



Review

Ambulatory electrocardiogram monitoring devices for evaluating transient loss of consciousness or other related symptoms

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ABSTRACT

Capturing electrocardiograms (ECGs) during spontaneous events is the most powerful available tool to identify or exclude an arrhythmic cause of symptoms, and often can elucidate the definite diagnosis for different conditions, such as transient loss of consciousness (T-LOC), lightheadedness, or palpitations. Current ambulatory ECG monitoring technologies include 24-hour Holter, wearable event recorder, external loop recorder (ELR), and insertable cardiac monitoring (ICM). Of them, Holter ECG is most frequently used in daily practice in Japan, while ELR and ICM are less frequently used. However, the appropriate monitor choice should be based on the expected frequency of symptoms. Frequent events may be adequately detected by Holter ECG, but less frequent symptoms are more effectively assessed by longer-term monitoring (i.e., ELR or ICM). In this report, based on our clinical experience, we review the usefulness of ambulatory ECG monitoring devices, especially of ELR, for evaluating T-LOC and other potentially arrhythmia-related symptoms. Specifically, we focus on the use of ELR and ICM for evaluating Japanese patients with T-LOC.

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1. Introduction

The gold standard to elucidate the etiologic diagnosis of spontaneous symptoms particularly during spontaneous transient loss of consciousness (T-LOC) is the electrocardiogram (ECG) registered during these episode. ECG is of special value when a definite cause cannot be obtained by history and clinical examinations. Several ambulatory ECG (AECG) monitoring technologies

are currently available, but the majority of them can be used only for a few days to several weeks. Longer-term monitoring is often essential to document symptoms that occur infrequently (e.g. once or twice a month or a few times per year). The use of an insertable cardiac monitor (ICM) is now strongly recommended by published practice guidelines for detecting infrequently, but clinically important symptoms [1]. Currently available ICMs can provide long-term ECG monitoring for approximately 3 years, and its clinical usefulness to confirm the diagnosis in patients with syncope of unknown cause has been well established [2–6]. In this report, we reviewed the usefulness of AECG monitoring devices for

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the evaluation of T-LOC and other related symptoms of unknown causes. Furthermore, we describe a more efficient evaluation strategy using ECG monitoring in patients with T-LOC in an outpatient clinic in Japan.

2. Characteristics of ECG monitoring devices

External wearable AECG monitors are categorized as either continuous short-term recorders (i.e., 24–48-hour Holter devices) or intermittent longer-term recorders (i.e., 2–4-week event recorder or external loop recorder [ELR]) [7–9]. A Holter ECG device consists of three to five ECG electrodes that are placed on patient's chest (yielding two ECG vectors), with leads extending to a wearable recording instrument, which is usually worn attached to a belt at the waist. Typically, the recording period is 24–48 hours, and the Holter ECG keeps in memory all ECG recordings during that period. The patient writes a diary to record the times of day when the symptoms occurred during ECG monitoring. The symptoms are very important in order to correlate ECG findings with symptoms, and it is crucial to encourage patients to maintain the diary. When the recording period is over, the patient returns the monitor to the hospital, and then the ECG recording is analyzed.

The wearable external event recorder is a relatively small device (about the size of a cell phone) that can provide ECG monitoring for several weeks, but it does not record every heart-beat; it records the cardiac activity only around the time that the patient presses a button indicating the occurrence of symptoms. When the patient activates the device, a one-lead ECG of approximately 30–180 s can be obtained by placing the device on the chest wall or the fingers (Table 1). Since the event recorder generally has a small storage capacity, it can save only a few ECG strips. Therefore, to minimize the loss of potentially diagnostic data, the patient needs to visit an outpatient clinic or send the data immediately when an event is recorded using a transmission system, such as a mobile phone. This device has fewer lifestyle restrictions than does the Holter. However, one of the disadvantages with the event recorder device is that asymptomatic





events cannot be recorded automatically. Consequently, certain arrhythmias can be missed because of the lack of symptoms.

