Use of a Patient-Activated Event Recording System in Patients with Tachycardic Palpitations: How Long to Follow Up?

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Introduction: Palpitations are a common symptom causing patients to consult a cardiologist, yet diagnosing a potential cardiac origin can be difficult. In patients with a nondiagnostic Holter-ECG, external loop-recorders are an additional tool to diagnose the clinical arrhythmia in these patients. The aim of our study was to evaluate the additional value of an external, patient-activated loop recorder and to determine the optimal time of follow up needed to achieve a symptom–rhythm correlation with the device.

Methods and Results: A total of 1404 patients presented to our outpatient clinic between November 2011 and November 2014 for first time evaluation of symptomatic arrhythmias. Of a total of 91 patients were included (age 43.6 ± 18.1 ; 69.2% female) in the study. All patients presented with tachycardic palpitations and a 48-hour Holter-ECG that did not detect relevant arrhythmias. All patients were given a “leadless” patient-activated event-recording system and regular follow-up visits were scheduled after 3, 6, and 12 months. Within a maximum follow-up time of 1 year, 72 patients (79.1%) recorded at least one ECG with the device. Of the recorded ECGs, 51% were recorded within the first week after the device was handed out. This figure rises to 80% and 93% after 1 and 2 months. The last recording was after 174 days.

Conclusion: For patients with tachycardic palpitations, the external “leadless” event recorders are effective in achieving a symptom–rhythm correlation. A follow up of 2 months will suffice to establish a diagnosis in a large majority of this patient group.

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Palpitations are a common symptom causing patients to seek help of a cardiologist. To determine whether the cause is benign or further specific treatment is needed, the initial diagnostic evaluation should always include a detailed history, physical examination, and 12-lead electrocardiography.¹ Yet, in most of the cases, the initial evaluation will be completely unremarkable and a diagnosis can only be presumed.²

To exclude or determine an arrhythmic cause, the cardiac rhythm has to be recorded during an episode of palpitations. Holter-ECG monitoring is commonly used as a first-line diagnostic tool. As

the preferred monitoring interval is 24–48 hours,³ the diagnostic yield can be very low, especially if symptoms do not occur daily. So other ambulatory monitoring devices that allow a longer follow-up must be used if the diagnosis is still unclear.

According to a position paper by the European Heart Rhythm Association,² external patient-activated event recorders are recommended in patients with nondiagnostic Holter-ECG with palpitations not accompanied by hemodynamic impairment. For this study, such patients presenting to our outpatient clinic were included. The aim of this analysis was to determine the optimal time of

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Figure 1. Flow chart demonstrating how patients were included in the study.

follow-up needed to achieve a symptom–rhythm correlation with the device.

METHODS

A total of 1404 patients presented to our outpatient clinic between November 2011 and November 2014 for first time evaluation of symptomatic arrhythmias. Ninety-one patients presenting with palpitations were included in this study. Included patients described tachycardic palpitations, had no known structural heart disease and normal transthoracic echocardiography. A 12-lead electrocardiography as well as 48-hour Holter could not establish a diagnosis. Exclusion criteria were a history of syncope as well as the presence of a pacemaker or an implantable defibrillator. Patients who were incapable of using the device adequately were also excluded (Fig. 1).

All patients were given a “leadless” patient-activated event-recording system (Omron HeartScan 801, Port Melbourne, Australia) and instructed on how to use it. Patients were advised to use the recorder only once or twice during symptoms and once again when symptoms had passed or significantly changed. The function of the device was described before by Kaleschke et al.⁴ Follow up was scheduled after 3 months. If no episode was recorded in this period of time, follow up was prolonged for up to 1 year with visits after 6 and 12 months. All recorded tracings were downloaded and analyzed by a trained cardiologist.

Table 1. Baseline Patient Characteristics

	(n = 91)
Age (SD) (years)	43.6±18.1
Female (%)	63 (69.2)
Structural heart disease (%)	0 (0)
Hypertension (%)	12 (13.2)
Diabetes (%)	2 (2.2%)
Beta adrenergic blocker	14 (15.4)
ACE/ARB	6 (6.6)
Symptoms	
Palpitations (%)	91 (100)
Dizziness (%)	12 (13.2)
Sudden onset (%)	16 (17.6)
Vagal maneuvers successful (%)	6 (6.6)

SD = standard deviation; ACE = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker.

Statistical Analysis

Data are expressed as mean ± standard deviation or as absolute values and percentages as appropriate. Statistical analyses were conducted using SPSS software (SPSS v22, IBM, Armonk, NY, USA).

