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Utility of the Implantable Loop Recorder: Current Status

Franco Giada, MD, Giorgio Corbucci, MD, Antonio Raviele, MD

Cardiovascular Department,
Umberto I Hospital,
Mestre-Venice, Italy

Of similar size to a pacemaker, implantable loop recorders (ILRs) are implanted subcutaneously in the left precordial region. The ILRs are equipped with a memory loop and, once activated by the patient by means of a magnet, record a 1-lead electrocardiographic trace, both retrospectively and prospectively, for several minutes. ILRs have a monitoring capability of up to 36 months and are explanted once the diagnosis has been made or the battery has run down. The current indication of ILRs as diagnostic tools is represented by the evaluation of transitory symptoms of possible arrhythmic origin, such as syncope and palpitations. Moreover, the theoretical capability of the new generation ILRs to record any kind of arrhythmic events automatically (from atrial fibrillation, to atrial flutter/tachycardia, from ventricular tachycardia to bradyarrhythmic events) suggests the possibility to use these devices also in the long-term evaluation of the total (symptomatic and asymptomatic) arrhythmic burden of patients at risk of arrhythmic events.

DIAGNOSTIC EVALUATION OF TRANSITORY SYMPTOMS OF POSSIBLE ARRHYTHMIC ORIGIN

Initial evaluation. In patients with transitory symptoms of possible arrhythmic origin, it is essential to ascertain whether there is a structural heart disease and/or heart disease at risk of arrhythmias, and to obtain an electrocardiographic recording during symptoms. Therefore, the initial evaluation will involve thorough clinical history, careful objective examination and 12-lead ECG (1,2). In some particular situations, it may be useful to perform blood chemistry examinations, such as hemochrome, electrolytes, blood glucose, and thyroid function tests (3). Effort stress testing is indicated in case of symptoms associated with physical effort, while tilt testing is indicated in patients without heart disease suffering from recurrent syncope of unexplained origin. The need for further investigations (echocardiogram, coronary angiography, etc) will depend on the nature of the heart disease suspected or ascertained.

In a good proportion of patients, this evaluation yields a definitive diagnosis of the cause of the symptoms, or at least excludes the presence of major arrhythmic disorders with reasonable certainty (3). However, the lack of an electrocardiographic recording during symptoms permits only a presuntive diagnosis (4). Thus, when the initial diagnostic evaluation results negative, and symptoms are clinically significant, (i.e. recurrent, poorly tolerated from the hemodynamic point of view, accompanied by reduction in quality of life and/or by traumatic injuries, or if the patient is suffering from heart disease), second-line diagnostic investigations, such as electrophysiological study (EPS), and prolonged ECG monitoring (AECG monitoring), should

Address for correspondence:
Franco Giada, MD
Cardiovascular Department,
Umberto I Hospital
Via Circonvallazione 50,
30170 Mestre-Venice, Italy
Tel. +39.041.2607201. Fax
+39.041.2607235
E-mail: francogiada@hotmail.com

be undertaken (1).

Electrophysiological study. EPS, in addition to being costly and invasive, has a low sensitivity in the case of symptoms of unknown origin, at least in patients without significant heart disease (5-8). Moreover, EPS is a provocative tests, thus the correspondence between the induced arrhythmia and the arrhythmia responsible for the patient's clinical symptoms is unproved. Indeed, EPS positivity only reveals the presence of a pathological substrate, which may (or may not) be responsible for the symptoms. It is therefore essential to establish the association between the induced arrhythmia and reproduction of the patient's spontaneous symptoms. Finally, the specificity and sensitivity of EPS depend on the stimulation protocol employed, the type of induced arrhythmias, and the patients studied: its diagnostic value is higher in patients with structural heart disease, while aggressive protocols increase the sensitivity of the test at the expense of specificity.

In patients with severe heart disease EPS should precede the use of AECG monitoring, while in all other cases, EPS is recommended only when AECG monitoring result negative. EPS does, however, offer the advantage not only of enabling the type of arrhythmia responsible for the symptoms to be correctly identified, but also of enabling ablation therapy of the arrhythmia itself (in case of induction of tachyarrhythmias) to be undertaken during the same session.

Prolonged ambulatory ECG monitoring. Twelve-lead electrocardiographic recording during the course of spontaneous symptoms constitutes the gold standard for the diagnostic evaluation of patients with symptoms of possible arrhythmic origin. Indeed, electrocardiographic recording is able to establish whether or not symptom are associated to a cardiac rhythm disorder and, in the majority of cases, leads to the correct diagnosis of the arrhythmia responsible (2,3). However, in normal clinical practice, it is not always possible to perform a standard 12-lead ECG during spontaneous symptoms, and AECG monitoring is often necessary (9-13).

