Diagnostic Yield and Optimal Duration of Continuous-Loop Event Monitoring for the Diagnosis of Palpitations

A Cost-Effectiveness Analysis

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Background: Continuous-loop event recorders are widely used for the evaluation of palpitations, but the optimal duration of monitoring is unknown.

Objective: To determine the yield, timing, and incremental cost-effectiveness of each week of event monitoring for palpitations.

Design: Prospective cohort study.

Patients: 105 consecutive outpatients referred for the placement of a continuous-loop event recorder for the evaluation of palpitations.

Measurements: Diagnostic yield, incremental cost, and cost-effectiveness for each week of monitoring.

Results: The diagnostic yield of continuous-loop event recorders was 1.04 diagnoses per patient in week 1, 0.15 diagnoses per patient in week 2, and 0.01 diagnoses per patient in week 3 and beyond. Over time, the cost-effectiveness ratio increased from $98 per new diagnosis in week 1 to $576 per new diagnosis in week 2 and $5832 per new diagnosis in week 3.

Conclusions: In patients referred for evaluation of palpitations, the diagnostic yield of continuous-loop event recording decreases rapidly after 2 weeks of monitoring. A 2-week monitoring period is reasonably cost-effective for most patients and should be the standard period for continuous-loop event recording for the evaluation of palpitations.

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Palpitations are one of the most common reasons why patients present to internists and cardiologists. Holter monitoring is routinely used to identify the cause of palpitations, but palpitations are often sporadic and may not occur during the 24 to 48 hours of conventional Holter monitoring (1, 2). Patient-activated continuous-loop event recorders allow more prolonged surveillance and have proven to be more efficacious and cost-effective than Holter monitoring for the diagnosis of palpitations (1, 3), but the optimal duration of event recording for the indication of palpitations has yet to be defined. To address this issue, we prospectively evaluated the yield and timing of diagnoses made with continuous-loop event recorders in 105 consecutive patients referred for evaluation of palpitations. We also sought to determine the incremental cost-effectiveness of each week of event monitoring for palpitations.

Methods

Patients

Between May and November 1996, 112 ambulatory patients were referred to the Arrhythmia Monitoring Laboratory of Beth Israel Hospital, Boston, Massachusetts, for placement of a continuous-loop event recorder to evaluate palpitations. Seventy percent of the patients were referred by general internists, and the rest were referred by cardiologists and electrophysiologists. We excluded 7 patients (6%) from analysis because of incomplete documentation of the timing of transmissions or because the patient could not confirm that the transmitted event represented his or her clinical palpitations. The remaining 105 patients made up the study sample.

Monitoring Protocol

All studies were done with a King of Hearts monitor (Instromedix, Hillsboro, Oregon). The duration of monitoring was determined by the referring physician. During each transmission, the technical staff of the Arrhythmia Monitoring Laboratory questioned the patient to ensure that the symptom provoking the transmission was identical to the palpitations for which the monitor had originally been

Table 1. Number of New Patients Receiving a Diagnosis and New Diagnoses by Week of Monitoring among 105 Patients Referred for Evaluation of Palpitations

Week	Patients Monitored	New Patients Receiving a Diagnosis	New Diagnoses		Diagnoses per Monitored Patient (95% CI)	
			Any	Serious	Any	Serious
	←		*n*			→
1	105	84	109	30	1.04 (0.84–1.24)	0.29 (0.19–0.39)
2	101	4	17	8	0.17 (0.08–0.25)	0.08 (0.03–0.14)
3	72	1	1	0	0.01 (0–0.04)	0
4	17	0	0	0	0	0

ordered. Serious arrhythmias were defined as atrial fibrillation or atrial flutter of any duration, any sustained supraventricular tachycardia, symptomatic sustained or nonsustained ventricular tachycardia, junctional rhythm, sinus bradycardia (<50 beats/min), and complete or high-grade heart block. Patients were informed of the nature of their rhythm only if it was defined as a serious arrhythmia or if they asked. Referring physicians were immediately notified of all serious arrhythmias or repeated transmissions (>3) of the same nonserious arrhythmia.

