Reprinted from ANNALS OF INTERNAL MEDICINE Vol. 124; No. 1, (Part 1), 1 January 1996
Printed in U.S.A.

Cardiac Event Recorders Yield More Diagnoses and Are More Cost-effective than 48-Hour Holter Monitoring in Patients with Palpitations

A Controlled Clinical Trial

Scott Kinlay, MBBS, PhD, FRACP; James W. Leitch, MBBS, FRACP; Amanda Neil, BSc; Barry L. Chapman, MBBS, FRACP; David B. Hardy, DMU, RDCS; and Peter J. Fletcher, MBBS, PhD, BMed(Sci), FRACP

Objective: To compare the diagnostic yield and cost-effectiveness of transtelephonic event monitors with those of Holter monitoring in patients with intermittent palpitations.

Design: Randomized crossover trial.

Setting: Diagnostic service of a teaching hospital and surrounding primary care practices.

Patients: 43 patients with previously uninvestigated palpitations who were referred for Holter monitoring.

Measurements: Patients were randomly allocated to receive an event monitor or 48-hour Holter monitor and then to receive the other device. Event monitors were used for 3 months or until two recordings were obtained while symptoms occurred. The main end point was an electrogram recorded during symptoms. The incremental cost-effectiveness of obtaining a diagnostic rhythm strip from event monitors was compared with that of Holter monitoring.

Results: The mean (±SD) patient age was 45 ± 19 years; 37 patients (88%) were women. Event monitors were twice as likely to provide a diagnostic rhythm strip electrocardiogram during symptoms as 48-hour Holter monitoring (29 patients [67%] and 15 patients [35%], respectively; $P < 0.001$). Event monitors detected 8 patients (19%) with clinically important arrhythmias (6 patients with supraventricular tachycardia and 2 with atrial fibrillation or flutter), whereas the Holter monitors detected no significant arrhythmia ($P < 0.005$). With the event monitors, most patients transmitted an electrocardiogram recording by 6 weeks. Event monitors were dominant and therefore more cost-effective than 48-hour Holter monitoring, resulting in a cost savings of $213 for each additional diagnostic rhythm strip obtained during symptoms.

Conclusions: Holter monitoring is a poor diagnostic test for intermittent palpitations. Event recorders provide better data and are more cost-effective.

Ann Intern Med. 1996;124(1 pt 1):16-20.

From John Hunter Hospital and and Centre for Clinical Epidemiology and Biostatistics, New South Wales, Australia. For current author addresses, see end of text.

Palpitation is a common symptom that sometimes results from a substantial cardiac arrhythmia. Establishing the cause of palpitations may be difficult because historical clues are not always accurate (1). A 24-hour ambulatory (Holter) monitor is usually used, but the yield of this instrument is low in patients whose symptoms occur infrequently (2–5).

Another instrument used to study palpitations is a transtelephonic post-event recorder. These handheld devices are given to patients and are applied to the chest when symptoms occur. The patient presses a button to record about 30 seconds of the cardiac rhythm, which is stored in the memory of the device. The recording is later transmitted over the telephone for printing and interpretation.

Although this instrument has been available for many years, concerns have been expressed about the quality of recording and the extent to which an unselected group of patients can provide diagnostic recordings. Because no randomized, controlled trials have compared these devices with Holter monitoring, we compared the yields of Holter monitoring with those of event recorders in diagnosing palpitations in an unselected population.

Methods

Patients

We considered for our study all 634 men and women referred to the cardiovascular unit at the John Hunter Hospital for Holter monitoring. We excluded patients being monitored for silent ischemia (7%), assessment of therapy (18%), syncope (18%), or other research studies or inpatient monitoring (8%); patients considered too old, too feeble, or too young to use the event monitor (16%); and patients who had previously had Holter monitoring for their symptoms (16%). The remaining 108 patients (17%) were eligible for the study.

