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Review Article

# Implantable Loop Recorder for Arrhythmia Detection and Monitoring

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## Abstract

Accurate arrhythmia detection is essential for the appropriate management of cardiac patients. For example, detection of the most common sustained arrhythmia, atrial fibrillation (AF), can provide an indication to commence anticoagulation potentially preventing catastrophic thromboembolic events. Meanwhile, classical supraventricular tachycardias (SVTs) such as atrioventricular nodal re-entry (AVNRT) and atrioventricular re-entrant tachycardia (AVRT) can lead to catheter ablation or guide medical therapy to greatly improve a patients' symptoms. Detection of ventricular arrhythmias and brady-arrhythmias may require defibrillator or permanent pacemaker (PPM) implantation.

It is vital that a cardiac rhythm monitor is accurate with a positive predictive value and negative predictive value as close to 100% as possible. Inaccurate detection of AF could potentially put patients at risk from serious bleeding events if anticoagulation is inappropriately commenced. We reviewed standard and novel indications for arrhythmia detection by the implantable loop recorder (ILR) and also evaluated its accuracy in a variety of different clinical settings.

***Keywords:*** *Implantable Loop Recorder; Arrhythmia; Atrial Fibrillation; Catheter Ablation*

## Introduction

Traditionally, ILRs have been indicated as a diagnostic tool to investigate unexplained syncope, palpitations, and suspected infrequent arrhythmias [1-8]. The technology has progressed significantly in recent years. The devices are smaller and more straightforward to implant. Indications for ILRs have expanded to cover a wide range of clinical scenarios [9,10]. For example, recent evidence has found a role for ILRs in the investigation of cryptogenic stroke and in the risk stratification of patients post myocardial infarction (MI). In addition, epidemiological considerations have gained increasing attention in recent years. For example, long-term beat-to-beat monitoring has transformed our understanding of the progression of atrial fibrillation, challenging previously held beliefs. Next-generation ILRs allow wireless telemetry for remote monitoring [8,9]. The purpose of this paper is to review the current clinical indications for ILR usage and future applications of the device. In addition, we have reviewed the accuracy of ILRs in arrhythmia detection to improve our understanding of the true benefits of this device.

### The Implantable Loop Recorder

ILRs are rectangular devices which measure approximately 6 cm x 2 cm x 1 cm and weigh between 12 to 26 grams depending on the device. Three commonly used ILRs are the Medtronic Reveal XT, St. Jude SJM Confirm™ and Biotronik BioMonitor. Sensing electrodes record a single-lead bipolar electrocardiogram (ECG), which can be retrieved with interrogation using a programmer interface. The battery has an estimated lifetime of between 36 months to 48 months according to the manufacturer.

In the past, cutaneous mapping techniques have been employed to aid device positioning. However, currently an anatomical approach has superseded this time-consuming method. A commonly used approach was described by Grubb., *et al*. in which the ILR is implanted midway between the supraclavicular notch and the left pectoral area [8].

An incision of approximately 2 cm in length is made under local anaesthesia and then blunt dissection is used to create the pocket for the device. If necessary alternative implant sites can be used (e.g. right parasternal) though these tend to be associated with a signal of lower amplitude. The ECG signal is stored in a circular buffer with a maximal storage capacity of 49.5 minutes (up to 30 events) allowing detection of pauses as well as high and low heart rate episodes. Newer injectable devices including the Medtronic Linq, St Jude Confirm II and BioMonitor II are significantly smaller and perform similarly although increased interelectrode distances in the larger devices improve sensitivity and specificity.

**Implantable Loop Recorders and Arrhythmia Detection**

There are usually two rate zones for tachycardia detection: ventricular tachycardia (VT) (for slower tachycardias) and fast VT (FVT) (for faster tachycardias) [11]. These zones are also used for tachycardias originating in the atria. The VT zone extends from a programmed VT interval up to the programmed FVT interval (maximum range is 520 - 250 ms) [11]. The FVT zone extends from the programmed FVT interval to the blanking period (maximum range is 400 - 150 ms) [10]. R-R intervals that fall within the VT zone increment a VT interval counter. A single detected R-R interval that is longer than the VT and FVT zones resets the VT interval counter [11]. The value of the VT interval counter is held for R-R intervals in the FVT zone. If the VT interval counter reaches the programmed threshold number of beats, then the episode is stored in the VT 'bin' [11]. An example of an ILR printout for tachycardia can be seen in figure 1.

