

# Are Implantable Loop Recorders Useful in Detecting Arrhythmias in Children with Unexplained Syncope?

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**Introduction:** Syncope and presyncope are symptoms that occur infrequently in children, are unpredictable, and represent a diagnostic challenge to the physician. Conventional diagnostic investigations are often unable to establish a diagnosis, making it difficult to determine patient risk and direct appropriate therapy. The implantable loop recorder (ILR) is a medical device that was created for prolonged monitoring of heart rate and rhythm and has been used in a limited number of pediatric studies in which the cause of the syncope is unknown.

**Methods:** This is a retrospective review of the clinical, surgical, and follow-up data of patients who had ILR devices implanted after conventional testing failed to identify a cause for their symptoms.

**Results:** The diagnostic yield of the ILR device in unmasking the cause for symptoms in our patient cohort was 64%. In our study, manually activated events accounted for 71% of all documented episodes and 68% of the cases involving hemodynamically important arrhythmias or transient rhythm changes. The ILR device can be safely implanted and explanted in children without significant morbidity, in most cases. None of our patients experienced any long-term adverse events associated with placement of the device and all were alive at last follow-up.

**Conclusions:** The use of the ILR device is a useful tool to help unmask arrhythmias as a cause of unexplained syncope in children. Patient selection for who should and should not have an ILR device implanted will continue to influence its diagnostic utility and generate controversy among stakeholders. (PACE 2009; 32:1422–1427)

**implantable loop recorders, syncope, arrhythmias, children**

## Introduction

Syncope and presyncope are common symptoms reported by children and adolescents.<sup>1,2</sup> In older patients, and those without structural heart disease, syncope is most often due to reflex-mediated syncope. In younger patients, and those at-risk for arrhythmias, this is a diagnosis of exclusion. While the etiology is benign in the vast majority of cases, presyncope and syncope may be an ominous sign for serious pathology.<sup>3–5</sup> Although the patient history, family history, and a physical examination are sufficient to make a diagnosis in most cases of syncope,<sup>6</sup> conventional diagnostic investigations are often unable to establish a diagnosis, making it difficult for the physician to determine patient risk and direct appropriate therapy. In a given patient these symptoms may occur infrequently and are unpredictable, and this adds to the difficulty documenting the episodes.

The implantable loop recorder (ILR) (Reveal<sup>®</sup>, Medtronic Inc., Minneapolis, MN, USA) is a medical device that was created for prolonged monitoring of heart rate and rhythm to capture diagnostic information during syncope. The physical dimensions and operational characteristics of the device have previously been described.<sup>3,4,7,8</sup> The platform for the Reveal<sup>®</sup> device has been modified (Reveal DX<sup>®</sup>, Medtronic Inc.) and there are now other devices available (Confirm<sup>™</sup>, St. Jude Medical, St. Paul, MN, USA). As the technology has evolved, the newer devices utilize improved sensing algorithms and have greater longevity. They can be set to activate automatically if the patient's heart rate goes above or below preset threshold limits or can be activated manually by the patient when they experience symptoms. Once activated, they will record the rhythm before, during, and after the event, and store the data so that it can be retrieved for analysis.

While its efficacy has been proven in adults with syncope, its use in children has been reported in a limited number of studies.<sup>3–5,7,8</sup> Rossano et al. reported on 21 children and adolescents who underwent ILR placement.<sup>4</sup> They were able to establish the association between symptoms and the underlying heart rhythm in all patients who continued to have symptoms. Kothari et al. reported

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on 18 pediatric patients, who had ILR placement.<sup>8</sup> Sixteen of 18 patients had an inappropriate activation of their ILR as a result of either a rhythm artifact or sinus tachycardia. Gass et al. reported on 12 children in whom there were multiple syncope episodes in nine of 12, with the ILR capturing arrhythmias in four and ruling-out arrhythmias in the remaining five.<sup>7</sup> Frangini et al. recently conducted a retrospective review of 27 consecutive pediatric patients and young adults who underwent ILR implantation at Boston Children's Hospital.<sup>3</sup> The ILR was found to have high diagnostic utility (95%), with no life-threatening events detected.

All of these studies support the use of the ILR device as a diagnostic tool to investigate selected patients with unexplained clinical symptoms that are usually associated with arrhythmias. As part of our review we wanted to evaluate the clinical utility of the device and to evaluate safety issues surrounding implantation, especially in lieu of the high prevalence of "high risk" patients with underlying structural heart disease and arrhythmias in our clinical practice.

