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J. Shah

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# Efficacy of Implantable Loop Recorders in Establishing Symptom-Rhythm Correlation in Young Patients With Syncope and Palpitations

Joseph Rossano, MD\*; Beatrijs Bloemers‡; Narayanswami Sreeram, MD‡; Seshadri Balaji, MDS; and Maully J. Shah, MBBS\*

**ABSTRACT.** *Objective.* To evaluate efficacy of the recently introduced implantable loop recorder (ILR) in establishing symptom-rhythm correlation in young patients with syncope, near syncope, palpitations, and acute life-threatening events (ALTEs).

*Methods.* A retrospective study was conducted with patients with ILR from 3 pediatric centers. Inclusion criteria were age  $\leq 25$  years and a minimum follow-up of 1 month. All ILR-stored events were analyzed regularly for the presence or absence of an arrhythmia at the time of the symptomatic event.

*Results.* Twenty-one patients (12 male, 9 female) with an average age of  $12.3 \pm 5.3$  years (range: 0.8–22 years) were included in the study. Five (24%) patients had structural heart disease, 2 (10%) had a family history of sudden cardiac death, 3 (14%) had QT prolongation on electrocardiogram, and 11 had no cardiovascular disease. Indications for ILR were recurrent syncope and near syncope ( $n = 15$ ), palpitations ( $n = 2$ ), and ALTE ( $n = 2$ ). Fourteen (67%) patients continued to have symptoms, and 7 (33%) had no symptoms after ILR over a follow-up period of  $8.4 \pm 4.7$  months (range: 1.9–16 months). Symptom-rhythm correlation was possible in all 14 patients who continued to have symptoms (supraventricular tachycardia in 4, ventricular tachycardia in 2, torsades de points in 1, asystole in 1, junctional bradycardia in 1, and sinus rhythm in 5).

*Conclusions.* ILR is useful in determining the presence or absence of an arrhythmia during symptoms of syncope, near syncope, and palpitations as well as ALTEs in patients with and without structural heart disease when conventional diagnostic testing, such as electrocardiogram, Holter monitoring, and/or external loop recording, is inconclusive. *Pediatrics* 2003;112:e228–e233. URL: <http://www.pediatrics.org/cgi/content/full/112/3/e228>; *implantable loop recorder, arrhythmias, syncope, palpitations.*

ABBREVIATIONS. HUT, head-up tilt; ECG, electrocardiogram; ELR, external loop recorder; EPS, electrophysiology study; ILR, implantable loop recorder; ALTE, acute life-threatening event; EEG, electroencephalogram; SVT, supraventricular tachycardia;

From the \*Department of Pediatrics, University of Washington School of Medicine, Seattle, Washington; ‡Department of Pediatrics, Wilhelmina Children's Hospital; and §Department of Pediatrics, Oregon Health Sciences University.

Dr Rossano and Beatrijs Bloemers made equal contributions and should be considered first authors.

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Reprint requests to (M.J.S.) Department of Cardiac Pacing and Electrophysiology, Heart Center, Children's Hospital, 4800 Sandpoint Way NE, Seattle, WA 98105. E-mail: mshah@chmc.org

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VT, ventricular tachycardia; RFA, radiofrequency ablation; LQTS, long QT syndrome.