One investigator interviewed eligible patients to confirm that their symptoms were palpitations. We asked patients to estimate how frequently they had symptoms, the length of their longest attack, wheth-

er their palpitations were regular, and whether they smoked or had a history of hypertension or ischemic heart disease. Each patient provided informed consent, and the Hunter Health Service ethics committee approved the study.

Our study was a randomized crossover trial. Each patient was randomly allocated to have either 48 hours of Holter monitoring (Marquette Electronics, Sydney, New South Wales, Australia) or an event monitor (Aerotel, Israel; Medtronic, Minneapolis, Minnesota). The patient kept the event monitor until two recordings were obtained during symptoms or until 3 months had passed. After the first monitor was returned, the patient was given the other device.

During Holter monitoring, patients were asked to record in a diary when their index palpitation symptoms occurred during the 48-hour recording period. Patients also recorded the symptoms associated with their palpitations, including dizziness, nausea, shortness of breath, chest discomfort or pain, and arm pain. We defined these criteria before the study. To check the correctness of the interpretation of arrhythmias, we used a full-disclosure method that allowed review of all 48 hours of electrogram recording. A cardiologist blinded to the results from the event recorder read the reports and electrocardiogram printouts of arrhythmias during symptomatic and asymptomatic periods. Tracings for the event recorder were read by another cardiologist who was also blinded to patient data and results of 48-hour Holter monitoring.

End Points

The primary end point was an electrocardiogram rhythm strip obtained while symptoms occurred that would establish a cardiac or noncardiac cause of the symptoms. The secondary end point was a clinically significant cardiac arrhythmia defined before the study as symptomatic sustained supraventricular tachycardia (supraventricular rate, >15 beats/min), atrial fibrillation or flutter, sustained ventricular tachycardia (ventricular rate, >10 beats/min), sinus pause longer than 3 seconds, non-Wenckebach second-degree heart block, or third-degree heart block.

Statistical Analysis

We analyzed the data using the STATA program (Stata, College Station, Texas). Because all patients received both devices, we used an exact binomial test of untied pairs to determine the statistical significance of the primary and secondary end points (6).

Cost-Effectiveness Analysis

We calculated incremental cost-effectiveness ratios (the additional cost per additional health outcome) of event monitors compared with Holter monitors for the primary and secondary end points. All costs were in 1994–1995 Australian dollars. The analysis was based on a time horizon of 21.5 weeks, which we estimated to be the period during which the study cohort of 43 patients (who could use either monitor) would present for monitoring. Assuming that the event monitors would be given to patients for 6 weeks, approximately 13 event monitors were required to monitor these 43 patients for 21.5 weeks.

We used a societal perspective in our analysis and estimated direct medical costs of capital, labor, and consumable goods and nondirect medical costs of telephone calls (event monitors only). We excluded overhead costs for central administration, cleaning, heating, and so forth (direct medical costs) and for travel expenses (direct nonmedical costs) on the assumption that these variables would not differ between the devices.

We calculated equivalent annual costs for capital using an annuitization procedure in which we assumed an expected life span of 5 years for both monitors and a 5% discount rate. The five Holter monitors and the analysis system in our unit cost approximately $106 193; this results in an equivalent annual cost of $24 528. Because Holter equipment is used for purposes other than investigating palpitations, we apportioned joint costs on the basis of the percentage of use attributed to patients with intermittent palpitations (17%). We apportioned an annual service cost, estimated to be 4.1% of the capital cost, on the same basis. The cost of 13 event monitors was estimated to be $6500 (Micromedical Industries, Labrador, Queensland, Australia), which resulted in an annual equivalent cost of $1561.

We estimated labor costs for technicians, secretaries, and cardiologists according to time and motion for the last five patients investigated. Our technicians spent an average of 113 minutes to explain how to use, put on, and remove the Holter monitor and how to analyze and download the tapes. Thirty-five minutes was needed to explain the event recorders and to prepare the rhythm strip for reporting. A cardiologist could interpret the Holter monitor recordings in about 16 minutes and could interpret the event monitor recordings in 2 minutes; the respective times for secretarial work were 10 minutes and 5 minutes. We assigned a value to these services using wages that were positively adjusted for annual and sick leave, superannuation entitlements, and worker's compensation premiums.

