# Diagnostic Yield of Automatic and Patient-Triggered Ambulatory Cardiac Event Recording in the Evaluation of Patients with Palpitations, Dizziness, or Syncope

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### Summary

*Background:* Recent studies have shown that patient-triggered cardiac event recorders (CER) have an increased diagnostic yield and are more cost effective than conventional 24h-Holter electrocardiograms (ECGs) for the evaluation of sporadic, potentially arrhythmia-related symptoms.

*Hypothesis:* The aim of this study was to determine the diagnostic yield of a patient-triggered CER combined with continuous automatic arrhythmia detection in the evaluation of sporadic dizziness/syncope or palpitations and its clinical relevance in assessing the further management.

*Methods:* We investigated 101 consecutive outpatients (54  $\pm$  20 years, 40 women), referred for evaluation of sporadic dizziness and syncope (36%) or palpitations (64%) of suspected rhythmogenic origin. All were monitored by patient-triggered CER with continuous automatic arrhythmia detection.

*Results:* After a mean monitoring period of  $103 \pm 38$  h, 83 patients registered symptoms and 57 patients had diagnostic or therapeutic relevant arrhythmias (relA). A total of 196 episodes of relA were recorded; 31 (16%) episodes were patient-triggered and 165 (84%) automatically recorded. Diagnostic relevant episodes (relA and/or typical symptoms) occurred in 94 patients, in 54% after the first 24 h of monitoring. According to the results of the CER, 80 patients needed no further diagnostic evaluation; 20 had additional diagnostic tests.

*Conclusions:* Cardiac event recorders with a continuous automatic arrhythmia detection function are a well-tolerated device for sporadic, potentially arrhythmia-related symptoms. The patient-triggered mode alone is not sufficiently reliable; the automatic continuous arrhythmia detection function has additional diagnostic and therapeutic consequences. In 54% of all patients, the first diagnostic event would not have been recorded with a single conventional 24-h-Holter ECG.

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## Introduction

Unexplained syncope, dizziness, and palpitations are among the most common reasons that patients present to internists and cardiologists.<sup>1,2</sup> The diagnostic evaluation with a conventional 24-h-Holter electrocardiogram (ECG) is sometimes unsatisfactory because of the sporadic and unpredictable nature of these symptoms, possibly due to cardiac arrhythmias. Therefore, cardiac event recorders (CER) offer an interesting possibility for prolonging the cardiac rhythm monitoring compared with standard Holter systems. According to the recent literature, patient-triggered CERs seem to be a valid alternative to 24-h-Holter ECGs, as they show an increased diagnostic yield and are more cost effective than conventional 24-h- or even 48-h-Holter ECGs.<sup>3-7</sup> Until now, most of the routinely used CERs are patient triggered only, allowing for registration of an ECG during typical symptoms.<sup>3-7</sup> In this study, a recently released CER was evaluated in patients with syncope, dizziness, and palpitations. This device features both automatic and patient-triggered arrhythmia detection up to 7 days of monitoring. Only few data are available about its efficacy and clinical relevance in unselected groups of ambulatory patients.<sup>8,9</sup> The aim of this study was to determine the diagnostic yield of this CER, with an added automatic arrhythmia detection function, in the ambulatory evaluation of sporadic syncope, dizziness, and palpitations, and to demonstrate its clinical relevance in assessing further patient management.

## Methods

#### Patients

In all, 101 consecutive patients, referred to our cardiology unit for evaluation of sporadic (less than one episode per day) syncope, dizziness, and palpitations, were prospectively enrolled in this study. Patients who experienced symptoms daily were excluded, as were patients in whom history and basic cardiological workup (physical examination, resting ECG, echocardiography) revealed the cause of their symptoms, that is, aortic stenosis, cerebrovascular disease, or arrhythmias present in the resting ECG. Baseline patient characteristics and indications for monitoring are shown in Table I.