Costs

The monitoring cost was determined on a weekly basis and included the costs of monitoring equipment, laboratory technical staff, and the interpreting physician. All costs were assessed from the perspective of the medical care system and were expressed in 1997 U.S. dollars (4). Equipment cost included the cost of the continuous-loop event recorder ($8.00 per week) and the cost of the central monitoring station (including an annual maintenance fee) ($6.54 per week). We assumed that a single central monitoring station would have an economic life of 5 years and would serve 20 monitors continuously during that time. Technical costs ($3.90 per transmission) for each patient were calculated on a weekly basis by using the number of transmissions per week, a mean duration of 15 minutes per transmission, and the average hourly technician's wage plus benefits. The cost of the interpreting physician was based on the 1997 Medicare fee schedule ($268.00 per standard 4-week monitoring period) and was pro-rated for actual duration of monitoring in each patient.

Data Analysis

For our purposes, any event (serious or not) that was transmitted by the patient and was confirmed to represent the patient's palpitations was considered diagnostic. For each patient, the initial transmission of a particular rhythm was counted as a diagnostic event. Further transmissions of the same rhythm were not counted as new diagnoses, but subsequent transmissions of a different arrhythmia were considered to represent additional diagnoses. Continuous data are expressed as the mean ± SD with median values and selected interquartile ranges. Weekly transmission rates were highly skewed and thus were compared by using the Wilcoxon rank-sum test.

The diagnostic yield of the continuous-loop event recorder was calculated in two different ways: as the percentage of patients successfully diagnosed as a function of time (patient-based analysis) and as the absolute number of new diagnoses per patient per week (diagnosis-based analysis). For the patient-based analysis, the cumulative percentage of patients with one, two, or three diagnoses as a function of time was estimated by using the Kaplan–Meier technique (5); 95% CIs were determined by using the Greenwood approximation. For the diagnosis-based analysis, the absolute number of new diagnoses made in a given week was divided by the number of patients who continued to wear the monitor during that week. For this approach, standard errors at each time point were calculated on the basis of the Poisson distribution.

Because we thought that patients could have more than one correct diagnosis for their palpitations, we chose cost per new diagnosis as the relevant measure of cost-effectiveness for the loop recorder. The incremental cost-effectiveness of each week of monitoring was calculated as the incremental cost for each week of monitoring divided by the number of new diagnoses per monitored patient for each week of monitoring. A 95% CI for each cost-effectiveness ratio was estimated by substituting the upper and lower confidence bounds for the number of diagnoses per monitored patient in the denominator of the ratio. Because previous studies have shown loop recording to be less costly and more effective than Holter monitoring for the diagnosis of palpitations (1), we did not consider Holter monitoring as an alternative strategy in the cost-effectiveness analysis.

Results

The study sample consisted of 78 women and 27 men with a mean age of 52 ± 21 years (median age,

52 years [range, 19 to 78 years]). The mean duration of monitoring was 18 ± 6 days (median duration, 16 days [range, 2 to 51 days]). All patients wore the continuous-loop event recorder for at least 2 days; 101 patients (97%) wore the device into week 2, and 71 (68%) wore it into week 3 or beyond.

During week 1, the mean number of transmissions per patient wearing the monitor was 5.3 ± 5.2 (median, 4 [interquartile range, 1 to 8]). During week 2, this number decreased to 3.7 ± 4.9 transmissions per monitored patient (median, 2 [interquartile range, 0 to 6]; $P < 0.001$). During week 3 and beyond, it further decreased to 1.2 ± 2.9 (median, 0 [interquartile range, 0 to 0]; $P < 0.001$). The decreasing number of transmissions was primarily due to less frequent transmissions among patients who had already received a diagnosis in week 1. Among patients who had at least one diagnostic transmission during week 1, the number of transmissions decreased from 6.6 ± 5.1 (median, 6 [interquartile range, 3 to 10]) to 4.4 ± 5.1 (median, 3 [interquartile range, 0 to 7]) during week 2 and 1.5 ± 3.1 (median, 0 [interquartile range, 0 to 1]) during week 3 ($P < 0.001$ for both comparisons). Patients without a diagnosis in the first week of monitoring had 1.0 ± 2.3 transmissions (median, 0 [interquartile range, 0 to 0]) during week 2 and no transmissions in week 3 and beyond.