## Methods

### Study Design

We conducted a retrospective review of the clinical, surgical, and follow-up data of all consecutive patients who presented to our clinics with symptoms of syncope, presyncope, palpitations, chest pain, or exercise intolerance. In these patients, conventional diagnostic testing did not provide a definitive diagnosis that could explain the presenting symptoms. As a result, an ILR device was inserted to identify arrhythmias, to provide a definitive diagnosis, and to guide patient management. The medical records of all patients who underwent ILR insertion between January 1, 1999, and December 31, 2006, at British Columbia Children's Hospital, Vancouver, and The Hospital for Sick Children, Toronto, were reviewed. We received ethical approval to conduct our study from Institutional Review Boards at both sites.

### ILR Implantation

All ILR devices were placed in the operating room by a cardiac surgeon or in the electrophysiology lab by a cardiac electrophysiologist with the patient under general anesthesia. All devices were implanted subcutaneously in the left prepectoral region using a small incision to minimize scarring. Mapping to identify the maximal recorded R-wave amplitude and to optimize the quality of the electrocardiogram (ECG) was done in all cases. Patients were typically discharged the same day.

### Statistical Analysis

Contingency tables were generated for all categorical data. Frequencies (percentages) were extracted from the tables. Group differences for categorical data were analyzed using the  $\chi^2$  test. A univariate procedure was used to analyze all continuous variables with the median (range of values) reported. Group differences for continuous variables were analyzed using the Wilcoxon Rank-Sum test. A P-value < 0.05 was used to indicate statistical significance. All statistical analyses were performed using SAS 9.3.1 Statistical Software (SAS Institute, Cary, NC, USA).

### Results

Forty-two patients (25 males) with a median age of 11.5 years (1.4–19.0 years) at the time of ILR insertion were included in this study. Eighteen patients had underlying structural heart disease; two had structurally normal hearts, but had a prolonged QTc on their initial ECG; three had structurally normal hearts, but had a family history of sudden unexpected death (SUD); and five had structurally normal hearts, but had a prolonged QTc on their initial ECG and a family history of SUD. For the purposes of our study, these 28 patients formed the *High Risk Group or HRG* for arrhythmias. Fourteen patients had structurally normal hearts and ECGs and formed our *Low Risk Group or LRG*.

All of the patients had ECGs and echocardiograms prior to insertion of the ILR device. Among our cohort 13 of 42 patients (31%) had abnormal ECGs, while 16 of 42 (38%) had abnormal echocardiograms. Thirty-eight patients (90%) had Holter monitoring with abnormal findings reported in seven of 38 cases (18%). Telephone transmitters were used in 15 of 42 patients (36%) with abnormal results reported in three of 15 cases (20%). Cardiac electrophysiology studies were performed in 11 of 42 patients (26%) with abnormal test results reported in one of 11 cases (9%). Tilt table tests were done in eight of 42 patients (19%) with abnormal results reported in one of eight cases (13%). Despite a number of abnormal test results in these patients, conventional diagnostic testing did not provide a definitive diagnosis that could explain the presenting symptoms and, as a result, an ILR device was inserted.

At the time of implantation, 29 of 42 patients (70%) had ILR device placement for syncope, four of 42 (9%) for palpitations, four of 42 (9%) for chest pain, and three of 42 (7%) for near-syncope, while the remaining two patients (5%) had device placement for cyanosis or pallor (Table I).

**Table I.**

Indications for ILR Placement (Columns) and the Number of Patients per Indication (in Parentheses). The Number of Patients with Each ILR Diagnosis Is Listed (Rows)

ILR Diagnosis	Indication				
	Syncope (N = 29)	Palpitations (N = 4)	Chest Pain (N = 4)	Near Syncope (N = 3)	Other (N = 2)
Reflex-mediated syncope	14		2		
Seizures	2			1	
Arrhythmias	2	1		1	1
Other-exclude arrhythmia	3				
No diagnosis	8	3	2	1	1

ILR = internal loop recorder.

### Patients with CHD or Inherited Life-Threatening Arrhythmias (HRG)

There were 18 patients with underlying structural heart disease. In these patients, the ILR device was implanted at a median age of 10.8 years (1.4–19.0 years). Hemodynamically important arrhythmias were ruled out in 16 of 18 patients (89%). One had previously undergone heart transplantation for hypoplastic left heart syndrome. He developed complete heart block and had a single-chamber pacemaker inserted. The ILR device captured intermittent complete heart block, and he subsequently had a dual-chamber pacemaker inserted. The second patient had arrhythmogenic right ventricular cardiomyopathy that was diagnosed during an endomyocardial biopsy procedure. This patient presented with frequent syncopal episodes for which the ILR device was implanted. No events were recorded by the device while it was implanted. While in the hospital, awaiting explantation of the device, he experienced a syncopal episode that was not recorded by the ILR device because the battery had reached its end-of-life. Fortunately, the episode was documented as ventricular tachycardia with a surface ECG and an implantable cardiac defibrillator was inserted.