Syncope, near syncope, and palpitations are common symptoms in the pediatric population. These events are frequently a source of concern and anxiety among patients and parents. It is estimated that at least 1 episode of syncope is experienced in 30% of patients by adolescence. Although syncope in children is generally a benign event, in some circumstances, it can herald a potentially lethal problem.<sup>2,3</sup> Finding the underlying cause is important for risk stratification as well as for rendering appropriate therapy. Neurocardiogenic syncope, the most common cause of syncope in young patients, can be diagnosed by a detailed history alone and sometimes warrants a head-up tilt (HUT) test. When other causes are suspected, conventional cardiovascular testing with an electrocardiogram (ECG), ambulatory Holter monitoring, and external loop recorders (ELRs) is implemented. An echocardiogram is performed when structural heart disease is suspected.<sup>4</sup> An electrophysiology study (EPS) is rarely needed in a child with syncope. Unfortunately, conventional cardiovascular tests have a low diagnostic yield.<sup>5–7</sup> The main reason for the reduced diagnostic efficacy of these tests is the difficulty of obtaining symptom-rhythm correlation, when symptoms are unpredictable and infrequent. An ECG at the time of the symptomatic event is the logical gold standard to diagnose or exclude an arrhythmia as the cause of symptoms. However, ambulatory Holter monitoring is generally brief (24–48 hours) and patients are often not symptomatic during this time. The usefulness of the ELR may be limited because of resolution of symptoms by the time the device is activated.<sup>6,7</sup> Recent advances in loop recording technology have led to the development of an implantable loop recorder (ILR; Reveal Plus; Medtronic, Minneapolis, MN) that is active for at least 14 months. This device incorporates a continuous loop recording of the heart rhythm that is stored when the device is activated by the patient, parent, or surrogate. There is also an autoactivation component that allows the device to record rhythms automatically if a patient's heart rate exceeds or goes below a preset limit. Use of this technology in children may increase the probability of making an accurate diagnosis and avoiding other extensive and repetitive testing.

## METHODS

Young patients who had syncope, near syncope, palpitations, and acute life-threatening (ALTEs) events and in whom a definitive diagnosis could not be made with conventional cardiovascular testing underwent implantation of a loop recorder. Conventional testing included surface ECG, Holter monitoring, and ELR. HUT was performed when neurocardiogenic syncope was suspected by the evaluating clinician. EPS, echocardiography, cardiac magnetic resonance imaging, and electroencephalogram (EEG) were performed when indicated.

### ILR Device

The ILR is an 8-cm<sup>3</sup> device that is 61 mm long, 19 mm wide, and 8 mm thick and weighs 17 g (Fig 1). It has battery life of at least 14 months and has 2 surface electrodes. The ILR continuously records a single-lead ECG for up to 42 minutes. The rhythm monitored before, during, and after a symptomatic episode can be stored and recalled using an external activator (Model 6191, Medtronic). In addition, the device can be set to activate automatically, when the patient's intrinsic heart rate goes above or below the preset limits. The programming of the ILR is individually set.

### ILR Implantation Technique

In this study, all devices were implanted under general anesthesia or with conscious sedation using local anesthesia. All devices were implanted by a pediatric electrophysiologist in the cardiac catheterization laboratory or procedure room using sterile precautions. Preimplant surface mapping with standard ECG electrodes was performed in all patients to determine suitable implant location and orientation. The device is nonvascular and is usually implanted in the left pectoral region in a subcutaneous or subpectoral pocket through a 2-cm incision. Implantation at other sites, such as abdominal (patient 6), submammary, and subaxillary, is also possible.

### ILR Programming and Follow-up

The ILRs were programmed at the time of implantation. This procedure included selecting number of patient-activated and autoactivated events to store, parameters for autoactivated events, ECG storage capacity, and optimal sensitivity and gain settings. All patients had regular follow-up after each event to analyze ILR stored events or at monthly intervals if no event occurred. Follow-up occurred at office visits with an electrophysiologist. Event analysis and ILR programming was performed via a programmer (Model 9790) with Model 9809 software (ECM/Vision compatible).

### Stored Events

Stored events are ECGs stored by ILR when the patient activates the device or when the device is automatically triggered when a patient's heart rate is above or below preset limits. All ILR stored events were analyzed for the presence or absence of an arrhythmia. Stored events were categorized into patient-activated events and autoactivated events. ECG captured an event when a patient or a surrogate triggered the ILR with a handheld device activator. ECG captured an event automatically when the detected heart rate was above or below the programmed rates. In this storage mode, bradycardia was characterized by 4 consecutive beats  $\leq 30$  beats per minute, tachycardia was characterized by 16 consecutive beats  $\geq 180$  beats per minute, and asystole was char-

acterized by absence of R waves  $>3$  seconds. These parameters were set independent of the age of the patient.

### Symptom-Rhythm Correlation

When the ILR was triggered at the time of symptoms, events that were stored by ILR were analyzed to distinguish between the presence or absence of an arrhythmia.

### Statistical Analysis

Comparisons were made using the  $\chi^2$  test, and results were considered significant at  $P < .05$ .