During week 1, 109 diagnostic rhythm strips were transmitted for an average of 1.04 diagnoses per patient (95% CI, 0.84 to 1.28 diagnoses per patient) (**Table 1**). Of these transmissions, only 30 (28%) were considered clinically important or potentially serious (**Table 2**). The remaining 79 diagnostic transmissions included transmissions of normal sinus rhythm (21%), atrial premature beats (22%), isolated ventricular premature beats (23%), and sinus tachycardia (6%). During week 2, the diagnostic yield decreased to 0.17 diagnoses per patient (CI, 0.03 to 0.25 diagnoses per patient). An additional 17 diagnoses were made in 17 patients; 8 were considered potentially serious (3 diagnoses of atrial fibrillation and 5 diagnoses of paroxysmal supraventricular tachycardia). Only one new diagnosis (isolated ventricular premature depolarization) was made in week 3; this occurred in a patient who had his first diagnosis established in week 1. Thus, the yield in week 3 was only 0.01 diagnoses per monitored patient (CI, 0 to 0.04 diagnoses per monitored patient). Because we considered any new rhythm transmitted during an episode of confirmed palpitations to be diagnostic, one patient could receive one or more diagnoses for his or her palpitations. In fact, multiple diagnoses were made in 38 patients (2 diagnoses in 35 patients and 3 diagnoses in 3 patients).

Table 2. Serious Diagnoses by Week of Monitoring

Diagnosis	Week 1	Week 2	Week 3
	← n (%) →		
Supraventricular tachycardia	15 (50)	5 (63)	0
Atrial fibrillation or atrial flutter	10 (33)	3 (37)	0
Nonsustained ventricular tachycardia	4 (13)	0	0
High-grade heart block	1 (4)	0	0