Loop recorders are available in either wearable or insertable/implantable forms. The term 'loop recorder' indicates that the device not only records ongoing current events, but also maintains in temporary memory recordings for minutes before device activation. Thus, these devices can provide the cardiac rhythm that occurred just prior to patient symptoms. The wearable external loop recorder (ELR) does require attached electrode patches to the patient's skin and with a few exceptions (iRhythm Ziopatch[®], Medtronic SEEQ[®]) can be removed prior to and replaced after taking showers, bathing, or swimming. When a patient activates the device, it stores one or two-lead ECGs for 30 seconds to 15 minutes before and after activation.

Apart from the looping memory function, wearable ELRs and ICMs with and without an auto-trigger function are available. This type of device uses proprietary algorithms (which differ among manufacturers) to trigger ECG storage of arrhythmic episodes, such as brady-arrhythmias or tachy-arrhythmias, asystole, and/or atrial fibrillation. Reiffel et al. retrospectively compared the use of Holter ECG to ELR with an auto-trigger function, in the presence or absence of symptoms and with or without the trigger function [10]. They reported that ELR with auto-trigger function improved the diagnostic rate and obtained earlier diagnosis compared to the conventional 24-hour Holter or a 30-day ELR without auto-trigger function [10]. It has been reported that the diagnostic rate of ECG monitoring for syncope using the ELR (55%) was superior to that of Holter ECG (22%) [11]. Linzer et al. reported that the diagnostic rate of Holter ECG for syncope was only about 10% [12]. Consequently, the ELR with auto-trigger function is able to detect ECG abnormalities even in patients with asymptomatic events. This can reduce the burden on patients to understand the technology or comply with instructions.

Currently available ICM technology has seen substantially miniaturized over time, and consequently became easier to use by patients. In addition, the modern ICM is capable of automatic and manual recording, and has a battery life of more than 3 years. Another important ICM advantage is that a remote monitoring function is already installed. It has also been reported that the diagnostic value of the ICM (approximately 55%) is superior to that

Table 1
Comparison of Cardiac Event Recorders in Japan.

				
Manufacturer	Card Guard	Parama-Tech	Omron	DailyCare BioMedical, Inc./TRYTECH
Model	CG-2100	EP-202	HCG-901	RMH4.2
Number of channels	1	1	1	1
One-time recording	32 s	24 s	30–180 s	30 s
Total number of recordings	1	12	15	100
Type of electrode	Skin electrode	Skin electrode or disposable electrode	Skin electrode or disposable electrode	Thumb electrode or disposable electrode
Automatic analysis of ECG	No	Yes	Yes	Yes
Transmission system	Fixed line, mobile phone	Mobile phone	No	No
Weight	55 g	120 g	140 g	150 g
Feature size	55 × 105 × 15 mm	124 × 18 × 60 mm	121 × 67 × 24 mm	124 × 78 × 24 mm

ECG, electrocardiogram.

of the typical wearable ELR (19%) [13]. However, in some countries (not yet in Japan) there are certain mobile telemetry ELRs (e.g., MCOT, Cardionet, Biotelemetry Inc.) that offer real time remote monitoring and thereby provide more effective monitoring than does a wearable ELR [14], but does not offer the long-term capability of an ICM.

3. Use of ECG monitoring devices in Japan

Use of the ambulatory wearable ELR device is effective for diagnosing symptoms, such as palpitations and/or syncope as long as the events fall within the usual tolerable recording duration of these devices (typically < 1 month).

Although several ambulatory ECG recording devices are available for clinical use in Japan, they are not widely used in daily practice, with the exception of the 24–48 hour Holter. However, in order to obtain the ECG documentation during syncopal episodes, the most important factor is that the monitoring capability is sufficient to encompass the period of infrequent events. Therefore, a relatively short-term ECG monitor (i.e., Holter ECG) is usually inadequate. Wearable ELRs or ICMs are much more likely to capture symptomatic events, but they are much less frequently used in Japan than in the United States or Europe (Fig. 1).

ICM has been available to use in patients with recurrent syncope of unknown causes in Japan since October 2009. The size of initial ILR (implantable loop recorder) was as large as a USB memory device and its shape could often be seen as a raised form under the chest wall in thin Japanese patients. In our experience, three of 88 patients (3.4%) with ILR developed skin infection or pocket erosion at the insertion site. Of 208 patients who had undergone ILR insertions as a part of the CRYSTAL AF trial, 5 (2.4%) patients had their devices removed because of infection or pocket erosion at the insertion site [15]. According to our independent survey, the number of used ILR per 100,000 people in Japan is estimated to be about 23 times lower than in the United States (unpublished data).

