**Study Overview**

**Objective.** To compare the diagnostic yield of loop recorders versus Holter monitors in the evaluation of arrhythmic causes of syncope or presyncope.

**Design.** Prospective, unblinded, randomized trial.

**Setting and participants.** Consecutive patients referred for cardiac monitoring at a single Canadian academic medical center were eligible for enrollment. Eligibility and exclusion criteria were not explicitly stated. Patients self-reported their symptom frequency and health care utilization. Presyncope was defined as a primary complaint of transient dizziness, lightheadedness, unsteadiness, or weak spells.

**Intervention.** Patients were allocated to either Holter monitor or loop recorder. Patients underwent continuous Holter monitoring (Series 8500 ambulatory tape recorders; Marquette Electronics Inc., Milwaukee, WI) for 48 hours. These patients were instructed to time-stamp the recording when they experienced symptoms and to keep a symptom diary. Patients randomized to the loop-recording group were monitored for 1 month. Loop monitoring (King of Hearts Express; Instromedics, Hillsboro, OR, or CardioCall ST80; Reynolds Medical, Hertford, UK) recorded a 5- to 10-minute single lead electrocardiograph strip when activated by the patient. After activation, the patient transmitted the recorded strips to the medical center for assessment. Patients allocated to the loop recorder group underwent 3 test transmissions before beginning monitoring and weekly test transmissions during the study. After completing the evaluation, patients whose diagnosis was still unclear were offered crossover to the other diagnostic testing strategy.

**Main outcome measures.** The primary outcome was clinically significant arrhythmias, defined as a sinus pause greater than 3 seconds, complete heart block, Mobitz type 2 second-degree block, atrial fibrillation with a slow ventricular response, symptomatic sinus bradycardia, sustained or symptomatic supraventricular tachycardia, and ventricular tachycardia. Symptoms necessary to define a clinically significant arrhythmia included transient dizziness, lightheadedness, unsteadiness, or weak spells. Diagnostic yield was calculated as the proportion of patients with either diagnosed or unexplained symptoms by each testing strategy.

**Main results.** 100 patients were enrolled in the study. 51 patients initially received Holter monitoring and 49 underwent loop recording. 41% of patients had undergone previous Holter monitoring and no patients had undergone loop recording. No significant differences in demographics, comorbid illnesses, or symptom index existed between the 2 testing groups. Overall, patients had a median of 1 prior syncopal episode and 7 prior presyncopal episodes at enrollment. One patient in the loop recorder group had a clinically significant arrhythmia detected versus no patients assigned to the Holter monitor group. 61% of patients (95% confidence interval [CI], 47%–75%) allocated to the loop recorder had an arrhythmia excluded (ie, experienced symptoms without a recorded arrhythmia) compared with 24% (95% CI, 12%–36%) in the Holter monitor group ($P < 0.001$). Of the patients allocated to the Holter monitor group, 57% (29/51) underwent study crossover and received a loop recorder. 45% of these patients (13/29) had an arrhythmia excluded. Only 4 of the 18 patients with a negative loop recorder test accepted crossover and none of these patients had an arrhythmia diagnosed or excluded. Of the 55 patients who received Holter monitoring, none had an arrhythmia diagnosed as underlying their syncope and 12 had an arrhythmia excluded. Of the 78 patients who received a loop recorder, one had an arrhythmia diagnosed as the cause of the syncope and 43 had an arrhythmia excluded. The Holter monitor’s overall diagnostic yield for excluding arrhythmia as a cause of syncope was inferior to that of the loop recorder (22% [95% CI, 11%–33%] versus 53% [95% CI, 44%–66%]; $P < 0.001$). In the loop recorder group, 23% of patients (13/57) with a recurrence of their symptoms while wearing the device improperly activated the recorder resulting in a nondiagnostic test.

**Conclusion.** The diagnostic yield for loop recorders is superior to that of Holter monitors in excluding arrhythmias as a cause of syncope or presyncope.
Commentary

The diagnostic evaluation of syncope and presyncope remains a clinical challenge. Because a wide range of diagnostic options exist, numerous clinical testing guidelines have been published to assist clinicians perform the most cost-effective and evidence-based evaluation [1,2]. While Holter monitors are recommended for patients with structural heart disease and a high likelihood of finding a clinically significant arrhythmia, the short duration of event monitoring (24 to 48 hours) has limited their overall diagnostic utility. Continuous loop recorders can be worn by patients for 30 days or longer, which could potentially increase a provider’s ability to detect a significant arrhythmia [3]. However, these devices require patients to activate the recorder during a period of symptoms and then transmit these results to a testing center. This additional complexity results in improper usage of the device and can limit some of the effectiveness of loop recording.

Sivakumaran et al’s study suggests that loop recorders have a higher diagnostic yield than Holter monitors with virtually all of the utility resulting from the improved ability to exclude arrhythmias as a cause of a patient’s symptoms. The study has several major limitations. First, it was unblinded, and the authors made the clinical decision if an arrhythmia was significant. The authors performed no inter-rater reliability testing on the reviewers’ evaluations of the monitor data. Second, there was no standardized pre-evaluation for patients prior to enrollment. This likely resulted in patients with a low probability of having an arrhythmic cause of syncope undergoing electrocardiographic evaluation. While this might be more like a community practice, the overall diagnostic yield for both methods would be expected to be less in this unselected population.

Applications for Clinical Practice

Loop monitors appear more effective at excluding arrhythmia as an etiology of syncope or presyncope than Holter monitoring. These results are limited in that almost one fourth of patients used these devices incorrectly despite patient education. In this study, clinically significant arrhythmias were rarely determined to be the underlying cause of syncope with either testing strategy.

–Review by Harvey J. Murff, MD, MPH

References


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