**A retrospective study of the clinical experience of the implantable loop recorder in a paediatric setting**

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**SUMMARY**

The implantable loop recorder (ILR) has proved highly efficacious in the management of syncope, presyncope and palpitations in selected populations. Limited information regarding patient selection and diagnostic yield exists in the paediatric setting. A retrospective evaluation of patients who underwent ILR implantation over a 66-month period, in a tertiary paediatric cardiology unit was conducted. Twenty-three patients (10 male, 13 female) following initial assessment and investigation, were referred for device implantation. The mean age at time of ILR insertion was 11.39 ± 4.34 (range, 2.0–16.8) years. The indications for ILR were recurrent syncope (n = 11), presyncope (n = 3) or palpitations (n = 9). Four (17.4%) patients had structural heart disease, three (13%) had a positive family history of sudden cardiac death and one (4%) had perinatal arrhythmia. One patient required ILR repositioning, and pocket infection necessitated explantation in one further patient. Minimum follow-up was 7.8 months during which symptoms were reported in 15 (65.2%) patients post-ILR insertion. Eight (34.7%) remained asymptomatic. Of the 15 who experienced symptom recurrence, eight (53.3%) had an arrhythmia recorded. Tachycardias recorded were polymorphic ventricular tachycardia (n = 1) and supraventricular tachycardia (n = 5). Clinically significant bradycardias documented, included sinus arrest (n = 1) and Mobitz type II second degree atrioventricular block (n = 1). The ILR had a high diagnostic yield, enabling an arrhythmic or non-arrhythmic diagnosis in 65.2% of patients with recurrent syncope, presyncope or palpitations in a selected paediatric population.

**Introduction**

Recurrent syncope, presyncope and palpitations are common symptoms prompting cardiac valuation in the paediatric setting. The reported incidence of syncope in the general population was 6.2 per 1000 person-years in the Framingham Heart Study (1). This study excluded children and adolescents, up to 25% of whom, may have one or more syncopal episode by early adulthood (2).

Despite the fact that many paediatric patients who experience syncope do not undergo medical evaluation, it comprises the presenting complaint in 3–5% of emergency room assessments in the USA (3,4). Neurocardiogenic and cardiac causes account for most presentations, with rarer causes of syncope resulting from psychogenic and metabolic disorders. Compared with the adult population the causative factor for syncope or presyncope in paediatric patients, is more likely to be benign. However potentially life-threatening diagnoses, such as inherited arrhythmogenic disorders or structural heart disease including hypertrophic cardiomyopathy must be identified, to allow appropriate management.

Like syncope and presyncope, the abnormal awareness of an irregular or unusually strong heart beat or palpitation, is a frequent presenting symptom. These symptoms together with chest pain, accounted for over 20% of referrals to the paediatric cardiology department in a tertiary academic hospital (5). Other common symptom manifestations of arrhythmia are dyspnoea and dizziness. Less-specific complaints include nausea, pallor and general malaise. Again the challenge for the clinician involves distinguishing the uncommon potentially lethal arrhythmia from the benign.

The initial assessment of patients involves a thorough clinical history and physical examination. Where a cardiac cause is suspected, electrocardiography (ECG) and echocardiography are usually performed. This initial evaluation is diagnostic in 60% of patients with syncope (6).
diagnosis of an arrhythmia-induced event is an ECG recording prior to and encompassing the symptomatic event. However, because of the episodic nature of the patient’s syncope or palpitations, this frequently necessitates other strategies. Symptom-rhythm correlation with ambulatory Holter and external loop recording remains poor, particularly amongst young children. The diagnostic yield for Holter monitoring is <10% (7). Transtelephonic electrocardiographic monitoring (TTM) offers the possibility of extended ECG monitoring. TTM enabled a diagnosis to be made in 48% of children and adolescents with suspected arrhythmia in one series. However the authors of this study concluded that TTM were not useful for the investigation of paediatric syncope or presyncope (8).