The more recent miniaturized ICM (LINQ™, Medtronic Inc., MN, USA) is much smaller and easier to implant than the first generation devices (Fig. 2). This smaller device has been available in Japan since September 2016 and has been increasingly used in Japan, because its small size is easier to use in thin and petite Japanese patients. Since remote monitoring is now installed as a part of the ICM, physicians can obtain an earlier diagnosis over the internet compared to having to wait for patient's scheduled visit,

which might be delayed for several months. On the other hand, since the ICM requires an invasive procedure (albeit very minor and often performed in the outpatient settings) and expensive medical costs, some patients are still hesitant to choose it over other devices.

A wearable ELR can be less expensive than an ICM, but also less effective as a diagnostic instrument (but better than a Holter). The ELR can be used for 2–4 weeks, after which the electrode patches often begin to irritate the skin. In any case, as discussed earlier, in Japan are available ELRs with both manual (i.e., patient triggered by an arrhythmic event) and automatic recording capability. In addition, an ELR that records for up to every 15 minutes before and after the event is available to use in Japan (Table 2).

Many physicians and patients consider the ELR device to be advantageous as it provides relatively long duration ECG monitoring (although much less than an ICM), and it is non-invasive, and relatively inexpensive. However, among the disadvantage of this device, the electrodes may cause blisters or skin rashes, electrical noise due to skeletal muscle, and it must be worn continuously. Additionally, although lethal arrhythmic events may (or could) occur while taking a bath or shower, or swimming, the patient has to remove the ELR (with a couple exceptions noted earlier) during these activities [16,17]. Use of the ICM should be considered if the patients had any symptoms during bathing or physical exercise.

4. Time to definite diagnosis after ICM in patients with syncope

The time required to diagnose syncope using an ICM depends on the cause of syncope. The time to definite diagnosis after ICM in patients with syncope has been investigated at University of Occupational and Environmental Health, Japan, and the results are shown in Fig. 3.

We retrospectively analyzed ICM outcomes in 85 patients with syncope (Fig. 4). Fifty-nine of the 85 patients (69%) with an ICM had the etiology of their syncope determined at a median duration of 176 days following ICM implantation (interquartile range [IQR]: 68–380 days). Of the 59 diagnosed patients, 16 (27%) were diagnosed within 4 weeks after ICM implantation and 42 (71%) experience a cardiac syncope and 17 (29%) had syncope due to non-cardiac causes. The 59 diagnosed patients were divided into the 2 groups based on the time to diagnosis after implantation of ICM (Figs. 3 and 4). The first group comprised patients who were diagnosed within 4 months of implantation (the early diagnosis), and the second group comprised patients who were diagnosed after 5 months or longer (the delayed diagnosis) after implantation. The median time to diagnosis was 110 days (IQR: 23–347 days). Of the 59 patients, 31 patients were in the early diagnosis group (53%; mean age, 68 ± 15 years; 22 men; mean follow-up period, 40 ± 36 days). Twenty-seven of the 42 (64%) patients with cardiac syncope were in this group. The remaining 28 of the 59 patients (47%; mean age, 71 ± 16 years; 17 men; mean follow-up period, 447 ± 303 days; $P < 0.0001$) were in the delayed diagnosis group. Thirteen of the 17 (76%) patients with non-cardiac syncope were in this group. A cardiac syncopal event was more commonly detected in the early diagnosis group than in the delayed diagnosis group ($P = 0.0039$). Interestingly, 27 of the 42 (64%) patients with cardiogenic syncope had no clinical symptoms.

