New research offers guidance for the atrial fibrillation epidemic

Mobile cardiac monitoring: Which device is the right choice?

Introduction

There have long been challenges in the diagnosis of Atrial Fibrillation (AF) and the consequences clearly have been established to include increased stroke and systemic embolism rates, with increased morbidity and mortality, if no oral anticoagulation is prescribed. While all types of AF have their own individual diagnostic challenges, Paroxysmal Atrial Fibrillation (PAF) is especially challenging given its episodic nature. In addition, patients with undiagnosed PAF often progress to more serious events, mainly stroke.

With a 2017 *Journal of Geriatric Cardiology* study[1] predicting an "atrial fibrillation epidemic" in the next 10 to 20 years, making the right choices about cardiac monitoring devices has never been more important.

Until relatively recently, the Holter monitor was the only method available for at-home patient cardiac monitoring. Today, however, selecting the right device is no longer limited to a single option. New technologies give cardiologists many choices, including event recorders, patches and various online-and offline-mobile arrhythmia monitoring systems.

While current guidelines for ECG monitoring at home recommend 24-or 48-hour Holter monitors for patients who've had a stroke, mounting evidence indicates that this may not be long enough. A review[2] of multiple clinical trials investigating the optimal duration of monitoring for PAF after acute ischemic stroke found that, with 24-and 48-hour Holter monitors, "the diagnosis of PAF is very often missed."

The crux of the selection process boils down to a basic question:

Which portable heart monitor is best-suited to detect all arrhythmias and give cardiologists and electrophysiologists all of the data and analysis they need to make the right diagnosis and treatment decisions?

TABLE OF CONTENTS

1. "Atrial Fibrillation: The Current Epidemic", *Journal of Geriatric Cardiology*, March 14, 2017, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5460066/

2. "Optimal Duration of Monitoring for Atrial Fibrillation in Cryptogenic Stroke: Nonsystematic Review", *Biomed Research International*, May 29, 2016, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4903126/

Groundbreaking research from the 2018 Heart Rhythm Society conference

Study finds one telemetry device increased diagnostic yield by 36% over multi-day patch

A new study[3] presented at the 2018 Heart Rhythm Society Annual Scientific Sessions provided further evidence to support the importance of long-term continuous heart monitoring. It analyzed 16,595 cardiac telemetry reports developed between January 1, 2016 and December 31, 2016, using the continuous and fully labeled recordings of the PocketECG online monitoring system to determine the monitoring duration required to detect the first AF episode for various AF burdens (AFBs). The mean duration of recording was 18.1 +/- 9.9 days.

The study then evaluated the impact of monitoring duration on diagnostic yield (DY) in patients with PAF (for AFB ≤ 1% and AFB ≤ 10%) and analyzed the difference in DY between the online method and simulated offline methods (24- and 48-hour Holter and 11- and multi-week offline patches)

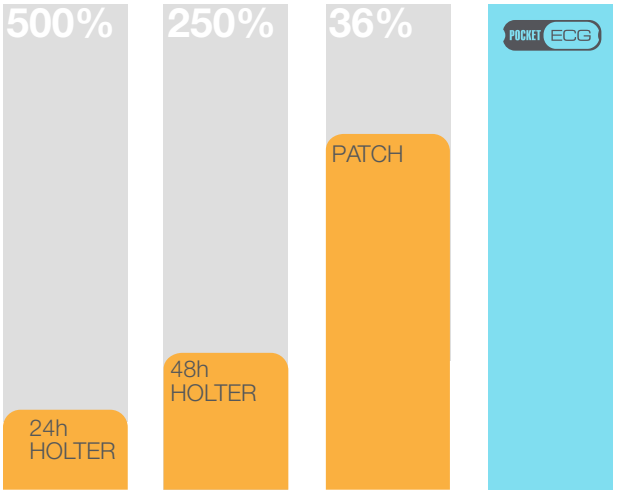
PocketECG comparison with different methods and durations	AF burden	DY results
24h of Holter monitoring	≤ 1%	PocketECG 6x DY
24h of Holter monitoring	≤ 10%	PocketECG 4x higher DY
48h of Holter monitoring	≤ 1%	PocketECG 3.5x higher DY
48h of Holter monitoring	≤ 10%	PocketECG 2.5x higher DY
Multi-week offline patch	≤ 1%	PocketECG 36% higher DY
Multi-week offline patch	≤ 10%	PocketECG 25% higher DY

3. "New Research Demonstrates Online ECG Monitoring is More Effective than Offline and Patch Methods to Detect Paroxysmal Arrhythmia", *Medicalgorithmics* Press Release, May 8, 2018, https://blog.pocketecg.com/hrs-study-online-full-disclosure-ecg-monitoring-outperforms-offline-holter-and-patches

New research: What to look for when choosing a device

Opinions and practices can vary widely regarding the selection and use of mobile cardiac monitoring devices. Of course, such decisions must consider the device's ease of use and the patient's condition, comfort and ability to comply. Broadly speaking, however, cardiologists' No. 1 concern is getting the information needed to correctly diagnose and treat patients.