RESULTS

A total of 91 patients were included. Baseline patient characteristics are summarized in Table 1.

Seventy-two patients (79.1%) recorded at least one ECG with the device. Patient on average recorded 22 ± 19 ECGs. The quality of the recorded ECG was sufficient in all patients to establish a diagnosis. Table 2 summarizes the recorded episodes.

Table 2. Results

	(n = 91)
Number of patients that recorded an ECG during symptoms (%)	72 patients (79.1)
Episodes recorded	
Sinus tachycardia (%)	25 (27.5)
Sinus rhythm (%)	19 (20.9)
Ventricular or supraventricular premature beats (%)	12 (13.2)
Atrial fibrillation/atrial flutter (%)	9 (9.9)
AVNRT/AVRT (%)	7 (7.7)

AVNRT = atrioventricular nodal reentrant tachycardia; AVRT = atrioventricular reentrant tachycardia.

The average time of follow-up until a rhythm-symptom correlation was achieved with the event recorder was 20.6 ± 30.4 days (median 7 days, IQR 23.5). Of the recorded ECGs, 51% were recorded within the first week after the device was handed out. This figure rises to 80% and 93% after 1 and 2 months. The last recording was after 174 days (Fig. 2). The maximum follow-up was 1 year. Patients with "true" arrhythmias recorded an ECG after a median of 21 (IQR 38) days, compared to a median of 4 (IQR 17) days for those that registered sinus rhythm or sinus tachycardia.

DISCUSSION

Event recorders do not register ECG signals continuously, but during shorter, programmable time periods. The patient is able to trigger the registration himself, which helps to diagnose infrequent episodes of palpitations.

External, patient-activated event recorders can be divided in two groups. The first group of recorders are continuously connected to the patient skin with sticky electrode patches. The second group has to be placed in contact with the chest during symptoms (so-called "leadless" event recorders). When used to establish a diagnosis in patients presenting with palpitations, external patient-activated event recorders showed a diagnostic yield of 66%.⁵ In another study by Brown et al.,⁶ ECG signals during symptoms were obtained in 68% of patients presenting with palpitation, dizziness, or syncope. One randomized clinical trial was conducted to evaluate the use of an external, patient-activated event recorder for patients who consulted their general practitioner for a new episode of palpitations and/or light headedness.⁷ A cardiac diagnosis explaining the symptoms was found in 67% of the participants. Another recently performed analysis even found a 86% diagnostic yield for palpitations when an external loop recorder was used.⁸

All these studies were performed using a "standard" loop recorder with electrode patches. The "leadless" event recorder used in our study was previously compared by Scherr et al. to the standard event recorder in the diagnosis of patients with palpitations.⁹ In this prospective comparative study, 18 patients received both a standard and a "leadless" patient-activated event recorder. Both devices showed comparable results.

Asmundis et al. performed a larger study comparing a leadless patient activated event recorder with traditional 24-hour Holter in patients with palpitations or dizziness.¹⁰ Although Holter

Figure 2. Percentage of registered ECGs with successful rhythm-symptom correlations at different time points of follow-up.

monitor recording was able to detect the clinical cardiac arrhythmia only in 1.8% of patients, the leadless patient activated event recorder detected symptoms-related arrhythmias in 89% of the patients.

In our study, a rhythm-symptom correlation was achieved in 79% of the patients, which again confirms the high diagnostic yield of the device. In addition, our goal was to determine the optimal time of follow-up.

In our collective of 91 patients, 72 (79.1%) recorded at least one ECG during symptoms within a maximum follow-up of 1 year. A total of 51% of the ECGs were recorded within the first week, 80% within 1 month, and 93% within 2 months. These results suggest that within a follow-up of two months, the overall majority of patients that will eventually record ECG signals during symptoms is included. Follow-up may be prolonged for another 1 or 2 months for individual cases. Interestingly, patients with "true" arrhythmias recorded an ECG later than those that registered sinus rhythm or sinus tachycardia.

In conclusion, external "leadless" event recorders are effective in achieving a symptom-rhythm correlation in this patient collective within a follow up of 2 months. Unfortunately, these devices are still quite costly and their number is limited. Cheaper, smartphone-based external event recorders are under development, which may provide a solution to this problem.

LIMITATIONS

The limited number of patients should be considered when interpreting our study. Nonetheless, the arrhythmias that were recorded (premature beats 13%, atrial fibrillation 9%, supraventricular tachycardia 7%) reflect the spectrum and incidence of arrhythmias that are expected in this age

group. In our opinion, it is unlikely that the distribution and type of arrhythmias (including sinus tachycardia) would be very different if the study was conducted in another center or if more patients were included.

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