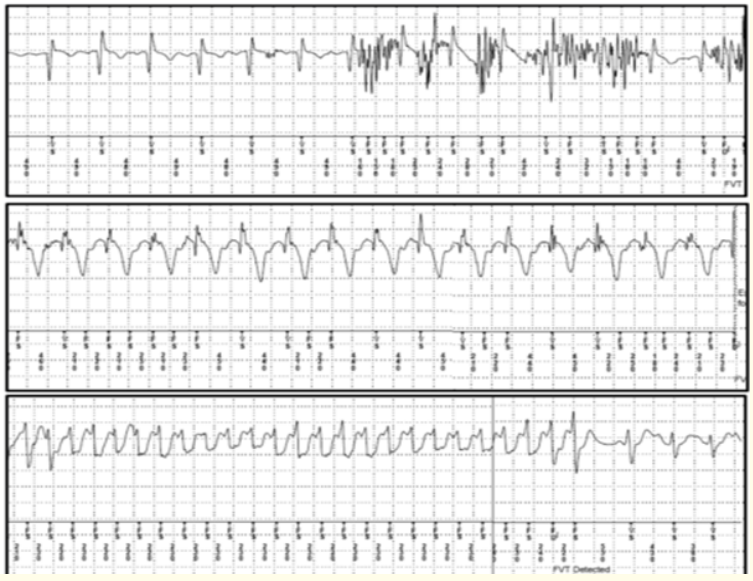

***Figure 1:*** *ILR Tachycardia traces taken from Volosin et al 2013 [11].*

*Top: Inappropriate detection of FVT because of noise. The noise abruptly stopped near the point of FVT detection (far right in the panel), so the noise rejection criteria failed to detect the noise. Middle: Inappropriate detection of FVT because of T-wave oversensing. Detection occurs at the far right of the panel. Bottom: Appropriate detection of a VT. The tachycardia spontaneously terminated one beat after detection occurred.*

For bradyarrhythmias, the electrocardiogram (ECG) data storage can be manually initiated or automatically triggered when arrhythmic events fulfil the pre-programmed cut-off criteria: asystole (pause lasting > 3s) or bradyarrhythmias (4 successive ventricular events < 40 beats/minute) [11,12].

A dedicated AF detection algorithm continuously assesses the regularity of R-R intervals within a 2-minute time window, see figure 2. It requires 2 minutes of AF for the device to recognise the rhythm as AF (shorter episodes may be captured if patient activated) [11,12].

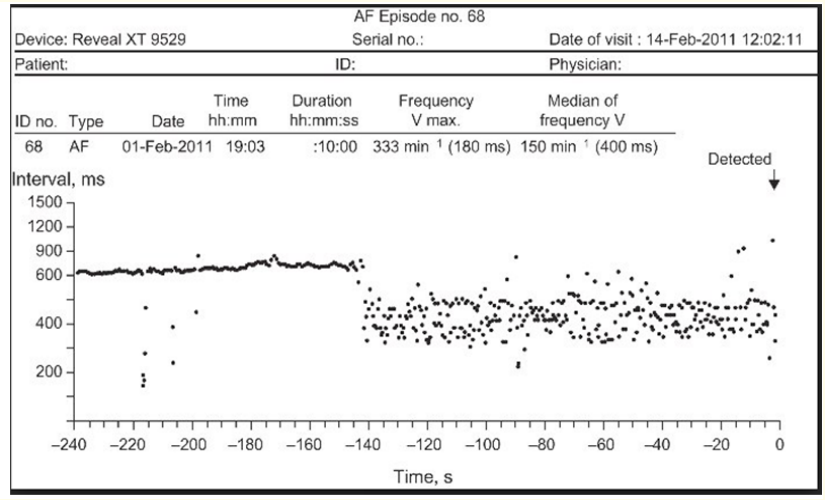


***Figure 2:*** *Plot of RR intervals corresponding to the onset of an episode of atrial fibrillation detected by the Medtronic Reveal XT.*

**Syncope**

A traditional indication for an ILR is in the investigation of syncope. Multiple randomised studies have assessed the use of ILRs for the evaluation of patients with syncope [6,7]. Syncope is a common problem that could be benign or potentially secondary to a life-threatening arrhythmia. Cardiac causes of syncope are known to carry a worse prognosis than non-cardiac causes. However, standard tests including echocardiography, tilt table testing, Holter monitoring, and invasive electrophysiological testing have a low diagnostic yield [6].