Five patients with structurally normal hearts were found to have abnormal ECGs. All of these patients were found to have long QT syndrome (LQTS), two with a QTc between 450 ms and 465 ms and three with a QTc between 500 ms and 550 ms. Eight patients had a family history of SUD, including three of the patients with LQTS. Among the patients with either LQTS or a family history of SUD, the ILR device was implanted at a median age of 9.7 years (7.2–13.4 years). Arrhythmias were ruled out as a cause of symptoms in all but one of these patients. This patient was

found to have high grade, transient second-degree atrioventricular block that required him to have a pacemaker implanted.

### Patients Without CHD or Inherited Life-Threatening Arrhythmias (LRG)

There were 14 patients (33%) with normal ECGs and echocardiograms. In these patients, the ILR device was implanted at a median age of 12.4 years (2.7–17.5 years). Twelve patients presented with syncope, one patient presented with frequent palpitations, and one patient presented with cyanosis. The ILR recorded events in 10 of 12 patients (83%) who presented with syncope. Hemodynamically important arrhythmias were ruled out in 12 of 14 of these patients (86%). Among the patients with hemodynamically important arrhythmias, one had a documented syncopal episode associated with sinus tachycardia. In the patient who presented with frequent palpitations, the ILR recorded several bouts of supraventricular tachycardia with a maximum rate of 240 bpm. He was referred for a cardiac electrophysiology study that showed dual atrioventricular node reentry tachycardia. He was successfully treated with cryoablation therapy. The other patient had a documented syncopal episode associated with asystole and, as a result, had a single-chamber pacemaker implanted.

### Events Recorded by the ILR Device

There were 65 events recorded by the ILR device. Seventy-one percent (46/65) of these events were manually activated. On only one occasion was the ILR device automatically activated because of under-sensing. Manually activated events were associated with hemodynamically important arrhythmias or transient rhythm changes in 68% of cases.

Hemodynamically important arrhythmias were ruled out in 29 of 34 patients with symptoms (85.3%). Among the five patients with hemodynamically important arrhythmias on the ILR, all had a normal ECG and only one patient had a family history that included SUD. All five patients required a pacemaker with/without an internal cardiac defibrillator or cryoablation therapy.

Seizures were entertained in three patients as the ILR device recorded sinus tachycardia during an event that clinically appeared to be a seizure. This led to further neurologic investigations resulting in two of the three patients being prescribed anti-seizure medication. The third patient was known to have epilepsy, but because of the atypical nature of the seizure activity, it was thought that the syncope occurred secondary to underlying cardiac pathology. This hypothesis was later ruled out by ILR device interrogation.

Eight patients did not experience any symptoms during the period of time the device was implanted and, in these patients, no events were recorded by the device.

**Complications**

Three patients had complications associated with implantation of the ILR device. Two of the patients developed superficial wound infections around the site where the device was implanted. The wounds were treated with appropriate antibiotics and promptly resolved. The other had a tight pocket where the size of the device appeared too large for the patient with noticeable skin stretching. This led to early explantation of the device after only 2 weeks.

**Outcomes, Explantation, and Follow-Up**

The ILR device was able to confirm a diagnosis, or rule out an arrhythmia as a cause for symptoms in 21 of 29 patients (72%) who initially presented with syncope: one of four patients (25%) with palpitations, two of four patients (50%) with chest pain, two of three patients (67%) with near-syncope, 1/1 patient (100%) with cyanosis, and 0/1 patient (0%) with pallor.

Among the 21 patients who presented with syncope, 14 of 21 (67%) were diagnosed with reflex-mediated syncope, two of 21 (9%) with seizures, and two of 21 (9%) with arrhythmias, while in three of 21 (15%) other causes were found, but we were able to rule out arrhythmias as a possible etiology. The two patients who presented with chest pain were both diagnosed with reflex-mediated syncope, while the two patients with presyncope were diagnosed with either seizures or an arrhythmia. The patients who presented with palpitations or cyanosis were both diagnosed with arrhythmias. Therefore, in our co-

hort the diagnostic yield of ILR device placement in establishing the cause for symptoms, or excluding an arrhythmia as the cause of symptoms, was 64%. In 15 of 42 patients (36%) no clear diagnosis was reached, although no arrhythmias were recorded during the period of time the ILR device was implanted.