We assessed the robustness of the results in multiway sensitivity analyses that examined the changes in the discount rate (0% and 10%), a 20% increase and decrease in service and labor costs, and a reduction of the proportion of Holter monitor costs

Table 1. Number of Patients with an Electrocardiogram Recorded during Symptoms or with Clinically Significant Arrhythmia*

Variable	Holter Monitor	Event Monitor
	n(%)	
Recording during symptoms [95% CI]	15 (35) [21% to 49%]	29 (67) [53% to 81%]†
Clinically significant arrhythmia [95% CI]	0 (0) [0% to 3%]	8 (19) [8% to 30%]‡

* Forty-three patients participated in the study.
† $P < 0.001$ from paired test.
‡ $P < 0.005$ from paired test.

attributed to Holter monitor use from 17% to 10%. The effectiveness was also varied by the 95% CIs.

Results

Of the 108 eligible patients, we asked 45 (40%) to participate in the study. We did not ask the others to participate because the two chief investigators were not available to interview them. Of the 45 patients asked, 43 (96%) completed the study. Two persons withdrew before receiving the event monitor because the Holter monitor leads were too uncomfortable.

Thirty-eight participants (88%) were women, and the mean age of all patients (±SD) was 45 ± 19 years. Thirty-four patients (81%) reported that palpitations occurred at least every 2 weeks, and 24 (56%) believed that their palpitations were regular; the average estimate of the longest attack was 74 ± 159 minutes. The mean resting pulse rate was 76 ± 15 beats/min; systolic blood pressure was 131 ± 26 mm Hg; and diastolic blood pressure was 77 ± 12 mm Hg. Four patients reported a history of ischemic heart disease, 14 (33%) reported a history of hypertension, and 7 (16%) were smokers. Twenty-four patients (56%) were randomly allocated to receive the 48-hour Holter monitor before receiving the event recorder.

Table 1 lists the results for the primary and secondary end points. Thirty patients (70%) sent in at least one electrocardiogram recorded by the event monitor while symptoms occurred. Two patients had a technically inadequate electrocardiogram recording transmission, but 1 patient subsequently sent two rhythm strips showing sinus rhythm. Therefore, 29 patients (67%) sent at least one recording from an event recorder that could be interpreted compared with the approximately one third of patients who obtained recordings during symptoms with the Holter monitor ($P < 0.001$). Furthermore, the Holter monitor detected no clinically significant arrhythmias. During event recorder monitoring, a clinically significant arrhythmia was documented in each of 8 patients (19%) (Tables 1 and 2; Figure 1).

Of the 29 patients who recorded an electrocardiogram with the event monitor, 20 (69%) made two recordings and returned the monitor before the maximum 3 months allowed. For 13 patients (65%) who sent in two recordings, the two recordings showed the same rhythm. For the remaining 7 patients, the discordant rhythms were supraventricular tachycardia and sinus tachycardia in 3 patients (2 of whom had supraventricular tachycardia on the first recording), atrial flutter and ventricular premature beats in 1 patient (atrial flutter on the first recording), sinus tachycardia and ventricular premature beats in 1 patient, and sinus rhythm and ventricular premature beats in 2 patients.

Of the 15 patients in whom symptoms occurred during 48-hour Holter monitoring, 4 (27%) had 2 separate symptomatic episodes. In 2 of these 4 patients, the rhythm recorded during symptoms was the same (sinus tachycardia). Both discordant patients had ventricular premature beats with one symptomatic episode and sinus rhythm with the other.

Figure 2 shows the cumulative number of patients who sent an electrocardiogram obtained by the event recorder during symptoms, according to the time taken to record a symptomatic episode. Most patients who eventually sent in recordings did so by 6 weeks.