In the Randomised Assessment of Syncope Trial (RAST), 60 patients (mean age 66 ± 14; 17 males) with unexplained syncope were randomised to "conventional" cardiac evaluation (external loop recorder (ELR), echocardiography, Holter monitoring, electrophysiologic testing) or prolonged monitoring using an ILR [2]. Prolonged monitoring (mean 19.3 ± 8.9 months) was more likely to result in a diagnosis than conventional testing (55 vs. 19%, p = 0.0014) [2]. Episodes of transient symptomatic bradycardia were the most common findings [2]. In the International Study of Syncope of Uncertain Etiology (ISSUE) study, ILRs were implanted and tilt table testing was performed in 111 patients [13]. The patients were analysed in two groups: 29 patients with tilt-positive (age 64 ± 15; 11 males) and 82 patients with tilt-negative results (age 63 ± 17; 45 males) [13]. Syncope recurred in approximately 34% of patients in both groups, and the most frequent cause was prolonged sinus pauses [13].

Sulke., *et al.* (EaSyAS II trial) randomly allocated 246 patients (mean age ± 70.3 ± 18; 99 male) with unexplained syncope to (i) attendance at syncope clinic, (ii) immediate insertion of ILR, or (iii) both or (iv) conventional investigation [14]. Median follow-up was 20 months. ILRs were found to achieve a more rapid diagnosis with 50% of patients diagnosed within 90 days. Conventional management of syncope failed to achieve an ECG diagnosis despite a larger number of investigative tests. Syncope Clinic and provocative tilt testing delivered a rapid ECG diagnosis, but did not prevent recurrent syncope during follow up [13]. However, ILRs resulted in a higher therapeutic intervention rate (e.g. pacemaker, ICD or ablation) with a significant decrease in subsequent syncope [14].

**Is the evidence base reflected in clinical practice?**

The European Heart Rhythm Association (EHRA) survey in 2014 assessed the use of different cardiac monitoring techniques in the evaluation of patients with unexplained syncope, palpitations, and in those with established diagnosis of AF. The survey found a discrepancy between clinical practice and the current guidelines on the use of ILRs in patients with unexplained syncope [15]. The current European Society of Cardiology (ESC) guidelines for the indications for ILRs appear in table 1. With the exception of high-risk patients

with recurrent syncope and negative screening, whereby 43% of the centres would resort to ILR implantation in the majority of the cases, in all other instances the use of ILRs was limited to < 20% of patients in most centres. This finding is supported by work from Vitale., *et al*. who also reported a large discrepancy between the use of ILRs in patients with unexplained syncope and indications according to the current guidelines with only 20% of the patients that qualified for and ILR being correctly treated [16]. In the same study, the proportion of patients receiving an ILR was even lower (14% of the cases) in the case of concomitant heart disease and unexplained syncope [16].

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| Class I. ILR is indicated:<br>• In an early phase of evaluation of patients with recurrent syncope of uncertain origin who have:<br>–absence of high-risk criteria that require immediate hospitalization or intensive evaluation, i.e. those listed in the Table 5; and<br>–a likely recurrence within battery longevity of the device (Level of evidence A)<br>• In high-risk patients in whom a comprehensive evaluation (that listed in Table 5) did not demonstrate a cause of syncope or lead to specific treatment (Level of evidence B)<br>Class II A. ILR may be indicated:<br>• To assess the contribution of bradycardia before embarking on cardiac pacing in patients with suspected or certain neurally mediated syncope presenting with frequent or traumatic syncopal episodes (Level of evidence B).<br>Class II B. ILR may be indicated:<br>• In patients with T-LOC of uncertain syncopal origin in order to definitely exclude an arrhythmic mechanism (Level of evidence C). |

***Table 1:*** *Indications for ILRs according European Society of Cardiology Guidelines 2009.*

**Atrial fibrillation and catheter ablation**

ILRs are an established diagnostic method for detection of AF. ILRs can record asymptomatic or infrequent AF episodes and potentially prevent thromboembolic events by allowing initiation of anticoagulation [12]. They can be used to assess therapeutic success after percutaneous or surgical ablation and thereby assist long-term anticoagulation decisions [12].