Age (years)	$54\pm20$
Men/women (n)	61/40
Indications for monitoring	
Palpitations (%)	65 (64)
Dizziness/syncope (%)	36 (36)
Known cardiovascular disease $a(\%)$	53 (52)
Coronary artery disease (%)	29 (29)
Hypertension (%)	9(9)
Valvular heart disease (%)	19(19)
Cardiomyopathy (%)	4(4)
Others (%)	6(6)
Monitoring time (h)	$103 \pm 38$

 
 TABLE I
 Baseline charactersitics and indications for monitoring in 101 patients with cardiac event recordings

<sup>a</sup> Defined as structural heart disease.

Data are presented as numbers (%) of patients or mean value ( $\pm$  standard deviation).

#### **Cardiac Event Recorder and Monitoring Protocol**

All patients were monitored with a commercially available CER (R-Test<sup>™</sup>Evolution, Novacor, France). This new monitoring device has a continuous loop analysis of up to 7 days and a 20-min solid-state memory. It combines patient-triggered recordings with a continuous automatic arrhythmia detection function and features additionally a continuous trend of heart rate monitoring. Both of these monitoring capabilities can be programmed separately for pre- and post-triggering delay. The most serious automatic and all patient-triggered events are recorded in a user-defined manner on the 20-min solid-state memory. The R-Test Evolution is able to register up to 10 categories of arrhythmic events, based on an algorithm which analyzes QRS prematurity and width, and 1 category of ischemic events. In the current protocol the preand post-triggering delay was programmed to 20 and 10 s, respectively, in the patient-triggered and automatic mode. The amount of solid-state memory available to each category of events (automatic and patient triggered) was programmed as follows: 8 min for pauses (16 events), 5 min for bradycardia (10 events), 4 min for tachycardia (8 events), and 3 min for patient-triggered events (6 events). Device setup, data recovery, and data analysis took a total of no more than 45 min. To obtain an optimal diagnostic yield, patients were asked to use the device continuously for 7 days.

#### **Data Collection and Data Analysis**

The 101 CERs were collected after 7 days. The ECG stripes of all patient-triggered and automatically recorded events were analyzed independently by two cardiologists blinded to the study. Relevant arrhythmias were defined as follows: ventricular tachycardia (> 100 beats/min and  $\geq$  3 beats), ventricular bigeminus, supraventricular tachycardia (> 100 beats/min and  $\geq$  3 beats), atrial fibrillation or flutter, bradycardia (< 40 beats/min) and pauses (RR-interval  $\geq$  3 s).

#### Results

The study sample consisted of 40 women and 61 men with a mean age of  $54 \pm 20$  years. One patient was lost to follow-up. Of the monitored patients, 36% complained of syncope or dizziness and 64% of palpitations; 52% had known structural heart disease. The frequency of symptoms before entering the study was one to five episodes per week in 30% of the patients, one to three episodes per month in 28%, less than one to three episodes per month in 33%, and 9% of the patients had one single symptomatic episode before referral only. The mean monitored time period available for analysis was  $103 \pm 38$  h (equal to 4.3 days of 7 monitoring days).