The development of the implantable loop recorder (ILR) allowing ECG monitoring over a prolonged period, has proved useful in evaluating patients with infrequent syncope or palpitations, whose diagnosis has eluded conventional investigations (9). The successful correlation of patient symptoms and cardiac rhythm employing the ILR, has been shown to be as high as 86% in one multicentre adult study of recurrent syncope (10). Less information regarding the efficacy of the ILR exists in the paediatric clinical setting. The purpose of this retrospective study was to evaluate our clinical experience using the ILR in a national paediatric cardiology unit over a 5½-year period.

**Methods**

Medical records of all patients who underwent ILR implantation between 1 January 2000 and 31 July 2005 at Our Lady’s Hospital for Sick Children were reviewed. Written informed consent was obtained from the patient’s legal guardian in each case. All patients referred for ILR had been assessed, and investigated by a paediatric consultant cardiologist. Baseline evaluation consisted of comprehensive history, physical examination, 12 lead ECG, 2D echocardiography and extended ECG monitoring (Holter or external loop recording) in each patient. Continuous variables are presented as mean ± standard deviation. SPSS V14 for Windows (SPSS, Chicago, IL) was used.

**Implantable loop recorder device and implantation**

Patients received either a Reveal ILR (model 9525; Medtronic, Minneapolis, MN) or an ILR with the addition of an auto activation capability-Reveal Plus (model 9526; Medtronic). This additional feature allows automatic ECG recording if the heart rate exceeds a programmed upper limit or drops below a set lower rate threshold. The technical details of both devices have been previously described (11). The ILR was inserted under general anaesthesia in all patients. The implantation site was chosen after surface mapping insured adequate ECG recording capability. The ILR was placed subcutaneously in the left or right parasternal area. Standard implantation technique was performed with the routine administration of prophylactic antibiotics. The ILRs were programmed postimplantation and patients (where feasible) along with parents/guardians were educated in event recording, using the external remote control. Patients were usually discharged within 24 h and were followed-up at 3-month intervals with device interrogation performed using a standard pacemaker programmer (Medtronic) at the cardiology outpatient clinics. They were advised to attend as soon as possible after a symptomatic recurrence.

**Results**

A total of twenty-three patients (10 male, 13 female) with a mean age of 11.39 ± 4.34 (range, 2.0–16.8) years were deemed appropriate for ILR insertion and were included in this study. Table 1 shows the clinical characteristics of the patients. Four (17.4%) patients had documented structural heart disease. Three (13.0%) had a positive family history of sudden cardiac death, while two (8.7%) patients had a previous history of arrhythmia; supraventricular tachycardia (SVT) (n = 1) and ventricular tachycardia (n = 1). Patient 7 experienced paroxysmal atrial fibrillation in the perinatal period. Patient 10 had transient borderline Long QT but did not fulfill the definitive diagnostic criteria for Long QT syndrome (12). A Holter recording was suggestive of a short run of non-sustained mono-morphic ventricular tachycardia. Thirteen (73.9%) had no relevant cardiovascular history at the time of presentation. In addition to the first tier of investigations, other tests performed prior to the receipt of an ILR were tilt testing (n = 2), exercise stress test (n = 2), CT Brain (n = 3), cardiac catheterisation (n = 1), electroencephalography (n = 2) and electrophysiological study (n = 3). None of these additional investigations yielded any significant abnormality which could account for the patient’s symptoms in each case. Nineteen patients had a Reveal Plus ILR implanted, and four received the Reveal device. One (4.3%) patient developed infection of the ILR pocket necessitating removal, while patient no. 10 had the ILR repositioned caused by local discomfort. The flow chart (Figure 1) outlines patient outcomes.
Recurrence of symptoms
Fifteen (65.2%) patients went on to experience further symptoms (syncope, presyncope or palpitations) after ILR implantation. The median time from ILR implantation to arrhythmia capture was 30 days (range 9–390 days). Of these, eight (53.3%) self-activated the ILR, while three patients had ILR activation performed by a relative during symptom events. Four patients had their events recorded automatically – two bradyarrhythmias (patients 14 and 20) and two tachyarrhythmias (patients 1 and 15). In total, eight (34.8%) patients had a significant arrhythmia recorded. See Table 2 for details.