PocketECG increased yield 36% over multi-day patch



Key findings

- PocketECG allows for better detection of paroxysmal atrial fibrillation (PAF)
- The ability to extend monitoring duration is critical to diagnostic yield
- Online monitoring reduces the time to diagnosis

Research shows that monitoring methods that provide cardiologists with these features and capabilities are more likely to increase diagnostic yield (DY).

- Continuous, full-disclosure ECG monitoring
- Extended monitoring duration time
- Measures heart rate at rest and during activity

For example, an oft-cited study comparing atrial fibrillation monitoring strategies after cryptogenic stroke[4] found that the duration of monitoring needed to detect AF was inversely proportional to AF burden and concluded that "long-term continuous heart monitoring is superior for AF detection." The updated guidelines from American Academy of Family Physicians for the "Pharmacologic Management of Newly Detected Atrial Fibrillation"[5] emphasize the importance of not just rhythm but heart rate control to stabilize disease.

4. "A Comparison of Atrial Fibrillation Monitoring Strategies After Cryptogenic Stroke (the Cryptogenic Stroke and Underlying AF Trial)", *American Journal of Cardiology*, September 15, 2015 https://www.ncbi.nlm.nih.gov/pubmed/26183793

5. "Updated Clinical Practice Guideline: Pharmacologic Management of Newly Detected Atrial Fibrillation", *American Academy of Family Physicians*, April 2017, https://www.aafp.org/dam/AAFP/documents/patient_care/clinical_recommendations/a-fib-guideline.pdf

Pros and cons of common ambulatory arrhythmia diagnostic methods

Holter monitors

Advantages: The biggest advantage of the Holter system is its ability to access continuous ECG data and quantitative representation of the analysis results. It automatically recognizes PQRST complexes morphology and counts all pathological and normal beats and presents the results in a concise, numerical format.

Disadvantages: The biggest limitation of this monitoring method is its inability to give providers access to the ECG data in real time, which means the recording duration must be set in advance. When monitoring sessions last longer than 48 hours, problems can occur with the quality of the ECG signal and patients' compliance with wearing the device.

Event monitoring systems

Advantages: These intermittent monitors (both non-looping and memory looping) are activated by patients when they experience symptoms. The benefit of the non-looping system is that the patient does not have to constantly wear electrode patches, which makes it suitable for patients with sensitive skin or have difficulty managing the patches. Since memory looping event recorders constantly store the most recent ECG signal, they can capture the pre-event signal recovered from the internal looping memory buffer.

Disadvantages: The biggest drawbacks for both types of event recorders are their inability to 1) automatically capture asymptomatic events, and 2) store continuous ECG signals. Given the often asymptomatic and paroxysmal nature of atrial fibrillation, such limitations can result in missed AF diagnoses. In addition to their inability to capture the pre-event ECG signal, non-looping memory monitors can have delays in recording the symptomatic ECG data.

Intermittent mobile cardiac telemetry systems

Advantages: These devices offer real-time monitoring over longer periods of time and can store and transmit symptomatic and limited types of asymptomatic events. Their biggest advantage is their ability to produce basic quantitative information regarding HR and AF burden, which is useful for detecting asymptomatic AF and monitoring post—AF-ablation patients or those undergoing antiarrhythmic drug therapy.

Disadvantages: Since these systems only capture a fraction of the actual signal (typically 30-second samples of ECG activity, called "trending strips," every 10 minutes), the limited sample size used for calculations calls into question the reliability of the quantitative analysis. Such devices may miss some ventricular and supraventricular arrhythmias and not provide any information on the onset or offset of arrhythmia episodes.

Updated guidelines from the AAFP emphasize the importance of not just heart rhythm, but heart rate control to stabilize disease.

Offline and online patches

Advantages: Many patients like the idea of wearing a patch instead of having electrodes attached to their bodies.