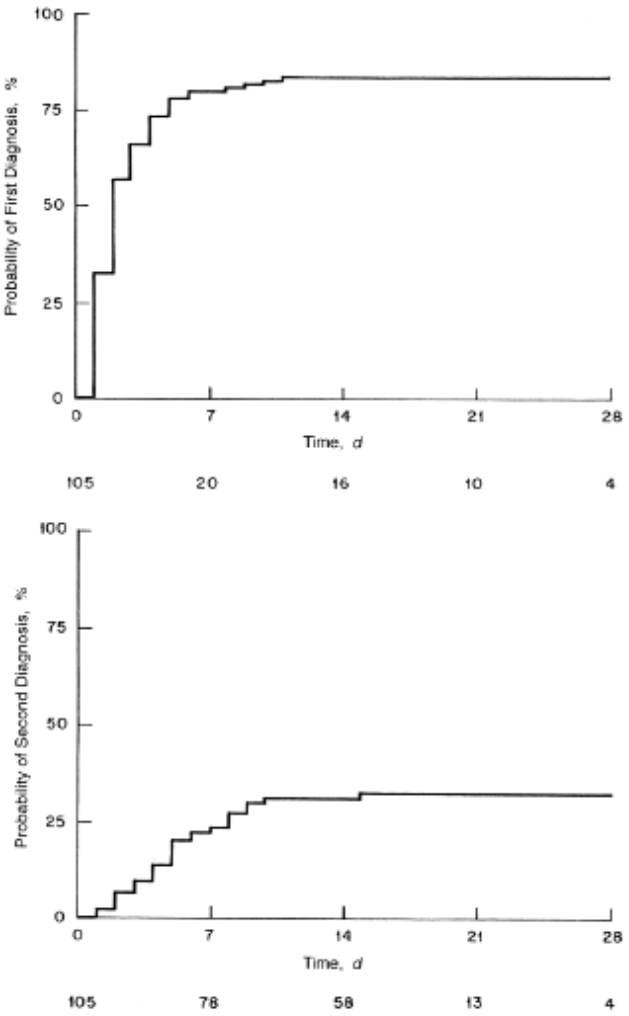

Figure 1. Cumulative diagnostic yield of the continuous-loop event recorder for all diagnoses associated with palpitations as a function of duration of monitoring. Top. Diagnostic yield for first diagnoses. **Bottom.** Diagnostic yield for second diagnoses. The numbers beneath the x-axis are the numbers of patients at risk (monitored patients without a diagnosis) at each time point.

Figures 1 and **2** show the cumulative diagnostic yield of the continuous-loop event recorder as a function of monitoring duration. When any transmission that was confirmed to represent the patient's symptom of palpitations was considered diagnostic, the per-patient yield was 80% (CI, 72.2% to 87.8%) after week 1, was 83.9% (CI, 76.7% to 91.1%) after week 2, and was unchanged after week

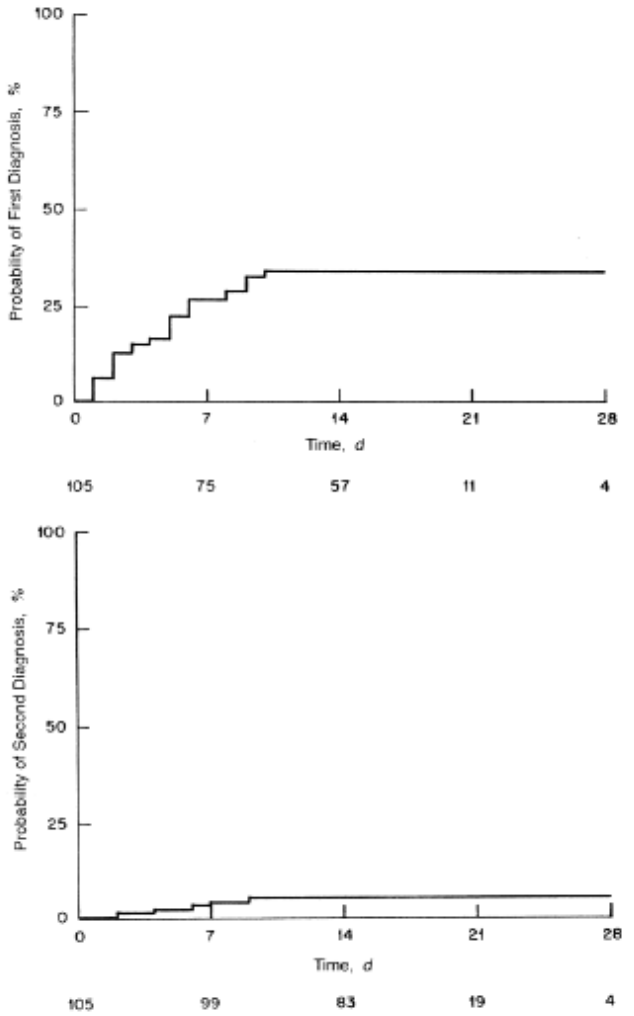

Figure 2. Cumulative diagnostic yield of the continuous-loop event recorder for serious diagnoses associated with palpitations as a function of duration of monitoring. Top. Diagnostic yield for first serious diagnoses. **Bottom.** Diagnostic yield for second serious diagnoses. The numbers beneath the x-axis are the numbers of patients at risk (monitored patients without a diagnosis) at each time point.