Syncope and presyncope
Fourteen (60.9%) patients underwent ILR monitoring for recurrent syncope or presyncope. Three had structural heart disease, all of whom went on to experience further symptoms post-ILR implantation. The only significant arrhythmia documented in this group was polymorphic ventricular tachycardia (n = 1). For those patients without structural heart disease (n = 11), seven experienced symptom recurrence. The following arrhythmias were recorded during symptoms: SVT (n = 1), sinus arrest of 2.5 s (n = 1) and type II atrioventricular (AV) block (n = 1). The remaining four had normal sinus rhythm during symptom episodes.

Palpitations
Nine (39.1%) patients had an ILR for recurrent palpitations, of whom one had structural heart disease (patient 9). This patient had no further symptoms post-ILR insertion. Four of the remaining eight patients, without a previous cardiac history, were diagnosed with SVT. One patient had normal sinus rhythm recorded during symptoms.

Asymptomatic group post-ILR
Eight (34.7%) patients had no further symptoms postdevice implantation. Half of these patients had ILRs inserted for recurrent syncope or presyncope. Only two (25%) of these patients still have an ILR in situ and both have remained symptom free for 7 months or more. Like all patients in this study, those who remained asymptomatic had a history of two or more symptom events prior to receiving an ILR.

### Table 1: Clinical characteristics of patients who underwent ILR insertion

| Patient no. | Age (years) | Sex | Significant cardiac history | Indication for ILR | ILR recording during symptoms |
|-------------|-------------|-----|-----------------------------|--------------------|-------------------------------|
| 1           | 13.2        | M   | None                        | Palpitations       | SVT                           |
| 2           | 10.5        | F   | None                        | Syncope            | NSR                           |
| 3           | 13.7        | M   | None                        | Presyncope         | SVT                           |
| 4           | 14.1        | M   | None                        | Palpitations       | N/A                           |
| 5           | 9.8         | M   | None                        | Syncope            | N/A                           |
| 6           | 14.7        | F   | None                        | Syncope            | Sinus tachycardia             |
| 7           | 6.9         | M   | Perinatal SVT               | Palpitations       | SVT                           |
| 8           | 14.4        | F   | None                        | Palpitations       | N/A                           |
| 9           | 3.1         | M   | VSD + PFO closure           | Palpitations       | N/A                           |
| 10          | 5.5         | F   | Possible Long QT/Possible VT| Palpitations       | N/A                           |
| 11          | 10.4        | M   | None                        | Presyncope         | N/A                           |
| 12          | 14.1        | F   | None                        | Syncope            | N/A                           |
| 13          | 11.8        | F   | None                        | Syncope            | NSR                           |
| 14          | 3.8         | F   | None                        | Presyncope         | Type II AV block              |
| 15          | 15.3        | F   | None                        | Palpitations       | SVT                           |
| 16          | 14.8        | M   | None                        | Palpitations       | SVT                           |
| 17          | 15.8        | F   | None                        | Syncope            | Sinus tachycardia             |
| 18          | 15.3        | F   | None                        | Syncope            | N/A                           |
| 19          | 2.0         | M   | None                        | Palpitations       | Sinus tachycardia             |
| 20          | 14.0        | F   | None                        | Presyncope         | PVCs 2.5 s sinus arrest       |
| 21          | 16.8        | F   | Double inlet LV, TGA, PDA, ASD| Syncope            | Sinus bradycardia             |
| 22          | 10.3        | F   | RVOT stenosis, VSD          | Presyncope         | Sinus tachycardia             |
| 23          | 11.8        | M   | ASD                         | Syncope            | Polymorphic VT                |

ILR, implantable loop recorder; SVT, supraventricular tachycardia; NSR, normal sinus rhythm; N/A, not applicable – patient did not experience further symptoms post-ILR insertion; VSD, ventricular septal defect; PFO, patent foramen ovale; PVC, premature ventricular complex; LV, left ventricle; TGA, transposition of great arteries; PDA, patent ductus arteriosus; ASD, atrial septal defect; RVOT, right ventricular outflow tract; VT, ventricular tachycardia.
Discussion