Table 3 shows the costs and incremental cost-effectiveness of event monitors compared with those of Holter monitors. Event recorders were dominant in obtaining an electrocardiogram during symptoms, resulting in a $213 cost savings per additional outcome detected. Event recorders were dominant compared with Holter monitors in all scenarios examined in the sensitivity analyses. Labor costs accounted for 52% of Holter monitor costs and 41% of event monitor costs.

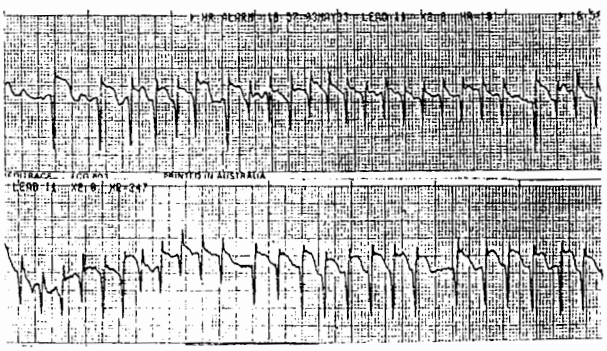

Figure 1. Electrocardiogram recording from an event recorder showing atrial fibrillation during palpitations.

Table 2. Types of Cardiac Rhythm from Electrocardiograms Recorded during Symptoms

Variable	Holter Monitor	Event Monitor
	n(%)	
Supraventricular tachycardia	0 (0)	9 (18)
Atrial fibrillation or flutter	0 (0)	3 (6)
Ventricular ectopic beats	4 (21)	6 (12)
Sinus tachycardia	7 (37)	14 (29)
Sinus rhythm	8 (42)	17 (35)
Total electrocardiogram recordings*	19 (100)	49 (100)

* In some patients, more than one type of cardiac rhythm was recorded.

Discussion

The diagnosis of intermittent palpitations is often difficult; the principal concern is whether symptoms are caused by a cardiac arrhythmia. In our study, 48-hour Holter monitoring recorded the cardiac rhythm while symptoms occurred in about one third of the patients, but it did not identify the eight patients (19%) who had a significant arrhythmia (that is, an arrhythmia that would lead to active treatment). This suggests that 48-hour Holter monitoring is a poor test for diagnosing cardiac arrhythmia as a cause of intermittent palpitations. The event recorders were twice as likely as the Holter monitors to provide a recording during symptoms.

Other studies comparing transtelephonic event recorders with Holter monitoring were not randomized (5, 7–11) and studied selected patients who had negative Holter monitoring results (8, 10, 11). In addition, it is not clear whether any of the studies comparing patients who had both monitors included blinded assessment of the recordings or used an appropriate paired statistical test.

Two studies of real-time event recorders, in which patients transmit a recording over the telephone while symptoms are occurring, reported a diagnostic yield of about 50% (5, 7). In contrast, the newer event recorders, such as the ones used in our study, have a memory facility that allows the patient to record the electrocardiogram during symptoms and transmit the recording at a later convenient time. The diagnostic yield of the newer devices reported in other studies is closer to our results (range, 55% to 83%) (3, 4, 10).

The types of arrhythmia detected by event recorders in other studies are also consistent with our results. Several studies have found that 28% to 66% of patients whose symptoms were recorded have sinus rhythm (3, 4, 7, 9–11), a finding similar to that in 11 of 29 patients (38%) in our study. In two other studies, event monitors recorded supraventricular tachycardia and atrial fibrillation or flutter in 19% (5) and 29% (3) of patients, respectively, compared with 19% in our study.

In our study, 6 weeks was sufficient for using the event monitor. In a report of a company database of patients who used event monitors, 96% of patients sent their first recording by 4 weeks (12). Although 4 to 6 weeks is usually adequate, some patients with very infrequent symptoms may need to use the event monitor for a longer period.