ELR may useful before ICM implantation since 16 (27%) of the 59 diagnosed patients were diagnosed within 4 weeks in our results. Consequently, a more aggressive use of ELR, but not of Holter, may be justifiable to prevent the unnecessary use of ICM. However, an ICM should be recommended if no diagnosis is obtained using ELR or if the frequency of symptoms is less than

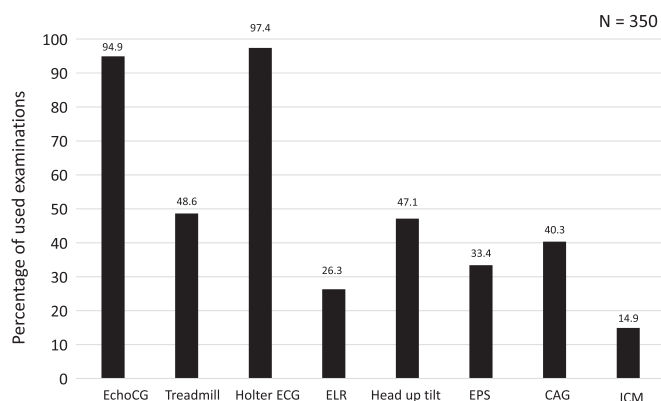


Fig. 1. Examinations used in patients with unexplained syncope Results of the questionnaire survey used in syncope clinics by cardiovascular specialists in Japan (n=350). EchoCG, echocardiography; ELR, external loop recorder; EPS, electrophysiology study; CAG, coronary angiography; ICM, insertable cardiac monitoring.

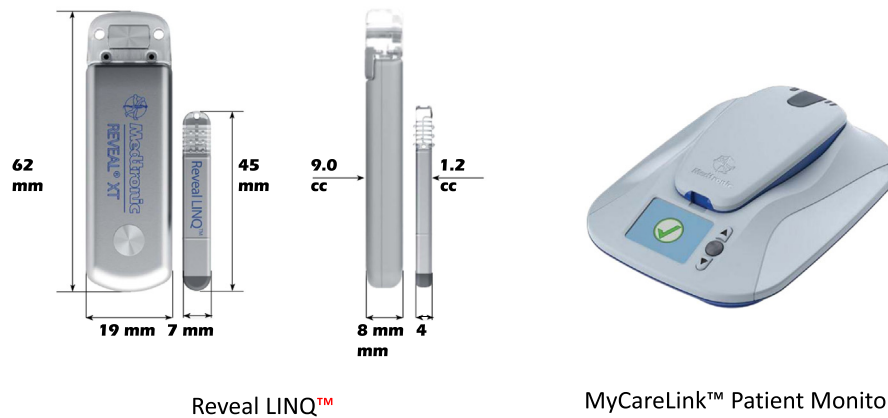






Fig. 2. Reveal LINQ™ insertable cardiac monitor and MyCareLink™ Patient Monitor for remote monitoring system (Medtronic Inc., Minneapolis, MN, USA).

Table 2

Comparison of External Loop Recorders in Japan.

				
Model and Manufacturer	CG-6106 Card Guard	FM-190 FUKUDA DENSHI	SpiderFlash-t AFIB Sorin/ JLL	EV-201 Parama-Tech
Style	Induction cord and electrode	Induction cord and electrode	Induction cord and electrode	Chest belt
Number of days to wear	14	3	40	7 (continuous mode or 21 (event mode))
Number of channels	1	1	1 or 2	1 or 2
Auto/manual trigger	No/Yes	Yes/Yes	Yes/Yes	Yes/Yes
Handheld device data storage capacity (before/after)	60 sec/27 sec	30 or 60 s/30 or 60 s	Auto trigger: 7.5 min/ 15 min Manual trigger: 7.5 min/ 15 min	Auto trigger: 15 min/15 min Manual trigger: 15 min/15 min
Event count	6 times	135 times	2000 times	500 times
Handheld device data storage capacity	8.7 min	4.5 h	100 h (maximum)	168 h (continuous mode) or 504 h (event mode)
Weight	35 g	78 g	50 g	280 g
Feature size	55 × 12 mm	65 × 62 × 18 mm	75 × 50 × 19.5 mm	110 × 70 × 20 mm

once per month. This strategy seems to be effective in minimizing medical cost, enhancing patient acceptance, and shortening the time to clinical diagnosis.

5. Use of the ELR in Japan

Kawasaki et al. reported the usefulness of ELR with auto-trigger function, which can detect and record any arrhythmic events manually and automatically, in patients with palpitation in Japan [18]. Fifty-nine patients with palpitation who visited their hospital received an ELR for about 8 days. Forty-two patients were diagnosed as having arrhythmic events by ELR. Symptomatic events in four patients were not related to any arrhythmias. They concluded that the ELR with auto-trigger function was useful for evaluating the relationship between symptoms and arrhythmias.

