review

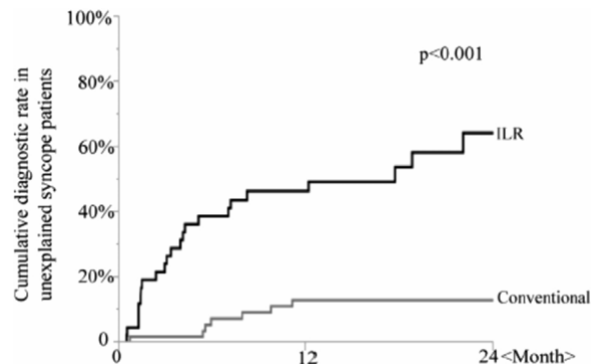
Use of implantable and external loop recorders in syncope with unknown causes

Kaoru Tanno*

Cardiovascular Division, Showa University Koto-Toyosu Hospital, 5-1-38 Toyosu Koto-Ku, Tokyo 135–8577, Japan

2.4. Cost effectiveness

Two studies analyzed the cost-effectiveness of using ILR or conventional management as diagnostic tools. The RAST study suggested that early intervention with ILR was more cost-effective than the conventional strategy, which includes ELR for 2–4 weeks, electrophysiological testing, and tilt-table testing [2]. Krahn calculated the cost of investigation based on the Ontario Health Insurance Program fee schedule for technical and professional fees, and also included an estimate of materials, labor, maintenance, and overhead costs for hospital-based investigations. The mean cost of ILR as the primary monitoring strategy was greater than that of the conventional strategy, but the cost of ILR monitoring per diagnosis was less than that of the conventional strategy. Farwell reported that overall mean costs were lower in the ILR group than in the conventional management group without statistical significance [3]. Length of follow-up might influence costs, as ILR may be more costly initially, but it might be balanced by a lower need for tests and hospitalization in the long term.



2.5. Adverse effects and disadvantages of the ILR

ILRs carry the risk of pocket infections that resolve with device explanation. This complication, which can occur either in the peri-procedural phase or later during the follow-up, was reported in 1 to 5% of patients. Another disadvantage of ILR includes the presence of under-sensing or over-sensing. This is due to the difficulty of distinguishing between SVT and VT, and the ambiguous P wave [13,21].





Contents lists available at ScienceDirect

Journal of Arrhythmia

journal homepage: www.elsevier.com/locate/joa

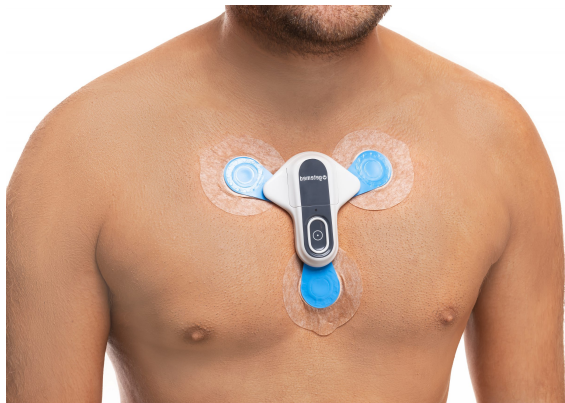


Review

Use of implantable and external loop recorders in syncope with unknown causes

Kaoru Tanno*

Cardiovascular Division, Showa University Koto-Toyosu Hospital, 5-1-38 Toyosu Koto-Ku, Tokyo 135-8577, Japan



3. External loop recorder

There are a few studies using ELR for patients with unknown syncope. The diagnostic yield of ELR was higher than standard 24h-Holter monitoring [24], and it was similar to the diagnostic yield of ILR in the same timeframe [25–27]. The limitations of ELR are patient compliance, failure to operate the device correctly, and difficulties handling cutaneous patch electrodes [26]. A cost-effectiveness analysis has indicated that the improvement in diagnostic yield offsets the cost of the ELR and that they are an economically attractive alternative when compared to Holter monitoring [28]. The use of ELR could be viewed as a first-choice tool for patients with early recurrence of syncope [23].





Implantable Loop Recorder: Diagnostic Yield And Possible Therapeutic Effect In Patients With Neurally Mediated Reflex Syncope

Unterhuber M¹, Rauhe W¹, Sgobino P², Pescoller F¹, Manfrin M¹, Tomaino M¹

¹Department of Cardiology, Central Hospital of Bolzano, Italy. ²Emergency Room, Central Hospital of Bolzano, Italy.

In our clinical experience we have found an important number of patients with disappearance of syncope during an observation period of 2,3 and 4 years. At first glance this results may suggest a possible placebo effect of the ILR and can be disappointing in the everyday clinical setting.

Still, this is the most controversial explanation for this phenomenon.

The ISSUE-2 experience gave us the possibility to use ILR as therapy- guiding device.

We analysed 84 patients (39 male and 45 female, mean age 71 years), during the period 2009-2013. 34 patients (40.5%) had not recurrences after a mean follow-up (FU) of 35 months, among these 17 patients concluded a FU of 4 years. 50 patients (59.5%) had recurrences and a specific diagnosis after an average period of 7 ± 8 months.

The prevalent form of neurally mediated syncope was the cardioinhibitory form (26 patients, 31%), followed by vasodepressive NMS (21 patients, 25%).

Tachyarrhythmias were diagnosed in 2 patients (2,4%) and 3rd degree- AV- Block (2 patients, 2,4%).

After these considerations and according to the findings of the scientific literature and our study, we can affirm that the ILR maintains its important diagnostic role, related to the capacity to focus on the electrocardiographic detection at the moment of the clinical loss of consciousness. Controversial is its potential placebo effect, considering the fact that, according to the natural history of NMS, we should monitor patients for a very long period, activity that is not necessary considering the benign condition of this form. For this reason it will be difficult to discriminate between a potential placebo effect of ILR and the statistical "regression to the mean".

Conclusions

The high rate of undiagnosed syncopes despite ILR implantation are most probably attributable to a combination of regression to the mean with not enough long FU- time and the main feature of syncope itself: the cyclicity of syncope.



- **Indicazioni estese negli ultimi anni**
- **Efficacia diagnostica nello studio della sincope dopo assessment primario**
- **Benefici legati al tipo di dispositivo:**
 - ridotte dimensioni del dispositivo;
 - semplificazione della procedura di impianto;
 - riduzione della degenza in ospedale (DH);
 - follow-up da remoto, che quindi aumenta comfort e sicurezza del paziente
- **Benefici legati alla strategia:**
 - Riduzione dei tempi e delle liste d'attesa grazie all'incremento del numero di procedure sostenibile delegando l'impianto a tecnici di cardiologia e infermieri
- **Complicanze rare**
- **Attenzione al corretto utilizzo diagnostico e alla migliore programmazione del device (HM)**

Take Home Messages









- **Sincope riflessa (o neuromediata)**
- È la forma più frequente. Include:
- **Vasovagale** (classica, emotiva, ortostatica prolungata)
- **Situazionale** (tosse, minzione, defecazione, deglutizione, dolore, post-esercizio)
- **Sindrome del seno carotideo**
- **Forme atipiche** senza prodromi, senza un chiaro trigger, presentazione atipica)