## RESULTS

### Patient Characteristics

Twenty-one patients (12 male, 9 female) with a mean age of  $12.3 \pm 5.3$  years (range: 0.8–22 years) were included in the study. Patient characteristics are shown in Table 1. Five (24%) patients had had structural heart disease, 2 (10%) had a family history of sudden cardiac death, 3 (14%) had QT prolongation on ECG, and 11 (52%) had no history of cardiovascular disease. One patient with QT prolongation on the ECG also had a history of recreational drug abuse. Indications for ILR were recurrent or near syncope ( $n = 16$ ), palpitations ( $n = 3$ ), and ALTE ( $n = 2$ ; Table 1). Fourteen (67%) patients continued to have symptoms after ILR over a follow-up period of  $8.4 \pm 4.7$  months (range: 1.9–16.0 months).

### Diagnostic Tests Before ILR

Conventional diagnostic tests before ILR were surface ECG ( $n = 21$ ), 24-hour Holter monitor ( $n = 18$ ), exercise test ( $n = 14$ ), HUT ( $n = 4$ ), ELR ( $n = 8$ ), EPS ( $n = 7$ ), echocardiogram ( $n = 19$ ), cardiac magnetic resonance imaging ( $n = 1$ ), and EEG ( $n = 2$ ). The diagnostic tests were performed at the discretion of each patient's physician.

### Symptom-Rhythm Correlation

The average time when the first event was recorded after ILR was  $4.1 \pm 4.6$  months (range: 0.25–14 months). Symptom-rhythm correlation was possible in all 14 patients who continued to have symptoms. Nine patients had arrhythmias (supraventricular tachycardia [SVT],  $n = 4$ ; ventricular tachycardia [VT],  $n = 2$ ; torsades de points,  $n = 1$ ; asystole,  $n = 1$ ; junctional bradycardia,  $n = 1$ ), and 5 patients had normal sinus rhythm at the time of their symptoms (Table 2). Single-lead ECG recordings of SVT from patient 13 and VT from patient 20 are shown in Figs 2 and 3, respectively. Seven patients had no additional symptoms after implantation.

Fig 1. Implantable loop recorder Reveal Plus.



**TABLE 1.** Clinical Characteristics of Patients at ILR Implantation

Patient No.	Age (Years)	Sex	Underlying Heart Disease	Symptoms
1	17	M	None	Palpitations
2	16.4	M	None	Syncope
3	13.2	F	None	Palpitations
4	20.0	F	None	Syncope
5	6.0	M	None	Syncope
6	0.8	M	None	ALTE
7	9	M	None	Syncope
8	9.9	M	None	ALTE
9	13.4	M	None	Syncope
10	9.5	F	None	Syncope
11	3.3	M	None	Syncope
12	18.8	F	Borderline prolonged QT on ECG	Syncope
13	13.3	F	Borderline prolonged QT on ECG	Syncope
14	11.3	F	Prolonged QT on ECG	Syncope
15	12.9	M	LVH	Syncope
16	22.0	F	Ebstein's anomaly	Syncope
17	8.3	M	TGA, sp ASO	Syncope
18	13.4	F	TGA, sp ASO	Syncope
19	9.5	M	AS, coarctation of Aorta, sp Ross procedure and coarctation repair	Syncope
20	15.4	M	FH of SCD	Palpitations
21	15.4	M	FH of SCD	Syncope

LVH indicates left ventricular hypertrophy; TGA, transposition of great arteries; ASO, arterial switch operation; Sp, status post; AS, aortic stenosis; FH, family history; SCD, sudden cardiac death.

**TABLE 2.** Symptom-Rhythm Correlation in 14 Patients With Symptoms After ILR

Patient No.	Symptom	Rhythm
1	Palpitations	SVT
2	Syncope	NSR
3	Palpitations	SVT
5	Syncope	NSR
6	ALTE	Junctional bradycardia with ST changes
7	Syncope	VT
11	Syncope	NSR
13	Syncope	SVT
14	Syncope	TDP
15	Syncope	NSR
16	Syncope	SVT
17	Syncope	Asystole
20	Palpitations	NS-VT
21	Syncope	NSR

NSR indicates normal sinus rhythm; TDP, torsades de pointes; NS, nonsustained.