The ELR, EV-201 (Parama-Tech Co., Ltd., Fukuoka, Japan) (Table 2), is commonly used in Japan. This device does not require

electrode patches and leads, and can be easily and discretely worn with a chest belt, especially by elderly patients. The longest ECG monitoring period of this device is 3 weeks; it is capable of obtaining recordings manually if triggered by the patient when symptoms occur, as well as automatically if triggered by arrhythmia events. It has a looping memory for 15 minutes before and after the event. In this device, both the Holter-ECG mode and event-ECG mode are available. In the Holter ECG mode, the device can record continuously for 168 consecutive hours (approximately 7 days). The selection of this mode will be recommended for the detection of asymptomatic arrhythmic events, such as asymptomatic atrial tachy-arrhythmias. In the event ECG mode, the device can record for 504 hours (approximately 3 weeks) with 500 event records. The selection of this mode is optimal for the detection of transient loss of consciousness events.

The EV-201 was used in our laboratory in 20 patients (57 ± 20 years of age, 6 men) with palpitations and 20 patients (63 ± 20 years of age, 12 men) with syncopal attacks (Fig. 5). Mean ECG

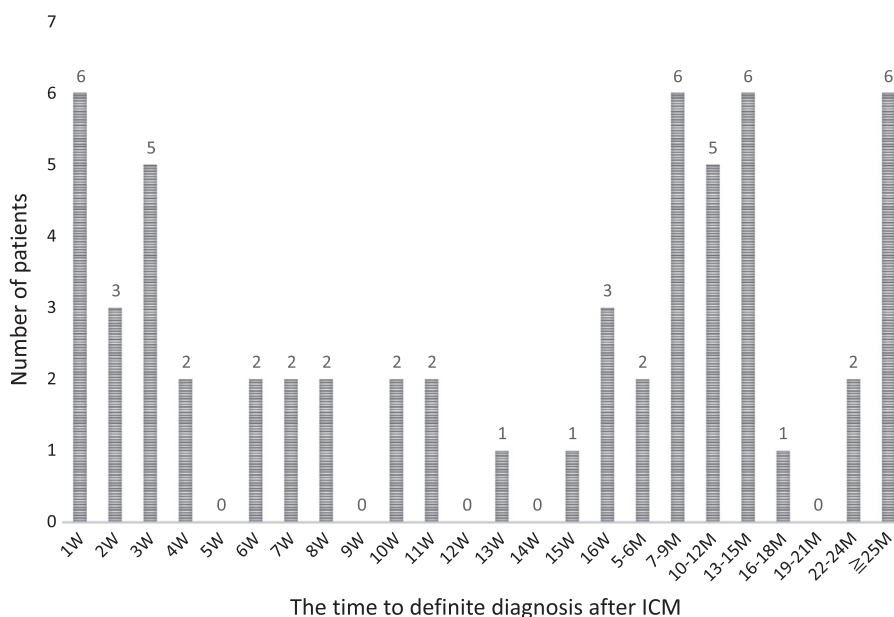


Fig. 3. Time to definite diagnosis after ICM in patients with syncope ICM, insertable cardiac monitoring; W, weeks; M, months.

