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Implantable Diagnostic Monitors in the Early Assessment of Syncope and Collapse

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ABSTRACT

The implantable diagnostic monitor, or loop recorder (ILR) is a subcutaneous monitor capable of continuous ECG monitoring up to 3 years. It is an elegant investigative tool for the assessment of patients with recurrent, unexplained syncope in whom an arrhythmic cause needs to be excluded, and is now increasingly utilised very early in the diagnostic work-up of these patients, in line with current guidelines.

This review examines the evidence underpinning these recommendations as well as the relevant clinical trials evaluating the use of the ILR in syncope. Continued research will be needed to validate its role as a first line investigation in a sub-select of syncopal patients, especially with the addition of remote monitoring capabilities.

Syncope is a very common symptom complex in the general population, with a prevalence of first faints between the ages of 10–30 years, and a peak at approximately 15 years of age in both genders.[1,2] Despite this, only a very small proportion of patients ever present to a clinician.[3] Framingham data reveals that up to 44% of patients with loss of consciousness do not seek medical help.[4] Nevertheless, syncope has significant effects on quality of life[5–7] and carries a risk of physical injury[8,9] and death in the presence of structural heart disease and significant conduction disorders.[10,11]

The unpredictability of symptoms, the high rate of recurrence and the low sensitivity and specificity of currently available conventional investigations hamper the efficient diagnosis and assessment of unexplained syncope.

Implantable diagnostic monitors, or loop recorders (ILRs) function by continuously recording and deleting the patient's ECG (hence, "loop") with the ability for a particular segment of recording to be "frozen" and stored either through manual activation (with a hand–held activator) or automatic activation (when heart rate exceeds or falls below pre-programmed parameters for tachy- or bradycardia).

ILRs are typically implanted in the left pre-pectoral region under local anaesthetic in a minor surgical procedure. Most importantly, they are capable of providing rhythm data during a spontaneous syncopal event, which is the ideal gold standard for evaluation.[12]

Overview of technology

The initial pilot study assessing prolonged loop recorder monitoring was conducted in 1995 by Krahn and colleagues utilising the original platform for the ILR (Reveal, Medtronic USA). This study recruited 16 patients with a high syncope burden (mean episodes 8.4) who were implanted with an ILR

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Abbreviations and Acronyms

ATP = adenosine tri-phosphate

AV = atrio-ventricular

BBB = bundle branch block

EaSyAS = Eastbourne Syncope Assessment Study

ECG = electrocardiogram

EP = electrophysiology

ILR = implantable loop recorder

ISSUE = International Study of Syncope of Unknown Origin study

NMS = neurally mediated syncope

RAST = Randomized Assessment of Syncope Trial

following negative tests including tilt testing, ambulatory monitoring and electrophysiological (EP) studies. Here, symptom–rhythm correlation was achieved in 60% of patients, with treatment commenced successfully in all 16 patients.[13]

A larger study by the same authors followed in 1999.[14] A total of 85 patients (mean age 59± 18 years) with recurrent undiagnosed syncope were recruited and monitored for a mean of 10.5 months post ILR insertion. From this group, 50 patients had recurrence during follow up and 42% of them achieved symptom rhythm correlation, the most common arrhythmia being bradycardia. Seven patients with non-significant bradycardia and sinus rhythm detected during events were diagnosed with neurally mediated syncope.

The original ILR device measured 61×19×8 mm and weighed 17 grams. In addition, it had 2 sensing bipoles 37 mm apart,[14] and was capable of recording a single lead ECG signal onto a circular buffer capable of retaining 21 minutes of uncompressed signal or 42 minutes of compressed signal in 1 or 3 divided parts.[14] Patients used a handheld activator during the time of a clinical event to "freeze" the memory buffer accordingly. In this manner, ECG signals several minutes before and after activation could be stored for interrogation at a later date.

The dimensions and functions of current ILRs have changed very little in the intervening decade, with other companies now also adopting similar proportions and memory capacity (Figs 1 and 2). Our unit has previously conducted preliminary studies with an experimental device containing a subcutaneous antenna that provided 58 mm of sensing distance between antennae tip and "can". This device was equally easily implantable and provided excellent electrocardiographic signals[15] (Fig 3A and B).

Slight variation exists between current devices in terms of the number and length of episodes stored. Supplementary functions in newer incarnations include atrial fibrillation detecting algorithms as well as the storing of regular heart rate trending data.

All currently available ILRs now have remote monitoring capability in line with other implanted cardiac devices. However, the decision to use this function is not globally widespread and still very much at the discretion of the implanting centre and the availability of local monitoring support from device companies.

One of the main limiting factors to remote electrocardiographic monitoring is the potential difficulties encountered in filtering a large amount of daily ECG data from monitored patients, some of which may not be diagnostic.

A pilot study (forty patients were recruited with a mean follow up of 8.5±5.1 months) examining the feasibility of remote monitoring in ILRs encountered 89% of transmitted ECG recordings as artefact, with an average of 660 recordings

Device	Dimensions (mm)/ Weight (g)	Approximate Battery Life (Years)	Memory Capacity	Activation	Remote Monitoring	Other features
Reveal DX (Medtronic)	62 x 19 x 8 mm 15g	3	42 mins	Patient (hand-held activator) and auto (asystole, bradycardia and tachycardia with programmable parameters)	Yes; stored data uploaded via analogue phone transmission to web server; Secure log in for data analysis	-
Reveal XT (Medtronic)	62 x 19 x 8 mm 15g	3	42 mins	Patient (hand-held activator) and auto (asystole, bradycardia and tachycardia with programmable parameters)	Yes; stored data uploaded via analogue phone transmission to web server; Secure log in for data analysis	AF detection algorithms
Confirm DM 2100/2102 (St Jude)	56.3 x 18.5 x 8 mm 12g	3	48 mins	Patient (hand-held activator) and auto (asystole, bradycardia and tachycardia with programmable parameters)	Yes; stored data uploaded via analogue phone transmission to physician for analysis with accompanying software	AF detection algorithms Heart rate trending data

Fig 1 – Currently available implantable loop recorders.