3 (**Figure 1**, *top*). Second diagnoses were made in 23.2% (CI, 14.4% to 32.0%) of patients during week 1, and the cumulative incidence of second diagnoses increased to 31.2% (CI, 22.0% to 40.4%) after week 2 and to 32.7% (CI, 23.3% to 42.1%) after weeks 3 and 4 (**Figure 1**, *bottom*). A third diagnosis was made in three patients during the monitoring period, for a cumulative incidence of 3.1% (CI, 1.4% to 4.8%) after week 2 that was unchanged thereafter. When only serious arrhythmias were considered diagnostic, the diagnostic yield was significantly lower at each time point (**Figure 2**) and did not increase at all after week 2 of monitoring. After a first diagnosis was made, the probability of an additional new diagnosis was 30.3% (CI, 20.5% to 40.1%) after 1 week of additional monitoring, 38.1% (CI, 27.5% to 48.7%) after 2 weeks of additional monitoring, and 40.5% (CI, 29.3% to 51.7%) after 3 weeks of additional monitoring (data not shown).

No diagnosis was made in 17 patients despite a mean duration of monitoring of 17 ± 4 days (median, 16 days [range, 14 to 27 days]). During a median clinical follow-up period of 15 months (range, 12 to 18 months), 1 patient died of unrelated causes and 1 patient had a diagnostic electrophysiologic study that resulted in a diagnosis of atrioventricular nodal tachycardia. The other 15 patients have had no further investigation for their palpitations and remain without a diagnosis.

Because fewer patients transmitted rhythm strips to the central laboratory as the monitoring period progressed, the incremental cost of each week of additional monitoring diminished over time. For week 1, we estimated the cost of monitoring (including physician and technical fees) to be $102. For week 2, the cost of monitoring decreased to $96; for week 3 and beyond, it further decreased to $81 per week. Because the diagnostic yield of the event recorder decreased over the same period, however, the incremental cost-effectiveness ratio for each additional week of monitoring increased with the duration of monitoring. If any diagnosis (serious or not) was considered meaningful, the cost-effectiveness ratio for 1 week of event monitoring was $98 (CI, $82 to $121) per diagnosis. During week 2, this increased to $576 per diagnosis (CI, $383 to $1066); during week 3, it increased further to $5832 per diagnosis (CI, $1975 to infinity) (**Table 3**). If only serious arrhythmias were considered meaningful diagnoses, the cost-effectiveness ratios were higher (that is, less favorable) at each time point. After week 2, the cost-effectiveness of continuous-loop event recorders was undefined because no new serious arrhythmias were detected in this period.

Discussion

Internists and cardiologists increasingly use continuous-loop event recorders to aid in the diagnosis of palpitations. Recent data have confirmed that these recorders are more cost-effective than Holter monitoring for this purpose (1). It is estimated that more than 250 000 event recorders are used to diagnose palpitations annually in the United States at

Table 3. Incremental Cost-Effectiveness of the Continuous-Loop Event Recorder According to Week of Monitoring

Week	Monitoring Cost	Incremental Cost-Effectiveness*	
		Any Diagnosis	Serious Diagnosis
	← $ →		
1	102	98 (82–121)	340 (261–536)
2	96	576 (382–1066)	1224 (686–3200)
3	81	5832 (1975–∞)	∞

* In 1997 U.S. dollars per new diagnosis.

a cost of nearly $90 million (Instromedix. Unpublished data). Nonetheless, despite the widespread use and considerable cost of these recorders, no studies to date have examined the optimal duration of monitoring for palpitations. Standard practice has been to monitor patients for 1 month. Although a 1-month monitoring period has been shown to be sufficient to capture even infrequent arrhythmias (6), our study shows that a shorter period may be equally safe and effective at a much lower cost to the health care system.