Although the event recorders had a greater diagnostic yield, some discordance was seen (35%) in the rhythms sent by patients who had two recordings. Discordance was also seen with 48-hour Holter monitoring in two of the four patients in whom two symptom episodes were recorded. Although most clinically significant arrhythmias were seen on the first recording from event monitors, obtaining at least two recordings while symptoms are occurring may be prudent.

Our study had adequate statistical power to address the main study hypotheses, but it was small. In a larger study, some patients with clinically significant arrhythmias recorded using 48-hour Holter monitoring would have been identified; we found no such patients in our study. Other studies have found that Holter monitors identify small numbers of patients with tachyarrhythmias. In one study of 40 patients, 24-hour Holter monitoring identified 2 patients with tachyarrhythmias, but these arrhythmias were not described further and were defined as any rhythm with a ventricular rate of 110 beats/min or greater (including sinus tachycardia) (11). In another study, 36 of 76 patients were given a 12-hour Holter monitor (5). Of the 7 patients with a recording during symptoms, 1 had paroxysmal atrial tachycardia, 4 had premature contractions, and 1 had junctional Wenckebach phenomenon (5).

The percentage of patients in whom 48-hour Holter monitoring recorded an electrocardiogram during symptoms was higher in our study (35%)

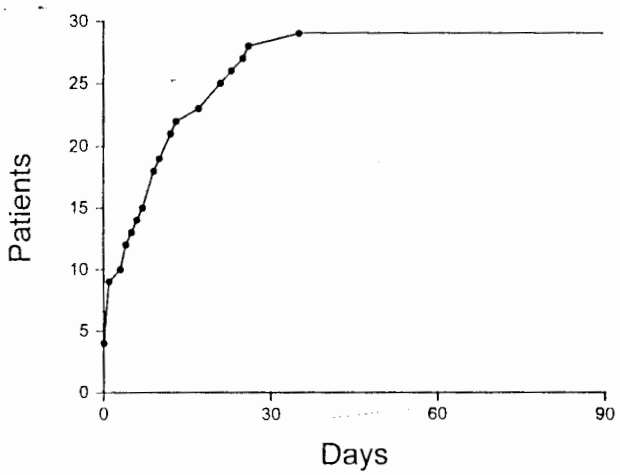

Figure 2. Cumulative number of patients who sent an electrocardiogram from an event recorder by the number of days needed to record an electrocardiogram while symptoms were occurring.

Table 3. Costs and Cost-Effectiveness of Each Device

Variable	Holter Monitor	Event Monitor
	$	
Cost for 43 patients for 21.5 weeks (range from sensitivity analysis)	4245 (2650 to 4994)	1258 (1049 to 1471)
Incremental cost-effectiveness for event monitors		
$\frac{\$1258 - \$4245}{29 - 15} = -\$213$ per additional electrocardiogram recorded during symptoms*		
$\frac{\$1258 - \$4245}{8 - 0} = -\$373$ per additional clinically significant arrhythmia detected*		

* This represents a cost-saving with event monitors.

than in other studies of patients with cardiac symptoms (2% to 20%) (2–5). However, these studies included Holter monitoring for 12 and 24 hours, and the difference in diagnostic yield may reflect these shorter recording periods.

The longer recording period with the event recorders is almost certainly the main reason that these devices had a higher diagnostic yield than the Holter monitors. The average number of days (total number of days monitored in all patients/number of patients) was much higher with the event recorders (34 days) than with the Holter monitors (2 days). Presumably, if Holter monitoring could be continued for a similar number of days, it would have a diagnostic yield similar to that of the event recorders. However, prolonged Holter monitoring is uncomfortable for patients and has higher costs for technician and cardiologist time.

Event recorders cannot replace all the functions of Holter monitors. In our study, only 17% of patients were considered eligible for event recorders. Another 16% would have been able to use these devices but were excluded because they had had previous monitoring. The remaining patients either could not use the event recorder (because of investigation for syncope or because of physical or cognitive limitations) or had indications that necessitated monitoring for asymptomatic electrocardiography changes (silent ischemia, assessment of pacemaker function or antiarrhythmic drugs, and monitoring of inpatients). As many as one third of patients in our teaching hospital population would be able to use the event recorder; this proportion may be higher in other centers or practices where the assessment of therapeutic devices or drugs is a less common indication for cardiac monitoring than is investigation of palpitations.