During the monitoring period, 83 patients registered symptoms (52 patients had palpitations, 29 dizziness, and 2 experienced a syncope) and 57 had relevant arrhythmias (manually or automatically triggered), as shown in Figure 1. Of the 83 symptomatic patients, 55% showed relevant arrhythmias, in 37% correlating with symptoms. A total of 196 relevant arrhythmias were registered (1.94 arrhythmic episodes per patient): 8 episodes of ventricular tachycardia, 14 episodes of ventricular bigeminus, 33 episodes of atrial fibrillation or flutter, 92 episodes of supraventricular tachycardia, 42 bradycardias, and 7 pauses. Thirty-one (16%) episodes were patienttriggered and 165 (84%) automatically recorded (Fig. 1). Of the 18 patients who were asymptomatic during the monitoring period, 11 (61%) had relevant arrhythmias registered by the automatic arrhythmia detection function only (18 episodes of supraventricular tachycardia, 6 episodes of atrial fibrillation or flutter, 6 episodes of ventricular bigeminus, and 1 pause). According to the results of the CERs, 80 patients had no need for further evaluation, 23 (29%) required therapy based on the results, and 57 (71%) could be reassured because of the harmless nature of their symptoms (Table II). Twenty patients had additional diagnostic tests, 6 patients as a direct consequence of the CER findings (3 ventricular electrophysiologic studies, 2 laboratory tests, and 1 cardiac magnetic resonance imaging for right ventricular dysplasia), and 14 needed further workup because of nonconclusive results (3 head-up tilt tests, 3 neurologic evaluations, 6 repeated R-Tests and 2 24-h-Holter ECGs). Diagnostically relevant episodes, defined as relevant arrhythmias and/or typical symptoms, occurred in 94 patients. Only seven patients had no symptoms or relevant arrhythmias during the monitoring period. In 54% of these 94 patients, the first registered event was recorded after the first 24 h of monitoring and, therefore, would have been missed with a standard 24-h-Holter ECG. Of the 80 patients who had no need for further investigations, 41 (51%) had their first diagnostic event after the first 24 h of monitoring. Similarly, 12 (60%) of the 20 patients who needed further tests had their first diagnostic event after the first 24 h. Of the 289 registered patient-triggered ECG strips, 225 (78%) showed normal sinus rhythm, 28 (9%) sinus tachycardia, 31 (11%) relevant arrhythmias, and only 5 (2%) episodes could not be interpreted because of a poor recording quality.

Separate analysis for the groups with and without structural heart disease (53 vs. 48 patients) showed a higher diagnostic

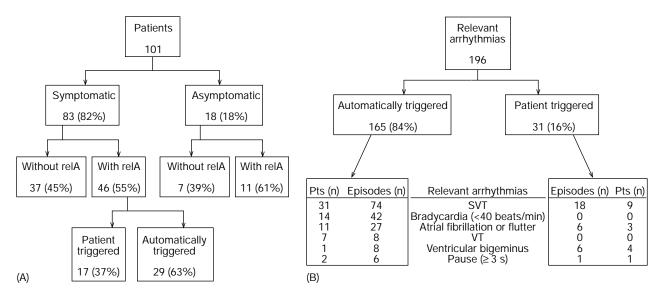


FIG. 1 (A) Flow diagram for symptomatic and asymptomatic patients during the monitoring period, showing positive and negative clinical correlation between symptoms and registered relevant arrhythmias. Data are presented as numbers (%) of patients. (B) Registered relevant arrhythmias sorted by the triggering mode and type of arrhythmia. Data are presented as numbers (%) of relevant arrhythmia episodes and numbers of patients. SVT = supraventricular tachycardia, VT = ventricular tachycardia, relA = relevant arrhythmias, Pts = patients.

yield in the group with organic heart disease. In this group, 72% had relevant arrhythmias compared with 40% in the group without structural heart disease. The number of patients registering symptoms during the monitoring period was not significantly different between these two groups: 81% (43/53) compared with 83% (40/48) (Table III).

## Discussion

Recent data have confirmed that the diagnosis of cardiac arrhythmias in the clinical evaluation of syncope, dizziness, and palpitations can be enhanced by CERs compared with conventional 24-h-Holter ECGs.<sup>3–7</sup> So far, the main limitation of routinely used CERs was the fact that all recordings used the patient-triggered mode only. We tested a recently released CER with an added automatic arrhythmia detection function in the evaluation of sporadic and potentially rhythmogenic symptoms. Very few data are available about the diagnostic yield and clinical relevance of combined automatically and patient-triggered registering devices. Until now, two studies have evaluated the automatic arrhythmia detection function of this CER in patients with simultaneously conventional Holter recordings.<sup>8,9</sup> Simonetti *et al.*, in a group of 31 patients with syncope, dizziness, and palpitations, found that during a monitoring period of 7 days all relevant arrhythmias registered by the 24-h-Holter ECG were also recorded by the R-Test Evolution.<sup>8</sup> Roche *et al.*, in 103 patients after myocardial infarc-

Table II	Diagnostic and	l clinica	l consequences
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	Further test <sup>a</sup>	Start therapy b	Reassurance	Unknown	Total
Symptomatic patients					
Patient-triggered relA	1	11	5	0	17
Automatically triggered relA	6	7	16	0	29
NorelA	8	3	25	1	37
Asymptomatic patients					
With relA	4	2	5	0	11
Without relA	1	0	6	0	7
Total	20	23	57	1	101

Data are presented as numbers (n) of patients.