There was a trend for patients in the HRG to have their ILR devices inserted at an earlier age (9.7 vs. 12.4 years;  $P > 0.05$ ) and to experience multiple recorded events (15/23 vs. 8/19 patients;  $P > 0.05$ ) when compared to patients in the LRG, although these differences did not reach statistical significance. Patients in the HRG had a longer QTc interval (443 vs. 400 ms;  $P < 0.0008$ ) when compared to those in the LRG. Patients in both groups reported a similar frequency of symptoms while the device was implanted (1.0 vs. 1.0;  $P > 0.05$ ). Interestingly, patients in the LRG were more likely to have their diagnosis confirmed by the ILR device (12/14 vs. 15/28 patients;  $P < 0.04$ ) (Table II). The length of implantation was similar for both groups (14.8 vs. 13.5 months,  $P > 0.05$ ), although patients in the HRG were followed for a longer period of time (21.3 vs. 12.0 months;  $P < 0.02$ ).

The ILR device was explanted in all of our patients after a median of 14.1 months (0.5–24.5) use. The device was explanted in 24 of 42 patients (57%) because a definitive diagnosis was reached, in 17 of 42 (41%) because the ILR battery had reached its end-of-life, and in one of 42 (2%) because of a tight ILR pocket. No adverse events occurred during explantation of the device

**Table II.**

ILR Diagnosis for Each of Our Patient Cohorts. Patients Without CHD, LQTS, or a Family History of SUD Were More Likely to Have a Diagnosis Confirmed by the ILR Device ( $P < 0.04$ )

	CHD (N = 18)	LQTS/Fam Hx SUD (N = 10)	No CHD/ LQTS/Fam Hx SUD (N = 14)
Reflex-mediated syncope	7	3	6
Seizures	1	1	1
Arrhythmias	2	1	2
Other	—	—	3
No diagnosis/arrhythmias	8	5	2

CHD = congenital heart disease; ILR = internal loop recorder; LQTS/Fam Hx SUD = long QT syndrome/family history of sudden unexpected death.

or during follow-up. Symptoms have resolved in 36 of 42 patients (86%). All of our patients were alive at a median follow-up of 19.0 months (0.5–78.8 months).

### Discussion

There are relatively few studies that review the use of ILR devices in children.<sup>3–5,7–9</sup> This study provides a review of our experience with ILR device placement in 42 children, and presents the results from the largest series of pediatric patients published to-date.

The diagnostic yield of ILR device placement in establishing the cause for symptoms in our patient cohort was 64%. This is similar to the diagnostic yield of 67% reported by Rossano et al. for their cohort of children with and without heart disease,<sup>4</sup> and is marginally higher than the diagnostic yield of 50% reported by Kothari et al. for children who had ILR devices implanted for syncope.<sup>8</sup> Our diagnostic yield is significantly lower than the 95% (19/20 cases) reported by Frangini et al.<sup>3</sup> However, when you analyze the cases in which a definitive diagnosis was made in their entire cohort of patients with and without symptoms, their diagnostic yield is reduced to 70.3% (19/27 cases). Ermis et al. reported a diagnostic yield of 38% for their cohort of adult patients with recurrent syncope and grade 0–1 arrhythmias, and 60% for patients with grade 0–3 arrhythmias.<sup>10</sup>

The selection of which patients will benefit from ILR device placement is essential for ensuring that the device will provide a high diagnostic yield. For example, Frangini et al. suggest that the ILR device is a good diagnostic tool in patients with recurrent syncope or palpitations, but should not be used in patients with acute, life-threatening events or episodes that required resuscitation procedures.<sup>3</sup> Rossano et al. suggest that there are two groups of patients who may benefit most from ILR device placement: those with structural heart disease and primary cardiac electrical abnormalities who are at high risk for malignant arrhythmias and have already had extensive conventional diagnostic testing without a diagnosis, and otherwise healthy patients whose clinical course is not consistent with neurocardiogenic syncope and the cause of the symptoms cannot be diagnosed with conventional diagnostic testing such as an ECG or Holter monitoring.<sup>4</sup>

Ermis et al. used an arrhythmia classification scheme to categorize their patients and suggest that the value of this approach may be clinically important in cases in which the prevalence of syncope is lower than expected. This scheme offers the potential to obtain diagnostic information in cases where arrhythmias occur in the absence of symptoms, where arrhythmias may incapacitate

patients, and in cases where the patient may not be able to manually activate the ILR device.<sup>10</sup>