Since its introduction in 1995, the ILR has proved to be useful in the detection of suspected cardiac arrhythmia, where conventional extended ECG monitoring has failed. In this retrospective study, the ILR resulted in successful symptom-rhythm correlation in 65.2% of children and adolescents. The lower diagnostic yield in comparison with several adult ILR studies may be influenced by patient selection. This
may somewhat be explained by the difficulty in obtaining an accurate history of the exact nature of symptoms in young children. Indeed, our findings were similar to previous reports of ILR usage in children and adolescents. A diagnostic yield of 50–67% in determining the aetiology of syncope or palpitations in young patients was reported in two retrospective studies (13,14). The additional technical features of the Reveal Plus ILR, incorporating an auto activation capability enhances its diagnostic yield. This is especially relevant in young children where self activation using the remote device may be challenging. One quarter of events were detected with this feature while the remainder were recorded after device activation by the patient (56.2%) or parent/relative (18.8%). The effectiveness of the ILR to automatically record episodes when the heart rate exceeds preprogrammed upper and lower limits, thereby improving the probability of arrhythmia detection, has been reported (15).

We found that the utilisation of the ILR allowed a specific therapeutic strategy to be implemented in 34.8% of patients. The higher incidence of tachyarrhythmia-induced symptoms (62.5%) was comparable with similar ILR paediatric study reports (12). In contrast, symptomatic bradycardia was almost three times more common in a large adult study involving 206 patients (16). The two bradycardias recorded (patients 14 and 20) were Mobitz Type II Atrioventricular block and sinus arrest respectively. Guardians of patient 14 were advised that she undergo permanent pacemaker implantation, however, she was subsequently lost to follow-up. Patient 20 underwent a comprehensive electrophysiology study which demonstrated a normal conducting system with no evidence of sinus or AV nodal incompetence. It was concluded that her presyncope was vagally mediated. This may relate to the more frequent use of electrophysiology studies as part of the initial adult work-up. Only 13.0% of our patients underwent EP studies prior to receiving an ILR, contrasting with 46% in the aforementioned ILR adult study. Four patients subsequently underwent electrophysiological study with radiofrequency ablation. Patient 1 commenced antiarrhythmic medication. In addition to betablockade, patient 23, who had documented polymorphic ventricular tachycardia, received an implantable cardiac defibrillator.

Patients (46.7%) who were symptomatic post-ILR insertion had non-arrhythmic-related events. Patient 6 was diagnosed with neurocardiogenic syncope and patient 2 with epilepsy. The ability to exclude an arrhythmia as the event mechanism provides considerable reassurance to the patient and family. In addition this helps direct further clinical investigation, if deemed necessary. Frequently, recurrent syncope in this setting resolves in the majority of patients who have had sinus rhythm documented during an event (17).

One of the most important limitations of using an ILR in clinical practice is that two invasive surgical procedures are necessary for device insertion and extraction. In addition to the attendant risks of infection and unsightly scar formation, many children require general anaesthesia for both procedures. This adds to the risk profile of employing ILR monitoring.

We encountered a complication rate of 8.7%. There were no deaths during ILR insertion or extraction. Our device infection rate of 4.3% (n = 1) is comparable to reported rates in adult studies (18). The procedure was well tolerated apart from patient 10 who required ILR repositioning because of persistent site discomfort. There were no reported adverse effects or dissatisfaction regarding the cosmetic effects of ILR implantation or extraction. Other device implantation sites have been employed to lessen the potentially adverse cosmetic effect particularly in young female patients. The success of inframammary insertion of ILRs in this regard has been reported (19).

**Study limitations**

This is a retrospective review of ILR usage in 23 patients in a single institution. Patient selection for ILR implantation was based on clinical criteria assessed by two consultant paediatric cardiologists. The study was neither randomised nor blinded. The number and extent of pre-ILR investigations were at the discretion of the clinician, all of which may have influenced the diagnostic yield of the device.

However, this study provides an accurate view of the clinical management of recurrent syncope/presyncope and palpitations in a tertiary referral paediatric cardiology unit.

**Conclusion**

The ILR facilitated the diagnosis and further care of the majority of a selected paediatric population with recurrent syncope, presyncope or palpitations. The high diagnostic yield, together with a relatively low complication rate suggests that ILR technology is a valuable resource in paediatric clinical practice.

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