<sup>a</sup> Three ventricular electrophysiologic studies, two laboratory tests, one cardiac magnetic resonance imaging, three head-up tilt tests, three neurologic evaluations, six repeated R-Tests, two 24-h Holter ECGs.

<sup>b</sup> Two pacemakers, one ICD, two radiofrequency ablations, 18 drug therapies.

Abbreviations: relA = relevant arrhythmias, ICD = implantable cardioverter defibrillator.

TABLE III Analysis for patients with and without structural heart disease

	Structural heart disease	
	Yes	No
	53	48
Symptomatic patients	43	40
Asymptomatic patients	10	8
Relevant arrhythmias	38	17
Patient triggered	10	7
Automatically triggered	35	17

Data are presented as numbers (n) of patients.

tion, found that the sensitivity of the R-Test Evolution, compared with a conventional Holter ECG, was 100% in detecting pauses, bradycardia, atrial fibrillation, and episodes of ventricular bigeminus; 70 to 82% in detecting supraventricular tachycardias; and 86% in detecting ventricular tachycardias.9 In the same study, while exclusively using the automatic mode in 35 patients, 6 (17%) of these patients revealed abnormal ECG findings that occurred beyond the first 24-h period. In our study, 54% of the patients had their first diagnostic event after the first 24 h of monitoring, which probably would not have been recorded with a single 24-h-Holter ECG. Zimetbaum et al. found that 80% of their patients examined for palpitations had at least one diagnostic event during the first week of monitoring.<sup>4</sup> This result is comparable with the rate of 82% we found in our cohort. In the same study, the average of 1.04 diagnostic rhythm strips per patient per week was also similar to the average of 1.09 in our study.

Compared with other CERs, the most important feature of this device is the added automatic arrhythmia detection function. This feature was helpful in detecting 84% of all relevant arrhythmia episodes, and at least one episode of relevant arrhythmia was registered in an additional 61% of our asymptomatic patients. Of those who did not trigger the recording of any relevant arrhythmia during their symptoms, 63% nevertheless showed relevant arrhythmias in the automatically registered ECG strips (Fig. 1). Thus, for the ambulatory workup of suspected sporadic arrhythmias, the patient-triggered function alone is probably not sufficiently reliable.

Up to now, conventional 24-h-Holter ECGs represented the standard of reference in the evaluation of potentially rhythmogenic symptoms; our data demonstrate the diagnostic yield and usefulness of CERs as complementary instruments compared with standard Holter technique. The CER was well tolerated. Setup, data recovery, and data analysis took no more than 45 min, even less than for a conventional 24-h-Holter ECG. The optimal monitoring time for cardiac event recorders in the examination of sporadic palpitations was found to be 2 weeks. After this period, there is very little additional diagnostic yield compared with rapidly rising costs.<sup>4</sup>

## Limitations

A limitation of the current study is the relatively small sample of patients studied in a tertiary referral center. An important issue is the lack of recording during hours when the CER was not in place (i.e., during bathing), including the possibility of missing relevant events. A third limitation of this study is that 52% of patients had known cardiovascular pathology and were likely to have an arrhythmia within the week of monitoring. Therefore, it is possible that such devices would yield the most benefit in patients with a higher likelihood of having an event within a week of monitoring, but may not be applicable in those without structural heart disease who are likely to experience arrhythmic events much more rarely.

#### Conclusion

Cardiac event recorders, with a continuous automatic arrhythmia detection function combined with a patient-triggered registering mode, are well tolerated devices for the ambulatory evaluation of sporadic, potentially arrhythmia-related symptoms. The patient-triggered mode alone is not sufficiently reliable; the automatic arrhythmia detection function has additional diagnostic and therapeutic consequences. In 54% of the patients, the first diagnostic event (relevant arrhythmia and/or typical symptom) occurred after the first 24 h of monitoring and therefore would not have been recorded with a single conventional 24-h-Holter ECG.

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