AECG monitoring devices (if we exclude the diagnostic functions of pacemakers and ICDs) include the following: Holter monitoring, mobile cardiac outpatient telemetry (MCOT), event recorders, external loop recorders, and implantable loop recorders (ILR). Holter monitoring is useful when symptoms have a daily frequency. Event recorders may prove useful in very compliant patients with infrequent symptoms that are fairly long-lasting to permit the activation of the device, and unaccompanied by hemodynamic impairment (such as syncope), that is likely to hinder their use. External loop recorders are recommended in cases of weekly symptoms, in very compliant patients, while ILRs are indicated in poorly compliant patients with infrequent symptoms (i.e. with a monthly frequency) (14).

AECG monitoring is regarded as diagnostic only when it is possible to establish a certain correlation between symptoms

and the electrocardiographic recording. Devices able to record arrhythmic events automatically (Holter and loop recorders) are regarded as probably diagnostic also if the patients will have evidence of asymptomatic sustained supraventricular or ventricular tachycardia, or significant bradyarrhythmias. Whenever it is possible to establish a relationship between patients symptoms and a ECG trace, the specificity of the test, at least to formulate the diagnosis of arrhythmic or non arrhythmic symptoms, is 100%. The sensitivity of the test, instead, is extremely variable, and depends upon the type of device employed, the duration of the monitoring period, the patient's compliance, and the frequency of symptoms.

In patients with palpitations of unknown origin, Holter monitoring has been shown to have a rather low sensitivity (33 – 35%) (12). In a meta-analysis of 7 studies conducted in patients with syncope and/or palpitations of unknown origin, the sensitivity of Holter monitoring has been reported to be only 22% (13). External loop recorders have displayed a sensitivity of 66- 73% in the study of palpitations of unknown origin (11). ILR devices have been used successfully in the study of syncope (15), in which they have shown a better cost/efficacy ratio than conventional tests, and recently, they also proved useful in the study of palpitations of unknown origin (16). The American FDA has approved the following indications for the use of ILRs: patients with clinical syndromes or situations at high risk of arrhythmia, and patients with transitory symptoms that may suggest a cardiac rhythm disorder. The European Society of Cadiology guidelines on management of syncope recommend the use of ILR in patients with syncope of possible arrhythmic origin, when all the other investigations result inconclusive.

LONG-TERM EVALUATION OF TOTAL (SYMPTOMATIC AND ASYMPTOMATIC) ARRHYTHMIC BURDEN

First of all, we must remember that no recommendations exist in the literature specifically regarding the use of AECG devices able to record arrhythmic events automatically. So we can only hypothesize some possible indications for the new generation ILRs where the long-term evaluation of the total (symptomatic and asymptomatic) arrhythmic burden of patients at risk of arrhythmic events may prove useful. Moreover, it must be underlined that the diagnostic value (i.e. sensitivity and specificity) of the present new generation ILR's algorithms to automatically detect supraventricular and ventricular tachyarrhythmic events are not yet definitively proved in clinical practice. So, all the followings are only hypothesis and they must be carefully verified and validated in clinical practice in the next future.

Silent atrial fibrillation. The algorithms to automatically

detect arrhythmic events contained in the new generation ILRs may be useful for the long-term monitoring of patients with atrial fibrillation (AF). Indeed, success and efficacy of any AF treatment (drugs, ablation, etc.) is not easy to establish, because paroxysmal asymptomatic AF episodes are very frequent and carry the same clinical risks (such as thromboembolic events and heart failure) of symptomatic events. Thus the symptom-based follow up tends generally to overestimate the success rate and the efficacy of therapy. Moreover, the symptom palpitation, which is frequently associated to an AF event, sometimes doesn't correspond to this arrhythmia. Furthermore, the patient's perception of AF may be change over time, especially after ablation. Therefore, the detection of both symptomatic and silent AF episodes results mandatory to verify the real success of any kind of treatment and to assess the need to continue anticoagulation therapy. In this setting, the new ILRs containing the algorithms to detect silent AF would probably be the optimal devices for the long-term monitoring of total AF burden of patients with previously documented paroxysmal/persistent AF, as well as of those at risk of developing AF, such as patients with cryptogenetic stroke, sleep apnea syndrome, chronic obstructive pulmonary disease, severe obesity, hypertension, and so on.

Sudden death risk stratification. Another possible future indication of these devices could be the long term monitoring of patients at intermediate risk of ventricular tachyarrhythmias and sudden death. This could be the case of those patients with ischemic heart disease or dilated cardiomyopathy with only moderately depressed left ventricle ejection fraction, and those with arrhythmogenic heart disease, such as hypertrophic cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy, Brugada syndrome, and Long QT syndrome, without clear indications to ICD implantation. Indeed, the long-term evaluation of ventricular tachyarrhythmic events by means of ILRs, could permit a better prognostic stratification of the risk of sudden death in these patients.

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