A long-term ECG recording system useful in patients with infrequent symptoms

Implantable loop recorders

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Overview

Loop recorders continuously monitor a patient's ECG and have a "retrospective" programmable memory to store heart rhythm abnormalities [1]. Loop recorders are available as either external (ELR) or implantable devices (ILR). An ILR is typically implanted in the subcutaneous tissue in the left parasternal region. Nowadays, the implantation can be done in an outpatient setting under local anaesthesia, and is technically easy with a low risk of complication. The ILR is capable of storing a single-lead ECG either automatically, independent of the patient's symptoms, as a result of significant brady- or tachyarrhythmia (the parameters for arrhythmia detection can be defined and programmed by the implanting physician, and at any time during follow-up) or upon patient activation. The battery lifespan of current devices is around 2–3 years, after which a decision has to be made to either explant the ILR or leave it in place. An ILR has a particular advantage over other long-term ECG recording systems in patients suffering from infrequent symptoms where the likelihood of symptom-ECG correlation is very low. Furthermore, the smaller size of these devices (fig. 1), home monitoring options and improved diagnostic algorithms made, or will make, ILRs very popular in daily clinical practice. In the future, an ILR may be used before, or even instead of, conventional investigations. Although this "early loop recorder approach" can be considered for the vast majority of patients suffering from non-high-risk problems, patients with potentially life-threatening conditions have to be identified and investigated accordingly. Hence, initial careful risk stratification is mandatory before implanting a loop recorder.



Figure 1: Implantable loop recorders currently available in Switzerland.

Indications

Patients suffering from syncope

Syncope is defined as a transient loss of consciousness due to global cerebral hypoperfusion. It occurs suddenly, is of short duration, and spontaneously recovers completely. Syncope is a frequent event in the general population [2]. On the basis of the underlying pathophysiological mechanism, it can be classified as either reflex syncope (neurally mediated; including vasovagal syncope, carotid sinus hypersensitivity or situational syncope), as a result of orthostatic hypotension, or due to cardiovascular causes (brady- and tachyarrhythmias, structural heart disease).

Conventionally, an ILR was implanted in patients suffering from unexplained syncope after an unremarkable conventional diagnostic work-up. The likelihood that an ILR will help to identify the cause of syncope varies between 30 and 80% [1, 3] (the wide range of positive results reflects the different populations studied). In the prospective PICTURE registry, 570 patients had an ILR implantation (without home monitoring option) after an episode of unexplained syncope despite intensive medical investigations. A third had another episode within the first year, and the ILR provided a definitive diagnosis in 78% [3]. On the other hand, pooled data from nine other studies found a symptom-ECG correlation in only 35% [1].

As mentioned above, traditionally an ILR was used as a last resort after careful conventional diagnostic investigations. However, various studies demonstrated the poor correlation of these investigations with elucidating the reason for syncope [4, 5] and, hence, early implantation of an ILR can be discussed. Krahn et al. randomised 66 patients with unexplained syncope to an ILR or conventional medical investigations [5]. A final diagnosis was possible in more than half of the patients with an ILR, whereas this was possible in only 20% of the patients in the control group. Several studies confirmed the benefit, as well as the safety (morbidity and mortality), of an early-stage ILR approach if patients at high risk of life-threatening events

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are carefully excluded (table 1). High-risk patients require immediate hospitalisation and an intensive diagnostic work up; if they are excluded, an ILR can safely be implanted. If such risk factors are not present, an ILR can be used at an earlier stage (fig. 2).

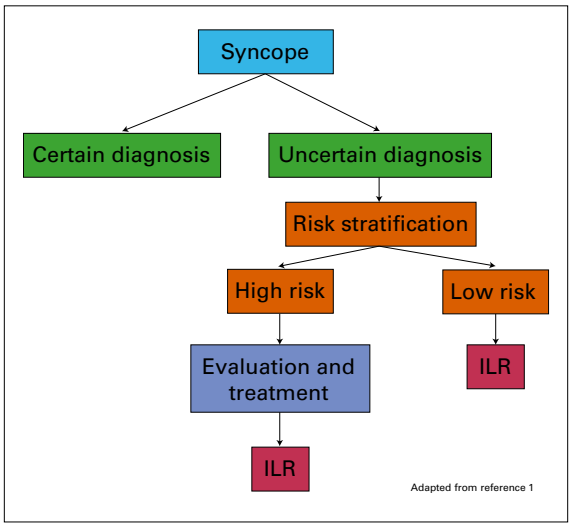


Figure 2: Recommended diagnostic work-up in patients suffering from syncope. ILR = implantable loop recorder

Table 1: High-risk characteristics that require intensive diagnostic work-up.