Our study shows that compared with Holter monitors, event recorders result in additional benefits at a lower cost when used for diagnosing intermittent palpitations. Even if costs are ignored, Holter monitoring is a poor diagnostic test in patients with palpitations. Event recorders provide better data, are more cost-effective, and should replace Holter monitoring for this purpose whenever possible.

Acknowledgments: The authors thank Helen Bednar, Fiona Broderick, Jenny Key, Jodie Pettit, Tammie Powell, and Mia Tolfree for technical assistance and Tammie Hodges for secretarial assistance.

Requests for Reprints: Scott Kinlay, MBBS, PhD, FRACP, Cardiovascular Unit, John Hunter Hospital, Locked Bag 1, Hunter Mail Centre, New South Wales 2310, Australia.

Current Author Addresses: Drs. Kinlay, Leitch, Chapman, Hardy, and Fletcher: Cardiovascular Unit, John Hunter Hospital, Locked Bag 1, Hunter Mail Centre, New South Wales 2310, Australia.
Ms. Neil: Centre for Clinical Epidemiology and Biostatistics, University of Newcastle, Royal Newcastle Hospital, Newcastle, New South Wales 2300, Australia.

References

1. **Leitch J, Klein G, Yee R.** Can patients discriminate atrial fibrillation from regular supraventricular tachycardia? Am J Cardiol. 1991;68:962-6.
2. **DiMarco JP, Philbrick JT.** Use of ambulatory electrocardiographic (Holter) monitoring. Ann Intern Med. 1990;113:53-68.
3. **Safe AF, Maxwell RT.** Transtelephonic electrocardiographic monitoring for detection and treatment of cardiac arrhythmia. Postgrad Med J. 1990;66: 110-2.
4. **Thomas LE, Shapiro LM, Perrins EJ, Fox KM.** Detection of arrhythmia: limited usefulness of patient activated recording devices. Br J Med (Clin Res Ed). 1984;289;1106-7.
5. **Judson P, Holmes DR, Baker WP.** Evaluation of outpatient arrhythmias utilizing transtelephonic monitoring. Am Heart J. 1979;97:759-61.
6. **Colton T.** Statistics in Medicine. Boston: Little, Brown; 1974:171-2.
7. **Shen WK, Holmes DR Jr, Hammill SC.** Transtelephonic monitoring: documentation of transient cardiac rhythm disturbances. Mayo Clin Proc. 1987; 62:109-12.
8. **Clair WK, Wilkinson WE, McCarthy EA, Page RL, Pritchett EL.** Spontaneous occurrence of symptomatic paroxysmal atrial fibrillation and paroxysmal supraventricular tachycardia in untreated patients. Circulation. 1993;87:1114-22.
9. **Goldstein MA, Hesslein P, Dunnigan A.** Efficacy of transtelephonic electrocardiographic monitoring in pediatric patients. Am J Dis Child. 1990;144: 178-82.
10. **Klootwijk P, Leenders CM, Roelandt J.** Usefulness of transtelephonic documentation of the electrocardiogram during sporadic symptoms suggestive of cardiac arrhythmias. Int J Cardiol. 1986;13:155-61.
11. **Grodman RS, Capone RJ, Most AS.** Arrhythmia surveillance by transtelephonic monitoring: comparison with Holter monitoring in symptomatic ambulatory patients. Am Heart J. 1979;98:459-64.
12. **Reiffel JA, Schulhof E, Joseph B, Severance E, Wyndus P, McNamara A.** Optimum duration of transtelephonic ECG monitoring when used for transient symptomatic event detection. J Electrocardiol. 1991;24:165-8.