### Stored Events

A total of 99 events were stored by devices and available for analysis. Twenty-four (24%) events were patient/surrogate activated, and 75 (75%) were autoactivated. Sixty-six percent of patient-activated events represented an arrhythmia compared with 17% of auto activated events that represented an arrhythmia ( $P < .05$ ; Fig 4). The arrhythmic events recorded during patient/surrogate-activated mode were SVT ( $n = 5$ ), atrial flutter ( $n = 1$ ), ectopic atrial tachycardia ( $n = 2$ ), VT ( $n = 4$ ), torsades de pointes ( $n = 1$ ), premature ventricular contractions ( $n = 2$ ), and 1 event of sinus tachycardia followed abruptly by junctional bradycardia. The last event was caused secondary to Munchausen syndrome by proxy, dur-

ing which the mother was suffocating the infant with a pillow and then recording the event with the activator. The arrhythmic events recorded during auto-activated events were bradycardia ( $n = 2$ ), VT ( $n = 10$ ), asystole ( $n = 1$ ), and SVT ( $n = 4$ ). There was 1 false-positive autoactivated event, which was triggered for tachycardia, but additional analysis revealed double counting as a result of T-wave oversensing in sinus rhythm.

### Outcome of Patients

There were no complications related to ILR implantation. All patients were discharged from the hospital within 24 hours after ILR, with 8 patients being discharged 4 hours after the procedure. A definitive diagnosis of symptoms was made in 11 of the 14 patients in whom symptom-rhythm correlation was possible. In the remaining 3 patients, an arrhythmia could be ruled out as the cause for symptoms (Table 3). Definitive therapy could be rendered to 8 patients with cardiac diagnosis (radio frequency ablation [RFA],  $n = 4$ ; implantation of cardioverter defibrillator,  $n = 1$ ; pacemaker implantation,  $n = 1$ ; antiarrhythmic therapy,  $n = 2$ ). Referral for management of noncardiac causes of symptoms was made in 3 patients (psychological counseling,  $n = 1$ ; maternal psychiatric treatment,  $n = 1$ ; sleep apnea evaluation,  $n = 1$ ). There were no deaths after ILR.

### Patients With Normal Hearts, Normal ECG, and No Family History of Sudden Death

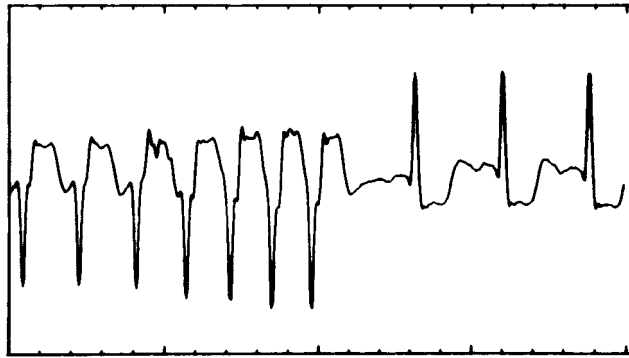
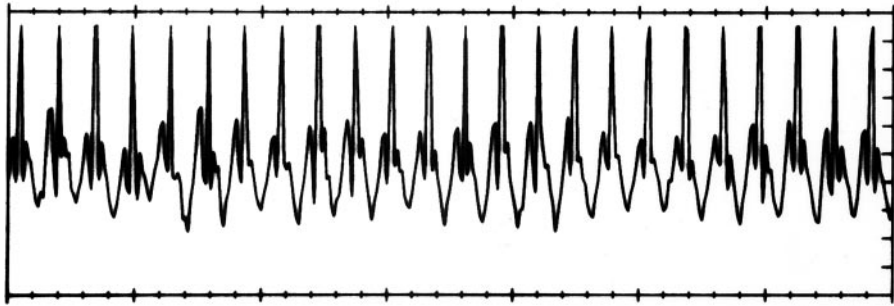
There were 11 patients in this category. In 3 patients, episodes of SVT (patients 1, 3, and 13) were captured by the ILR, and 2 (patients 3 and 13) underwent successful RFA. Patient 1 is treated with an antiarrhythmic medication. In patient 7, a diagnosis of monomorphic VT was made and the patient had an RFA. In 3 patients, normal sinus rhythm was documented during episodes of syncope evoking nonarrhythmic causes for syncope. It is possible that these patients had neurocardiogenic syncope with more vasodepressor than cardioinhibitory response. Four patients remained asymptomatic after ILR.