High-risk criteria
Clear indication for an implantable cardioverter-defibrillator or a pacemaker
Severe structural heart disease (including coronary artery disease) with signs of heart failure or significantly impaired left ventricular ejection fraction
ECG signs suggesting a relevant arrhythmic syncope:
– Syncope during exertion or in supine position
– Palpitations at the time of syncope
– Family history of sudden (cardiac) death
– Non-sustained ventricular tachycardia
– Bundle branch block with QRS duration of >120 ms
– Wolff-Parkinson-White syndrome
– Prolonged or short QT interval
– Signs of Brugada ECG (right bundle branch block pattern with ST-elevation in leads V_1–V_3)
– Signs of arrhythmogenic right ventricular dysplasia

Patients with infrequent, undocumented palpitations

Palpitations represent a very common symptom in the outpatient setting. They have various causes including arrhythmias (such as premature beats, sustained supraventricular and ventricular arrhythmia), and noncardiac conditions resulting in sinus tachycardia (anxiety, fever, anaemia, hyperthyroidism). Since short-term monitoring, including 24–48-hour Holter ECGs, are of limited value in this population, ILRs can potentially detect the arrhythmia, but play a minor role in this situation compared with patients suffering from syncope. The majority of patients with unexplained palpitations in whom high-risk criteria (table 1) are excluded can be reassured and managed even without reaching the correct diagnosis. We usually recommend implanting an ILR only in patients suffering from severe symptoms affecting normal activity. However, other potential diagnostic options, such as the AliveCor® system, which the patient can apply during an episode of palpitations to record a simple one-lead ECG via a smartphone, can be used in this situation.

Patients at risk for atrial fibrillation

Atrial fibrillation (AF) is the most common supraventricular arrhythmia worldwide, with considerable morbidity and mortality. Since in the early stages either AF episodes are infrequent or asymptomatic, recording AF on an ECG is challenging, and long-term monitoring may be necessary. Especially in survivors of a cryptogenic stroke (defined as a stroke in which the cause could not be identified), diagnosing of AF is crucial because the patient may qualify for oral anticoagulation. According to current data, around a fourth of all strokes are classified as cryptogenic [6]; in up to 20% of these patients an episode of AF following the event can be documented [7]. The CRYSTAL-AF study investigated patients suffering from cryptogenic stroke and randomised them to either "standard" follow-up or an ILR [8]. They found that the number of documented AF episodes was significantly higher in the intervention (ILR) group as compared with the controls (8.6 vs 1.4% at 6 months, p <0.001); furthermore, more patients with an ILR were on oral anticoagulation treatment at the end of the study as a consequence of documented AF episodes. However, whether documentation of an episode of AF following a stroke can retrospectively be identified as the source of the neurological event and whether oral anticoagulation in this setting will be of long-term benefit is still a matter of debate and has not yet been proven scientifically. In summary, indication for an ILR in patients with suspected AF is less straightforward than in the population suffering from syncope. Nonetheless, in cryptogenic stroke survivors, for whom standard neurological and cardiology work-up did not identify an explanation for the cerebral event, implantation of an ILR should be considered to identify silent AF, according to the updated European Society of Cardiology AF guidelines (Recommendation class IIa, level of evidence B) [9].

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ILR for risk stratification in inherited cardiomyopathies

In patients suffering from Brugada syndrome, long or short QT syndrome, hypertrophic cardiomyopathy or arrhythmogenic right ventricular dysplasia, a syncopal event is usually an ominous finding indicating a high risk of sudden cardiac arrest, and as a consequence an implantable cardioverter-defibrillator (ICD) is frequently used. Nonetheless, even though these individuals are at high risk for sudden cardiac death related to ventricular arrhythmias, the mechanisms leading to syncope can still be heterogeneous, involving both arrhythmic and nonarrhythmic causes. Indeed, in patients suffering from Brugada syndrome, those who received an ICD because of episodes of syncope without documented ventricular arrhythmias were not more likely to have at least one appropriate ICD shock than were asymptomatic patients [10]. Differentiation of benign and malignant syncope in this population is obviously difficult, but an ILR could potentially help in the decision for or against an ICD in younger patients without documented life-threatening ventricular arrhythmias.

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Key messages

- Implantable loop recorders (ILRs) offer the potential for long-term ECG monitoring over 2–3 years with a minimal intervention risk
- In patients suffering from syncope or palpitations, ILR offers the chance to document a symptom-ECG correlation, especially in patients with rare or infrequent episodes
- Before implanting an ILR, it is essential to correctly exclude high-risk patients who could benefit from other devices such as ICDs
- Insurance coverage needs to be checked for some of the indications, as reimbursement across countries and insurances varies substantially

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