Rhythm monitoring after AF ablation is generally advocated but has not been standardised. To evaluate the efficacy of catheter ablation and to detect AF recurrences, discontinuous scheduled or symptom-initiated ECG monitoring (e.g., 24-h to 7-day Holter ECG) is still being used in many centres and trials, even though sensitivity is less than 50% and negative predictive value for AF absence is between 20 - 40% [18-24]. By contrast, implantable permanent pacemakers (PPMs) and ILRs offer the advantage of uninterrupted rhythm surveillance. Veasey., *et al*. sought to evaluate the true efficacy of catheter ablation for AF in patients with sophisticated PPMs capable of continuous long-term rhythm monitoring [17]. Twenty-five patients (aged 63.7 ±9.4; 20 males), seven with persistent AF and 18 with prolonged paroxysmal AF, underwent a mean of 1.7 ablation procedures. Initial baseline AF burden was 43.8% (±35.5). After catheter ablation(s), this was significantly reduced to 14.5% (±28.1) ($p = 0.002$) at 6 months. In addition, catheter ablation for AF significantly improved patient symptoms and reduced AF burden after long-term beat-to-beat monitoring by implanted cardiac PPM devices. Given the more straightforward ILR implant procedure these devices are more appropriate than PPMs in this role (see below).

Past studies using ILRs reported on ablation success rates (i.e., AF termination after 12 months) ranging from 59 to 88% [18-24]. Although, "ablation success" is typically referred to as freedom from AF recurrences over a certain time period, a uniform definition remains to be achieved [18-24]. Confirmation of successful AF eradication and detection of AF recurrences after catheter ablation are required to improve post-ablation management (e.g., medication adjustment including temporary antiarrhythmic agents or scheduling of re-ablation procedures). In addition, the potential of post-ablation cessation of oral anticoagulation therapy in patients with a low-to-moderate stroke risk guided by ILR monitoring is of great therapeutic importance.

Furthermore, ablation techniques are not standardised and new technologies are continuously being evaluated. We propose that continuous monitoring should be mandatory in all studies to accurately determine optimal ablation strategy.

**Are ILRs accurate in detecting AF?**

Podd., *et al*. compared REVEAL(®)XT ILRs and permanent pacemakers (PPMs) in fifty patients with paroxysmal AF prior to pulmonary vein isolation and 1 year post intervention [25]. PPMs were programmed to monitoring only (ODO). All patients also underwent 7-day full disclosure ELRs. Device ECGs and electrograms (EGMs) were compared for AF burden. Correct identification of AF was significantly better in the PPM group (97% vs. 55% $P < 0.001$). Sensitivity and specificity for each episode of AF was significantly better in the PPM group (100% vs. 79% and 98% vs. 66%, respectively, $P < 0.001$). The positive predictive value for the detection of any AF was significantly better in the PPM than the ILR (100% vs. 58%, $P = 0.03$). However, the negative predictive value for the absence of AF was not significantly different between the PPM and ILR (100% vs. 92%, $P = 0.076$) suggesting that the absence of AF detected by an ILR is adequate to guide future therapies e.g. withdrawal of anticoagulation. Given the significant, and often underappreciated, risk from oral anticoagulation we believe this should be a significant role for ILRs post AF ablation.

**ILRs in Cryptogenic Stroke**

The major risk associated with undiagnosed AF is ischaemic stroke, which may be prevented by a prompt diagnosis of AF and consequent anticoagulant therapy [26]. There is poor correlation between the occurrence of AF and symptoms, therefore continuous ECG monitoring is needed when paroxysmal AF is suspected. This is typically the case for patients with cryptogenic stroke (defined as stroke with unknown aetiology after thorough evaluation), in whom AF episodes most often occur asymptomatically [26].

In the CRYSTAL AF trial four hundred and forty-one patients aged 40 years or more with a diagnosis of cryptogenic stroke or transient ischaemic attacks (TIAs) of undetermined cause were randomly assigned to an ILR or a conventional ECG monitoring strategy (median of 23 hours of Holter monitoring and telemetry with a median duration of 68 hours) [28]. AF was diagnosed at 6 months in 19 (8.9%) of the 221 patients randomised to the ILR compared with three patients (1.4%) in the control group ($P < 0.001$). The majority of AF episodes occurred in the first 6 months after randomisation, but the diagnostic yield of the ILR accrued until the end of the follow-up period. By 12 months, AF had been correctly diagnosed in 29 patients (12.4%) in the ILR group and only four patients (2%) in the control group ($P < 0.001$).