### Patients With Structural Heart Disease

Three patients had surgery for congenital heart disease (patients 17, 18, and 19). Arrhythmias are a known complication after the arterial switch operation and the Ross procedure.<sup>8,9</sup> Patients 17 and 18 had syncope status after the arterial switch operation. Both patients had an EPS before ILR, and ventricular arrhythmias could not be induced. After ILR, both patients have remained asymptomatic. Patient 17 underwent pacemaker implantation after several ILR autoactivated events demonstrated asystole  $>3$  seconds. He remains free of syncope after pacemaker implantation. Patient 19 had syncope status after the Ross procedure for relief of congenital aortic stenosis. He has not had syncope after ILR. Patient 16 with Ebstein's anomaly of the tricuspid valve had syncope and palpitations. A patient-activated event revealed SVT and subsequently had a successful RFA. Patient 15 with left ventricular hypertrophy had 26 autoactivated events, all of which showed sinus tachycar-



**Fig 2.** The single-lead ECG tracing from ILR in patient 13 showing SVT at 214 beats per minute.



**Fig 3.** The single-lead ECG tracing from ILR in patient 20 shows nonsustained VT with abrupt termination, followed by normal sinus rhythm.

dia, and 1 parent-activated event during syncope, which showed normal sinus rhythm. The latter event demonstrated that the syncope was not related to an arrhythmia.

#### Patients With QTc Prolongation

In patients with familial long QT syndrome (LQTS), syncope is usually caused by torsades de pointes.<sup>10</sup> In patients with borderline QTc and no family history of LQTS, it is difficult to ascertain whether the cause of syncope is a ventricular arrhythmia or another mechanism.<sup>11</sup> Two patients (12 and 13) had a borderline QTc (465 ms and 470 ms, respectively) measurement on their surface ECG with no family history of LQTS. Patient 12 had a history of anorexia and recreational drug use. She was empirically treated with multiple antiarrhythmic drugs at another medical facility because the putative cause of syncope was an arrhythmia. An EPS was negative for inducible arrhythmias. All antiarrhythmics were subsequently discontinued and an ILR was implanted. After ILR, she has had no additional episodes of syncope, suggesting that there may have been a psychogenic component to the syncope. In patient 13, the ILR captured an autoactivated event at the time of syncope that revealed SVT at 190 bpm (Fig 2). A successful RFA was performed with no additional occurrences of syncope. Patient 14 with familial LQTS continued to have self-limited episodes of syncope on  $\beta$ -blockers. A parent-activated event revealed torsades de pointes. An automatic implantable cardioverter defibrillator was placed to prevent sudden death.

#### Patients With Family History of Sudden Cardiac Death

The father of patient 21 had a diagnosis of arrhythmogenic right ventricular dysplasia and succumbed to sudden cardiac death. This patient activated 3 events for near syncope; all events showed normal sinus rhythm, and a potentially life-threatening cause could be ruled out as the cause for symptoms. Patient 20's mother has cardiomyopathy and VT. This patient had an extensive evaluation that included ECG, Holter monitor, ELR, echocardiogram, endomyocardial biopsy, and an EPS, all of which were normal. The patient activated his ILR several times for palpitations, and all events revealed ventricular couplets and 1 run of self-limited VT. Antiarrhythmic therapy with  $\beta$ -blockers was subsequently started. The ILR continues to be used to monitor for recurrence of arrhythmias after treatment.