Disadvantages: The quality and robustness of diagnostic information from offline patches does not compare well with other online systems and physicians often must wait weeks before receiving the results. Since the batteries of online patches must be small to keep them lightweight, these devices cannot stream a continuous ECG signal and lack the processing power needed to perform online ECG analysis. Signal quality is another major concern because the weight of the patch and its battery on the patient's skin can cause more motion artifacts than ECG wires with electrodes. Patients with wireless patches also must always carry or be near a smartphone or wireless gateway to be able to transmit directly to the mobile network.

Continuous, online monitoring devices

Advantages: Monitoring methods that capture a full-disclosure ECG signal for every heart beat provide the most complete picture of a patient's arrhythmia activity. By providing cardiologists online real-time access to diagnostic findings, these devices allow them to end a study once an arrhythmia is detected or extend it when further monitoring is required. Devices that also monitor physical activity enable cardiologists to differentiate between heart rate changes caused by physical activity and those caused by an arrhythmia.

Disadvantages: As with all electrode-based monitoring devices, comfort and compliance can be issues, especially for patients with sensitive skin.

Monitoring methods that capture a full-disclosure ECG signal for every heart beat provide the most complete picture of a patient's arrhythmia activity.

PocketECG: Continuous, full-disclosure ECG monitoring for all cardiac events

As we've seen, continuous ECG monitoring and longer monitoring duration times significantly improve the likelihood of AF detection. Equally important, however, is the reliability, comprehensiveness, timeliness, availability and relevance of the information provided by cardiac monitoring devices.

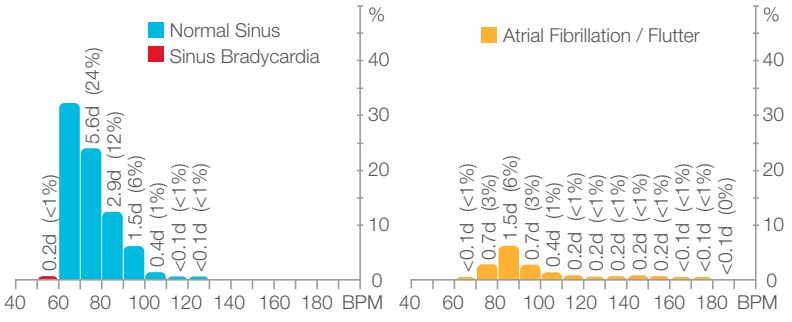
The PocketECG heart monitoring system is a complete diagnostic solution designed to meet all these critical performance criteria. Roughly the size of a smart-phone, it captures and labels every heart beat and transmits a full-disclosure ECG signal for up to 30 days. Its unique features and capabilities include:

- Online, full disclosure ECG analysis and transmission with morphology classification of every heartbeat, including complex ventricular and supraventricular arrhythmia
- Patented self-learning ECG interpretation algorithm that detects QRS complexes and classifies heart beats' morphology in real-time, including VT, SVT, Bigeminies and Trigeminies (new research[6] shows that short supraventricular tachycardia events defined as < 30 seconds likely represent early stages of AF or atrial myopathy)
- Symptom tracking and direct correlation between symptoms and arrhythmia
- Physical activity monitoring to differentiate rate changes due to physical activity and those caused by an arrhythmia
- High resolution online HR and HR variability measurements to better guide pharmacotherapy decisions
- Ongoing access to diagnostic findings enables cardiologists to end a study once an arrhythmia is detected or extend it when further monitoring is required

The gold standard in reporting

- Daily and event-driven urgent reports, which feature easily interpreted statistical ECG analysis summaries
- Complete statistical and graphical presentation of the arrhythmia, activity and symptoms in the diagnostic report
- An End of Study (EoS) report published after the conclusion of monitoring features:
  - Results reported in a numerical format similar to Holter applications with a front-page summary analysis of hundreds of thousands of heartbeats
  - Full statistical reporting that includes PVC count, PAC count, AF and sinus rhythm
  - Extreme values for each type of arrhythmia
  - A chart showing all symptomatic and asymptomatic events
  - A calendar view of trends for symptoms, AF, ventricular and supraventricular arrhythmias, and sinus bradycardia, which can be used to correlate HR, patient-triggered symptoms, and rhythm changes with the patient's weekly activity.

Visit our Interactive Report Guide online, at:
https://pocketecg.com/interactiveguide



Rate vs. Rhythm Distribution: An analysis of patients' heart rate distributions while within sinus rhythm and atrial fibrillation—particularly useful to help clinicians regulate rate control and dosing of pharmacotherapy.