In total, 9 times more AF was detected in the ILR group but at 36 months only 30% of the ILR group were found to have AF compared with 3% in the control group. This suggests that the majority of cryptogenic stroke patients do not have AF and therefore AF is not the main cause of cryptogenic stroke. This finding is crucial and suggests that AF is, in fact, only a marker of increased risk for stroke and not the direct cause. However, even if AF is solely a marker of increased risk, detection of the arrhythmia is of course highly relevant in aiding management decisions for individual patients.

**ILRs and Structural Heart Disease**

Solano., *et al*. investigated the incidence, diagnostic yield and safety of ILRs in patients with or without structural heart disease (SHD) [29]. 2052 patients with syncope were evaluated. The diagnosis remained unexplained in 371 (18%). Of these, 103 patients (5% of total, 28% of unexplained syncope) received an ILR. SHD was present in 38 (37%), and absent in 65 (63%). During follow-up of 13 months, syncope was recorded in 52 patients. Patients with SHD more frequently had paroxysmal AV block and tachyarrhythmias and patients without SHD more frequently had sinus bradycardia/sinus arrest or no arrhythmia. The authors concluded that the mechanism of syncope is different in patients with and without SHD; diagnostic yield and safety are similar in both groups. These findings are reflected in the European Society of Cardiology 2009 guidelines which consider SHD to be a high-risk feature in patients with transient loss of consciousness and thereby recommend implantation of an ILR for further evaluation (see Table 2).

- Situations in which there is a clear indication for ICD or pacemaker treatment independently of a definite diagnosis of the cause of syncope according to recent ICD/CRT guidelines
- Severe structural cardiovascular or coronary artery disease (heart failure or low ejection fraction or previous myocardial infarction)
- Clinical or ECG features suggesting an arrhythmic syncope:

  –Syncope during exertion or supine

  –Palpitations at the time of syncope

  –Family history of sudden death

  –Non-sustained ventricular tachycardia

  –Bundle branch block (QRS duration ≥ 0.12 s)

  –Inadequate sinus bradycardia (< 50 bpm) or sinoatrial block in the absence of negatively chronotropic medications except physically-trained person

  –Pre-excited QRS complexes

  –Prolonged or short QT interval

  –Right bundle branch block pattern with ST-elevation in leads V1–V3 (Brugada syndrome)

  –Negative T waves in right precordial leads, epsilon waves, and ventricular late potentials suggestive of arrhythmogenic right ventricular dysplasia
- Important comorbidities (severe anaemia, electrolytic disturbance, etc)

***Table 2:*** *ESC Guidelines 2009: High risk features in patients presenting with transient loss of consciousness.*

**The Investigation of Palpitations**

Giada., *et al*. compared the diagnostic yield and the costs of ILRs with those of the conventional strategy in patients with unexplained palpitations [4]. 50 patients were included. Before enrolment patients had a negative initial evaluation. Patients were randomised either to conventional strategy (24-h Holter recording, a 4-week period of ambulatory ECG monitoring with an external recorder, and electrophysiological study) (n = 24) or to ILR implantation with 1-year monitoring (n = 26). Hospital costs of the 2 strategies were calculated. A diagnosis was obtained in 5 patients in the conventional strategy group, and in 19 subjects in the ILR group (21% vs. 73%, P < 0.001). The authors concluded that in subjects without severe heart disease and with infrequent palpitations, ILR is a safe and more cost-effective diagnostic approach than conventional strategy [4].

Silveira., *et al*. investigated 62 patients with ILRs in situ, 50% men, with a mean age of 62.5 ± 18.8 years [30]. Previously to ILR implantation 88.7% of patients had undergone a Holter, 17.7% ELR, 33.9% tilt test and 29% an electrophysiological study. The implantation indications were recurrent syncope in 90.3%, palpitations 8.1% and ischaemic stroke in one patient. Mean follow-up time was 17.1 ± 16.3 months. They found that the ILR enabled the identification or exclusion of serious rhythm disturbances in more than half of patients and allowed a targeted therapeutic intervention [30].