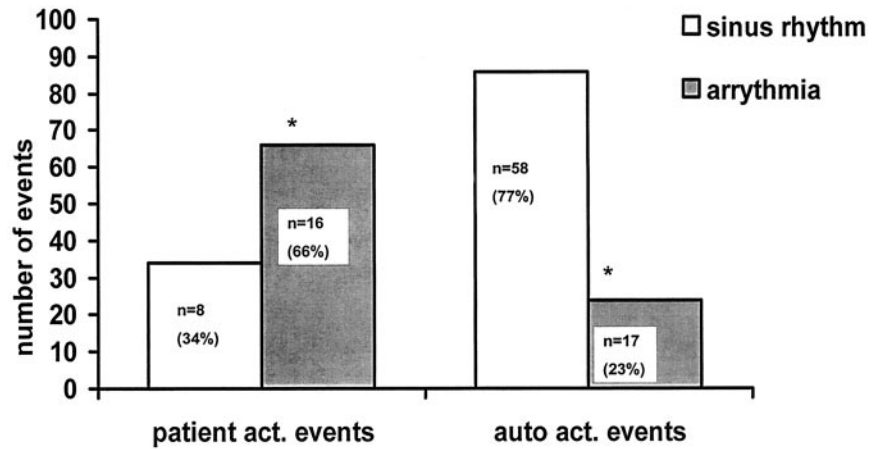
#### ALTEs

The youngest patient in this study is an infant who was evaluated for recurrent life-threatening events. All events were reported by the mother. At the time of performing cardiopulmonary resuscitation, paramedics observed that the patient had an irregular pulse and cyanosis. Despite extensive cardiac work-up, no cause could be identified. After ILR, the mother reported another ALTE. ECG recorded by the ILR showed sinus tachycardia for 3 minutes followed by sudden junctional bradycardia with ST segment changes for 4 minutes, a finding suggestive of ischemia. This was followed by return of sinus rhythm. Additional inquiry resulted in the mother's admitting to suffocating the child with a pillow to precipitate the event. A diagnosis of Munchausen syndrome by proxy was made, and the mother was referred for psychiatric treatment.<sup>12,13</sup> Patient 8 had an ALTE when swimming. Cardiopulmonary resuscitation was performed, and the patient recovered completely. Extensive diagnostic work-up did not reveal any abnormalities. An ILR was implanted to document cardiac rhythm. The patient has not had any more events during a follow-up of 5 months.

#### Psychogenic Syncope

Adolescents and children may also have syncope as a manifestation of hysteria or other psychological problems.<sup>3,14</sup> Psychogenic syncope was suspected in 2 patients. Patient 12 had 4 episodes of syncope in 12 months before ILR and no episodes of syncope after ILR during a follow-up period of 18 months. Patient

**Fig 4.** Total number of patient-activated and autoactivated stored events from ILR of all patients in the study. Patient-activated events consisted of a significantly higher number of events showing arrhythmias than did autoactivated events ( $P < .05$ ). \*Statistically significant at  $P < .05$ .



**TABLE 3.** Patients With Definitive Diagnosis and Their Outcome After ILR

Patient No.	Diagnosis	Outcome
1	SVT	Antiarrhythmic medication
2	Conversion disorder	Psychological evaluation
3	SVT	RFA
5	Sleep apnea	Sleep apnea management
6	Munchausen by proxy	Maternal psychiatric treatment
7	VT	RFA
13	SVT	RFA
14	TDP	ICD
16	SVT	RFA
17	Asystole	Pacemaker
20	NS-VT	Antiarrhythmic medication

ICD indicates implantable cardioverter defibrillator.

2 had an episode of syncope while he was walking on the street. All episodes of syncope occurred in public places. The ILR was activated by his mother and showed normal sinus rhythm. The patient did not regain consciousness for 30 minutes despite documentation of normal blood pressure and heart rate by paramedics and normal serum chemistry from blood sample obtained at that time. EEG was normal. He was suspected of having a conversion disorder and was referred for psychological counseling.

#### Asymptomatic Patients With No ILR Events

Seven of the 22 patients in the study have had no symptoms and no recorded arrhythmias since ILR. One patient (12) described above was thought to have psychogenic syncope. The other 6 patients have a relatively short follow-up (median: 2.5 months; range: 1–4 months).