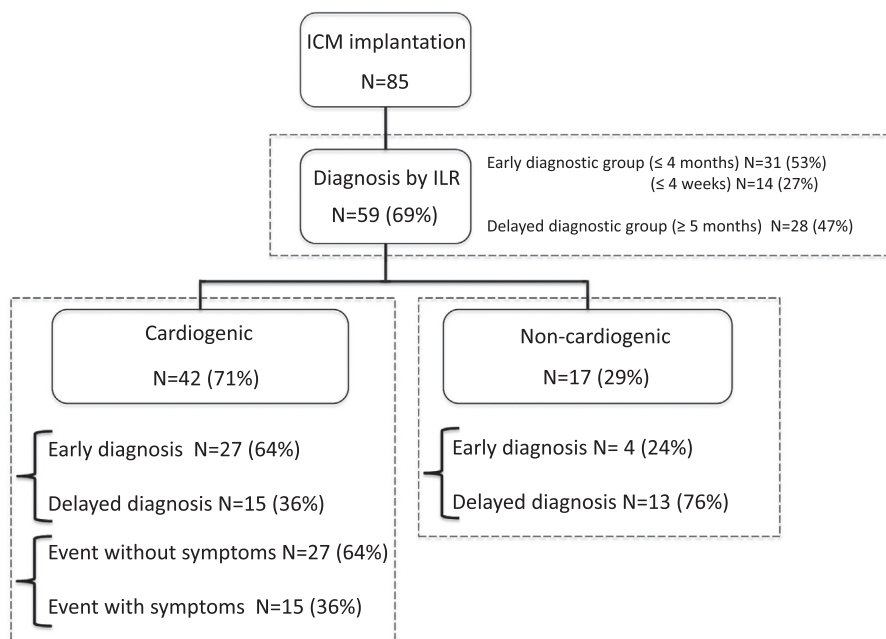


Fig. 4. Diagnostic rate when using ICM in patients with syncope at the University of Occupational and Environmental Health in Japan. ICM, insertable cardiac monitoring; ILR, implantable loop recorder.

monitoring periods were 12.8 ± 7.1 days in patients with palpitations and 15.8 ± 5.6 days in patients with syncope. The event ECG mode was selected in 17 patients (85%) with syncope, and the Holter ECG mode was selected in 11 patients (55%) with palpitations. In the 10 out of the 20 patients with palpitations (50%), a definite diagnosis of paroxysmal atrial fibrillation was established in five patients, the other diagnosis was as follows: paroxysmal supra-ventricular tachycardia (1 patient), premature ventricular contractions (1 patient), Wenckebach-type AV block (1 patient), sinus tachycardia (1 patient), and postural orthostatic tachycardia syndrome (1 patient). Among the 20 patients with syncope, a definite diagnosis was established in six cases. Two of these

patients were diagnosed with bradycardia-tachycardia syndrome and four were diagnosed with non-cardiac syncope. After the use of ELR in the 20 patients with syncope, 14 patients were undiagnosed. Five of these patients received an ICM thereafter. Of these five patients, four were diagnosed within an average of 2.7 months using the ICM. Fig. 6 shows a typical case of bradycardia-tachycardia syndrome demonstrated using an EV-201 ECG device.

Finally, as was previously mentioned, a notable progressive development in ambulatory external ECG monitoring technology occurred recently. Specifically, a patch-type ELR monitor that is not affected by exposure to water and can be worn continuously is already being used in Europe and the United States, but is not yet

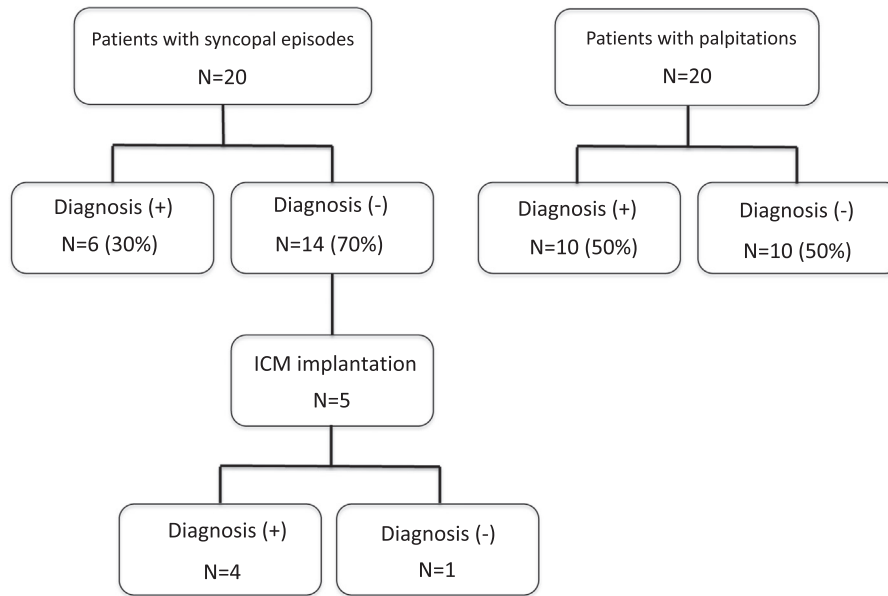


Fig. 5. Diagnostic rate when using ELR (EV-201) at University of Occupational and Environmental Health, Japan. ELR, external loop recorder; ICM, insertable cardiac monitoring.