We found that the diagnostic yield of continuous-loop event recorders for palpitations was high during week 1 of monitoring and diminished rapidly thereafter. Specifically, 80% of patients transmitted at least one rhythm strip corresponding to their symptoms during week 1 of monitoring. During the rest of the 4-week monitoring period, only an additional 3.9% of patients successfully received a diagnosis, and no patients received a diagnosis after week 2 (**Figure 1**). When diagnostic yield is expressed in terms of the absolute number of diagnoses (because many patients had more than one), a similar pattern emerges. During week 1, 1.04 new diagnoses were seen per monitored patient; 28% of these were considered to represent potentially serious arrhythmias. In week 2, 0.17 new diagnoses were seen per monitored patient; half were serious. After week 2, the incidence of new diagnoses was only 0.01 per monitored patient, and no serious arrhythmias were seen.

These findings have several possible explanations. First, the decrease in the diagnostic yield over time reflects the common economic principle of "diminishing marginal returns." That is, most readily identifiable diagnoses are made during the first 2 weeks of monitoring, and relatively few patients remain without a diagnosis by the end of this abbreviated monitoring period. In addition, the declining diagnostic yield of these devices over subsequent weeks may be attributable to a decrease in transmissions over time. In our study, we saw a progressive decline in the number of transmissions per patient from 5.3 in week 1 to 1.2 in week 3 and beyond. This decline in the transmission rate was seen mainly among patients in whom a diagnosis was made during week 1 of monitoring. This group may have been less inclined to transmit over time if they perceived that a diagnosis had already been made. Those patients who did not transmit a diagnostic tracing in week 1 also had a low transmission rate in subsequent weeks. This group may be a subset of patients with such infrequent palpitations that even the standard 4-week monitoring period may be insufficient. For these patients, such alternative diagnostic methods as the automatic, implantable loop recorder may be appropriate (7).

Given its declining diagnostic yield over time, the incremental cost-effectiveness ratio for continuous-loop recording increased exponentially with a progressively longer monitoring period. During the first 2 weeks of monitoring, the cost-effectiveness ratio ranged from $98 to $600 per diagnosis made. However, in week 3 and beyond, this ratio increased to more than $5000 per diagnosis made and was undefined when only clinically significant diagnoses were considered. Although these ratios lack an external reference for comparison, the cost-effectiveness ratio of $5800 per diagnosis made for monitoring in weeks 3 and 4 seems relatively unfavorable, particularly for non–life-threatening conditions. Although the confidence limits around this ratio are wide, even the lower 95% confidence bound ($1975 per new diagnosis) was nearly 20 times greater than it was for week 1 of monitoring.

On a practical level, our study thus suggests that a 2-week rather than a 4-week monitoring period is reasonable for most patients. Extrapolation from our own laboratory suggests that using 20 monitors over a 1-year period to evaluate 240 patients for 1 month each would yield a diagnosis in 201 patients (83.9%) for a total of 287 diagnoses at an annual cost of $86 388. If the monitors were allocated for only 2 weeks, however, twice the number of patients (n = 480) could be monitored over a 1-year period, and a total of 402 patients would be diagnosed with a total of 566 diagnoses at a slightly increased cost to the medical system of $95 140. Alternatively, by using a 2-week monitoring period, a smaller laboratory with only 10 monitors could yield almost the same number of diagnoses (283 compared with 287) for almost half the cost ($47 570 compared with $86 388) as a laboratory with a 20-monitor capacity using a 4-week monitoring period. Given the relatively wide CIs for the diagnostic yield of monitoring beyond 2 weeks, we cannot exclude the possibility that as many as 4 additional diagnoses per 100 monitored patients could be missed by a 2-week monitoring protocol. Nonetheless, we believe that the relatively benign nature of most diagnoses causing palpitations and the substantial cost savings that could be achieved by restricting the initial monitoring period to 2 weeks justify this strategy in most cases.

In summary, our prospective data show that in patients referred for placement of a continuous-loop event recorder for the evaluation of palpitations, most diagnoses will be made in the first 2 weeks of monitoring. Although the cost continues to increase with more prolonged monitoring, little additional diagnostic yield is obtained by extending the monitoring period to 4 weeks. Selected patients with intermittent undiagnosed palpitations may benefit from longer periods of monitoring, but our data suggest that this practice should not be routine.

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