#### Device Malfunction

There were no instances of device malfunction. There was 1 false-positive autoactivated event for tachycardia as a result of T-wave oversensing. This problem was easily overcome by adjusting the electrogram sensitivity. Electromagnetic interference is a potential source for device malfunction, but this was not encountered in this study.<sup>15</sup>

### DISCUSSION

The vast majority of syncope, near syncope, and palpitations in young patients can be diagnosed eas-

ily with a thoughtful history, physical examination, and perhaps an ECG. The HUT may be of additional help in diagnosing neurocardiogenic syncope.<sup>16</sup> When the history is not suggestive of neurocardiogenic syncope, other causes are considered. Syncope, near syncope, and palpitations may be benign in nature or may be a harbinger of malignant arrhythmias, especially in patients with structural heart disease, primary electrical cardiac abnormalities, and family history of sudden cardiac death.<sup>2,3</sup> It is difficult to sort this out without having the ability to obtain an ECG at the time of the symptomatic event. Typically, patients undergo a cascade of investigations that result in a low diagnostic yield. Alternatively, patients may be treated with empirical medications that may not adequately treat the underlying cause of their symptoms. Holter monitoring allows rhythm evaluation for 1 to 2 days, but often the patient is asymptomatic during the recording. Holter monitoring has a low diagnostic yield, providing a symptom-rhythm correlation in <10% of patients.<sup>4</sup> The use of an ELR increases the likelihood of capturing the rhythm at the time of symptoms, but up to 35% to 50% of pediatric patients will not have a symptom-rhythm correlation.<sup>5,6</sup> Although ELR allows for prolonged ambulatory monitoring for approximately 1 month, its use is sometimes confounded by a high rate of noncompliance. The device must be activated by the parent or the child when symptoms occur. In addition, the device is big and noisy when activated, often drawing attention to the patient, which may further decrease compliance in school-age children and adolescents. Exercise testing can be performed when exercise is suspected to trigger an underlying arrhythmia. However, >50% of patients will not reproduce symptoms during formal exercise testing.<sup>17</sup> The passive HUT test has a high specificity but only a moderate sensitivity in the diagnosis of neurocardiogenic syncope.<sup>18</sup> Echocardiography and invasive EPS have a limited yield in the evaluation of syncope in patients with no cardiac history.<sup>4,19</sup>

In adults with recurrent undiagnosed syncope, ILR technology allowed for symptom-rhythm correlation in 52% to 94% of patients.<sup>20,21</sup> In children and young adults, its diagnostic role has not been defined.<sup>22</sup> In this study of young patients with and

without heart disease, the ILR had a 67% diagnostic yield in establishing the cause for symptoms.

There are 2 main groups of patients who may benefit from ILR technology. One group consists of patients with structural heart disease and primary electrical cardiac abnormalities who have already undergone extensive investigations, including a negative or nondiagnostic EPS.<sup>22</sup> These patients are deemed to be at high risk for developing malignant ventricular arrhythmias. However, presyncope, syncope, and palpitations are common symptoms in the general population and may occur occasionally in this group of patients without being the harbinger of ventricular arrhythmias. The second group is otherwise healthy patients whose clinical course is not consistent with neurocardiogenic syncope and the cause of palpitations cannot be established with ECG, Holter monitoring, or ELR. ILR-mediated symptom-rhythm correlation allows for directing medical therapy appropriately.

### Drawbacks of ILR

The main drawback of ILR technology is that it requires surgical implantation, which results in scar formation. This may not be acceptable to some patients and their families. A second surgical procedure is required to remove the device. There is potential for wound infection, although it was not encountered in this study. In addition, the cost of the device, related surgical procedures, and follow-up clinic visits need consideration, although the ILR has been found to be more cost-effective than conventional diagnostic tests.<sup>23</sup> Muscle movements during seizure activity can result in ECG artifact that may be mistaken for an arrhythmia if not analyzed carefully.<sup>22</sup> Last, there is always the potential that it will not be useful as a diagnostic tool, which will generally occur if the patient does not continue to have symptoms. This occurred in 7 patients in our study. However, most of these patients had a short duration of follow-up time (1–4 months), and it is conceivable that with longer follow-up, the patients will have symptoms captured by the ILR.

### CONCLUSIONS

In our cohort of young patients, ILR was useful in establishing symptom-rhythm correlation in the majority of the patients with syncope, presyncope, and palpitations. Consideration should be given to earlier implementation of this technology to avoid extensive and repetitive diagnostic tests as well as to avoid implementation of empirical therapy for incorrectly assumed cause.

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## Efficacy of Implantable Loop Recorders in Establishing Symptom-Rhythm Correlation in Young Patients With Syncope and Palpitations

Joseph Rossano, Beatrijs Bloemers, Narayanswami Sreeram, Seshadri Balaji and Maully J. Shah

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