Summary

Many choices, one priority

According to current CDC data[7], atrial fibrillation:

- Affects an estimated 2.7–6.1 million people in the United States
- Causes more than 750,000 hospitalizations
- Contributes to an estimated 130,000 deaths each year—a death rate that has been rising for more than two decades

Yet despite major advances in monitoring strategies, clinicians too often miss the diagnoses of AF, especially PAF, due to its intermittent occurrence and asymptomatic presentation. And each missed diagnosis increased the chances that a patient will be hospitalized or die.

Cardiologists can choose from many different types of heart monitoring devices for their patients and have varying factors to consider when making these decisions. But with the coming of the "atrial fibrillation epidemic" and the inherent difficulty of AF detection, a top priority should be selecting a device that:

Captures more and better data points on the patient's heart activity to reduce the likelihood of missing a diagnosis and to guide the course of treatment.

As the research cited in this paper demonstrates, continuous ECG monitoring and longer monitoring duration times significantly improve the likelihood of AF detection. And the one mobile device with the most accurate and comprehensive data points is the PocketECG system.

To see how the PocketECG can help you avoid missed diagnoses, visit:
https://i.pocketecg.com/detect

6. "Regularity and Lack of P Waves in Short Tachycardia Episodes Predict Atrial Fibrillation and Ischemic Stroke", *Heart Rhythm Journal*, June 2018, Volume 15, Issue 6, Pages 805-811, https://www.heartrhythmjournal.com/article/S1547-5271(18)30108-5/abstract

7. "Atrial Fibrillation Fact Sheet", *Centers for Disease Control and Prevention*, August 22, 2017, https://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_atrial_fibrillation.htm

8 cm x 13 cm
FITS INSIDE A POCKET

Marek Dziubinski, Ph.D.

Founder, CEO and CTO of Medicalgorithmics

Scientist, innovator and businessman, Marek Dziubinski, Ph.D., is chief executive officer and chief technology officer (CTO) of Medicalgorithmics, a Poland-based technology company focused on the development of cardiac monitoring and diagnostic solutions.

Dr. Dziubinski established Medicalgorithmics as a start-up in 2005, and grew it into a company with a global reach listed on the Warsaw Stock Exchange (WSE). He is the creator of the PocketECG system, a world-leading, non-invasive technology for diagnosing heart arrhythmia. He also invented algorithmic solutions used by Medicalgorithmics to analyse and process signals in the PocketECG system.

Marek closely collaborates with the scientific community, and the PocketECG technology is used in substantial research projects by electrophysiologists across the U.S. and the EU. He also works in active cooperation with Harvard–MIT Division of Health Sciences and Technology, and his work has significantly contributed to the development of databases of physiological signals (Physionet), created and used by scientists and engineers all over the world to develop new IT technologies for medicine.

Dr. Dziubinski is currently focused on growing the Medicalgorithmics business and also works on new diagnostic solutions as well as applications of technology he created.

Dr. Dziubinski earned his doctoral degree from the Faculty of Electronics, Telecommunication, and Information Technology of Gdansk University of Technology.

About Medicalgorithmics

Medicalgorithmics is a leader in cardiac monitoring and diagnostic solutions. Its PocketECG system is used for remote monitoring of cardiac disorders, arrhythmia diagnosis, and heart-rate monitoring around the world, and used in clinical trials to evaluate the efficacy of new therapeutic methods.

Medicalgorithmics is developing several other products, including a device for cardiac rehabilitation, software for optimizing repetitive tasks in hospitals, and algorithms for remote interpretation of multi-lead electrocardiography (ECG) signals. The Company also provides services in the field of information technology, biotechnology and scientific research. For more information, www.medicalgorithmics.com.

About Medi-Lynx

Medi-Lynx Cardiac Monitoring LLC, is the U.S. service provider and subsidiary of Medicalgorithmics, delivering best-in-class cardiac diagnostic solutions and service to enable the best possible care for patients. The Company's team of highly-trained technicians and customer care specialists work seamlessly to provide round-the-clock monitoring, reporting, training and support for cardiology practices and their patients. To learn more, visit www.medi-lynx.com.

PocketECG is available in the U.S. through Medi-Lynx Cardiac Monitoring, www.medi-lynx.com, and is reimbursed by the majority of U.S. health care insurers.

MEDICALgorithmics
INNOVATIVE SOLUTIONS IN MEDICINE

POCKET ECG