**Epidemiological Considerations**

Continuous, long-term rhythm monitoring has provided key epidemiological data for certain arrhythmias. For example, Veasey., *et al*. utilised the continuous rhythm monitoring capabilities of implanted PPMs to better define the natural history of AF [31]. The study in-

cluded 356 patients with PPM devices capable of continuous atrial rhythm monitoring (186 male, mean age (± SD) 79.5 ± 8.9 years). The study follow-up period (± SD) was 7.2 ± 3.1 years. Over the study period, 179 of 356 patients (50.3%) had at least one episode of persistent AF. Of the 356 patients, 314 (88.2%) had paroxysmal AF and 42 (11.8%) had persistent AF at the time of diagnosis. The predominant AF subtype at latest follow-up was paroxysmal for 192 patients (53.9%), persistent for 77 (21.6%) and long-standing persistent/permanent for 87 (24.4%). Univariable predictors of progression to persistent AF were (1) male gender, (2) increasing left atrial diameter, (3) reduced atrial pacing and (4) increasing ventricular pacing. The authors concluded that although many patients with AF have persistent episodes, long-term continuous pacemaker follow-up demonstrates that the majority will have a paroxysmal, as opposed to persistent, form of the arrhythmia. Manipulating the rhythm monitoring properties of PPMs is not always feasible and we believe that ILRs also have a crucial role in this regard.

Sugihara., *et al*. investigated 323 patients with dual chamber PPMs and AF, describing a cumulative total of 1031 patient-years of beat-to-beat monitoring [32]. After accounting for age, heart failure (HF) had a significant interaction with AF burden (P = 0.0004). Eighteen of 70 (26%) patients with persistent AF had pacemaker documented episodes of sinus rhythm (i.e. reversion to 'paroxysmal AF') after the onset of persistent AF. The authors concluded that in this cohort, the development of AF over time appears more complex than current definitions suggest. AF can remain low burden without progression, remit-relapse, or progress. These findings are of great interest because this study utilised beat-to-beat monitoring to describe long-term patterns of AF challenging popularly held beliefs and show that current definitions are suspect. The findings are relevant for patients with PPMs in situ. ILRs may also be indicated to provide such epidemiological data in a wider non-PPM cohort [33,34].

**Risk stratification post MI**

There may be a role for ILRs in the risk stratification of post-MI patients. The CARISMA trial followed 1393 patients who received an ILR 11 ± 5 days following an acute MI with subsequent left ventricular ejection fraction < 40% [25]. At a mean follow-up of 47 days, the ILR had detected atrial tachyarrhythmias in 8 of 28 patients, nonsustained ventricular tachycardias in 2, and transient third degree atrioventricular block in 3. An indication of an ICD or PPM was observed in 9 out of 29 patients (31%). An average of 2.3 events stored by the ILR were due to inappropriate triggering. The development of intermittent high-degree atrioventricular (AV) block was the most potent predictor of mortality [25].

## Conclusion

In allowing long-term beat-to-beat heart rhythm monitoring, ILRs have a significant clinical and research potential. Prolonged early monitoring with an ILR is a proven superior strategy to conventional testing with short-term monitoring and provocative tilt and electrophysiological testing in patients with syncope, a finding replicated in multiple randomised controlled trials. ILRs provide more rapid diagnosis, increase the likelihood of syncope being reported, demonstrate a high rate of intermittent bradycardia requiring pacing, and help reduce recurrent syncope. However, despite overwhelming support for the use of ILRs in assessment of syncope, this evidence based approach is not being widely utilised in current clinical practice, even is high-risk patients.

In patients with palpitations and suspected infrequent arrhythmias, ILRs remain the only viable option for long term cardiac monitoring, despite the advent of new ELRs providing up to 60 days of continuous monitoring. ILRs significantly increase the probability of detecting AF post cryptogenic stroke but also reveal that the majority of cryptogenic stroke patients have no AF providing further insight into this leading course of mortality and morbidity.

Future directions for ILR use include continuous rhythm monitoring after AF ablation and following myocardial infarction. Meanwhile, in heart failure and cardiomyopathy, ILRs have the potential to provide supportive clinical data with therapeutic impact.

By detecting AF recurrence after catheter ablation, next-generation ILRs with automated wireless remote transmissions will help to decide when oral anticoagulation should be discontinued reducing the significant risk of major bleeding events of at least 2% of patients

per year will experience a serious bleeding event. ILR AF detection has a high degree of artefact, which reduces its specificity and sensitivity. However, despite the deficiencies of ILR monitoring the negative predictive value of the ILR is satisfactory if zero AF burden is the aim of therapy.

**Summary**

ILRs are designed for long-term monitoring of cardiac rhythm and they can provide a diagnosis in patients when traditional Holter monitoring has failed, thus guiding therapy. Remote transmissions of ECG from ILRs may facilitate the follow-up of patients, possibly reducing economic burden on the healthcare system. Devices with more sensitive algorithms for automatic detection or arrhythmias are under development.

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