Our series included a large number of patients with risk factors for arrhythmias including 18 patients with structural heart disease and 10 patients with LQTS and/or SUD. Interestingly, patients without these risk factors were more likely to have their diagnosis confirmed by the ILR device. Although our study involved two centers and a number of referring physicians, we believe that the threshold used to determine whether or not to implant the loop recorder was lower in these high-risk patients. This may reflect a reluctance to make the diagnosis of reflex-mediated syncope, perhaps more so by those less familiar with the condition. Therefore, even in those high-risk patients who present with typical reflex-mediated syncope, there is a need to exclude a more ominous underlying etiology.<sup>11,12</sup> The finding of sinus rhythm during symptoms in a significant number of these patients highlights another potential use of the ILR, that is, to exclude hemodynamically important arrhythmias in our high-risk patients.

In our study, manually activated events accounted for 71% of all documented episodes and 68% of the cases involving malignant arrhythmias or transient rhythm changes. Rossano et al. reported that 60% of all manually activated events were associated with arrhythmias, while only 17% of automatic-activated events were associated with arrhythmias.<sup>4</sup>

This contrasts the findings of the study by Ermis et al. involving a cohort of 50 adult patients who had ILR device placement to investigate the cause of recurrent syncope. They reported that automatically activated events accounted for 86.9% of all the documented arrhythmia episodes and 87.1% of all arrhythmia diagnosis.<sup>10</sup> The authors concluded that automatic-activation features of the second-generation ILRs were more effective than manual-activation features for detecting arrhythmias, and that automatic-activation of the ILR device increased the likelihood of making a definitive diagnosis in the absence of syncope.<sup>10</sup> In their paper, Kothari et al. point out an important limitation of ILR device use in children that may help to explain these discrepant results. They believe that the automatic-activation features of the ILR device fails to distinguish between malignant arrhythmias such as polymorphic ventricular tachycardia, noise, and sinus rhythm and leaves it up to the child or a family member to activate the device manually during an event.<sup>8</sup>

In a study of 167 adult patients with recurrent unexplained syncope, Assar et al. found that 75% of the syncopal episodes were captured by the ILR device within the first 6 months of monitoring and 90% within the first 12 months of

monitoring.<sup>13</sup> During the monitoring period, they identified the risk factors for syncope as age less than 65 years, more than three preimplant syncope episodes, and the absence of heart disease.<sup>13</sup> This might dictate the need for longer monitoring periods in patients in which there is a high suspicion of an arrhythmogenic etiology that is associated with infrequent or rare syncope episode(s). The newer generation of ILR devices with an extended battery life of 3 years may help to overcome this issue.

Only one of the pediatric studies that we reviewed reported the death of a child with the ILR device in place.<sup>8</sup> This occurred in a 15-year-old boy who died suddenly at home. He had no previous activation of his ILR device during the 5 months it was implanted, but it was activated just prior to the boy's death, although a cause of death was never determined.<sup>8</sup> Frangini et al. reported that two children developed localized pocket infections and had to have their devices explanted after 1 and 4 months use,<sup>3</sup> while one of our patients had to have their device removed because of an undersized ILR pocket after only 2 weeks use. Two of our patients developed superficial wound infections around the site where the device was implanted. The wounds were treated with appropriate antibiotics and the infections promptly resolved without the need to explant the device. Complications relating to the surgical implantation or explantation of an ILR device have not been reported.<sup>3-5,7-9</sup>

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## Conclusions

The ILR device is an important diagnostic tool that can be used to document arrhythmias associated with unexplained symptoms in children. The diagnostic yield of the ILR device in establishing the cause for symptoms in our patient cohort was 64%, and compares favorably with the results published from other pediatric studies. The selection of which patients will benefit from ILR device placement is essential for ensuring that the device will provide a high diagnostic yield. Additionally, the utility of the device may be to exclude hemodynamic important arrhythmias in patients thought to be at high risk, sometimes to provide reassurance to referring physicians, patients, and their families.

In our study, manually activated events accounted for 71% of all documented episodes and 68% of the cases involving malignant arrhythmias or transient rhythm changes. Our findings are similar to those reported for other pediatric studies, but contrast the findings of adult studies that show that automatically activated events account for the majority of documented arrhythmia episodes.

The ILR device can be safely implanted and explanted without significant complications, in most cases. In our series, two patients experienced wound infections that were treated successfully with appropriate antibiotics and another had a tight ILR pocket that required that the device be explanted after only 2 weeks of use. All of our patients were alive at last follow-up.