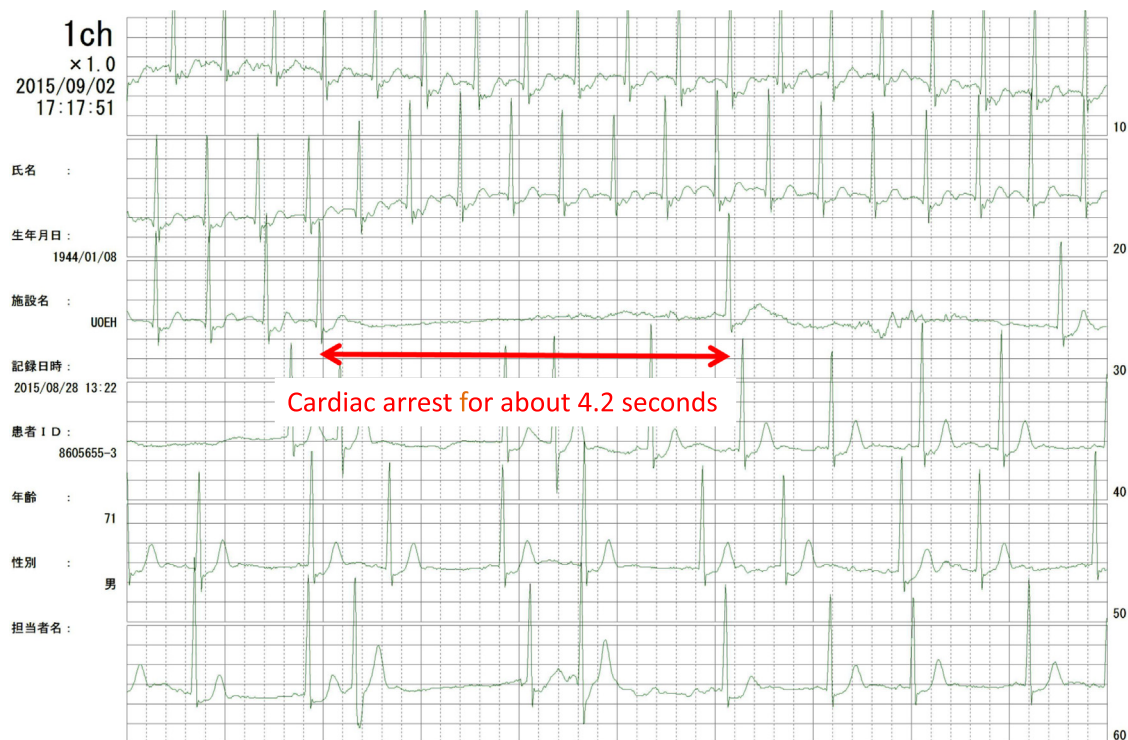


Fig. 6. Example of ECG abnormalities detected using ELR (EV-201) in a patient with syncope. ELR, external loop recorder.

available in Japan. These newer technological developments have already markedly enhanced clinician's ability to diagnose the cause of symptoms in patients with suspected arrhythmias in a more accurate and cost-effective manner.

6. Conclusions

Long-term ECG monitoring is essential for the detection of arrhythmias that cause syncope and other related symptoms. The less frequent symptomatic events, the longer the monitoring duration is required. Thus, Holter ECG is only useful if events occur

every day or every other day. ELRs are most effective if events occur every week to within 3 weeks. Therefore, ICMs are the monitoring tools of choice. One could argue that since ELR devices are non-invasive, inexpensive, and have only minimal effect on patient's quality of life, the proactive use of ELRs in patients with unexplained, potentially arrhythmic symptoms (and with suspected syncope in particular) seems justified prior to proceeding to an ICM implantation.

Conflict of Interest

Ritsuko Kohno and Haruhiko Abe declare no conflicts of interest.

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None.

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