

The AMPS Insider

An AMPS LLC Magazine

The AMPS Insider is a quarterly magazine dedicated to all AMPS' partners and customers. Published by AMPS, it provides news and information about AMPS' products and initiatives.

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Executive Overview

Effectiveness of wearable patch devices for the detection of atrial fibrillation. Product news.

Editorial

We are honored to host in our quarterly newsletter a contribution by Prof. Jeffrey Olgin, Chief of Cardiology at UCSF, sharing his opinion on the state of the art of the wearable eCG devices and wrist watches and their effectiveness in detecting atrial fibrillation episodes. Prof. Olgin's clinical research has focused on atrial fibrillation and sudden cardiac death mechanisms, epidemiology, genetics, and interventions. He has run clinical trial coordinating centers and developed mobile and digital health tools for performing large, pragmatic research studies. Additionally, he has developed the *Health eHeart Study*, an eCohort to study cardiovascular disease prevention and to validate mobile health applications in disease outcomes studies, with many studies using the platform and over 300,000 participants recruited. This novel approach to doing clinical trials has been expanded beyond cardiovascular disease through an NIH grant to create the *Eureka Research Platform for Mobilized Research*. Through all of these programs, we have developed the infrastructure and experience to manage large, blended teams of software developers, designers and research coordinators, data managers and epidemiologists to create a novel "digital" coordinating center. Prof. Olgin lab has been using **CER-S** as part of a few of their recent studies on the validation of wearable devices and their usefulness to detect atrial tachyarrhythmias, and more specifically in the study that validated a consumer smartwatch to

monitor atrial fibrillation [1]. We have asked Prof. Olgin a few questions on the use of ECG wearables in clinical practice.

We are continuing the **AMPS'** tradition of participation in research projects in this **TAI** issue, as we feature one new paper published in the past quarter: *Association of N-Acetyl Asparagine with QTc in Diabetes: A Metabolomics Study*. By Giacomo Gravina, Melissa Y. Y. Moey, Edi Prifti, Farid Ichou, Olivier Bourron, Elise Balse, Fabio Badilini, Christian Funck-Brentano, and Joe-Elie Salem

The Abstract reads: Changes in the cardio-metabolomics profile and hormonal status have been associated with long QT syndrome, sudden cardiac death and increased mortality. The mechanisms underlying QTc duration are not fully understood. Therefore, an identification of novel markers that complement the diagnosis in these patients is needed. In the present study, we performed untargeted metabolomics on the sera of diabetic patients at a high risk of cardiovascular disease, followed up for 2.55 [2.34–2.88] years (NCT02431234), with the aim of identifying the metabolomic changes associated with QTc. We used independent weighted gene correlation network analysis (WGCNA) to explore the association between metabolites clusters and QTc at T1 (baseline) and T2 (follow up). The overlap of the highly correlated modules at T1 and T2 identified N-Acetyl asparagine as the only metabolite in common, which was involved with the urea cycle and metabolism of arginine, proline, glutamate, aspartate and asparagine. This analysis was confirmed by applying mixed models, further highlighting its association with QTc. In the current study, we were able to identify a metabolite associated

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with QTc in diabetic patients at two chronological time points, suggesting a previously unrecognized potential role of N-Acetyl asparagine in diabetic patients suffering from long QTc.

You can find the full article here: *Biomedicines* 2022, 10, 1955.

<https://doi.org/10.3390/biomedicines10081955>

[1] Avram R, Ramsis M, Cristal AD, Nathan V, Zhu L, Kim J, Kuang J, Gao A, Vittinghoff E, Rohdin-Bibby L, Yogi S, Seremet E, Carp V, Badilini F, Pletcher MJ, Marcus GM, Mortara D, Olgin JE. Validation of an algorithm for continuous monitoring of atrial fibrillation using a consumer smartwatch, *Heart Rhythm* 2021; 18(9):1482-1490. <https://doi.org/10.1016/j.hrthm.2021.03.044>.

Prof. Olgin Q&A:

AMPS: In the recent years there has been a proliferation of ECG wearable devices that claim to reliably detect atrial tachyarrhythmias favoring a home-based patient care approach. What is your general opinion?

JO: There are many options, and the decision is basically dependent on patient characteristics. For example, patients with “worrisome” symptoms (such as syncope, rule out heart block or a high suspicion for ventricular tachycardia) that would require immediate diagnosis, a real-time (MCOT) type monitor is required. For symptoms such as palpitations or quantifying amount of ectopy or AFib, a “non-realtime” monitor is appropriate. A second important feature is convenience and patient comfort. This has been one area of major advancement over the past decade. And finally, another important consideration is the algorithm for detecting arrhythmias and the ease of reading the report.

There has been a proliferation of consumer-grade arrhythmia monitoring devices that use either ECG or PPG to monitor heart rate and can detect atrial fibrillation. Some consumer ECG devices can also detect other arrhythmias. Here again, there is a trade-off between the PPG and ECG technologies. Most wearable ECG devices are “on-demand” while PPG devices allow for more continuous monitoring. However, because of the inherent “noisy-ness” of the PPG signals, they are less reliable at detecting short episodes and require significant signal processing.

Moreover, the algorithms used by commercial devices are often “black boxes” and access to data around accuracy is lacking. ECG devices tend to be better at confirming AFib and primary data (or at least filtered ECGs) are available for a physician read to determine agreement with automated algorithms (unlike PPGs where this is not easily accessible). However, the majority of consumer-grade ECG devices are not capable of continuous monitoring and are used for period checks (e.g., if a patient feels symptoms or an alert from a PPG). There are of course, ECG patches that are available (though there are not really any consumer grade devices currently). These provide the best of both worlds in that it provides ECG data and continuous monitoring.

AMPS: Smart watches and patches. What is preferable? Does it depend on the use case?

JO: Whether to use a smartwatch (or portable device like AliveCor Kardia) or patch depends on the use case, as described above. In addition, there is a compliance issue. So, a general rule of thumb I subscribe to is that the best device is the one a patient is more likely to use. An intermittent patch is of no use if the patient doesn't wear it.

AMPS: Better 30 seconds (triggered by the patient on the basis of symptoms) or 30 days continuously?

JO: Depends on use case as described above.

AMPS: Which patients should most benefit the use of these devices? Is there a risk to monitor the wrong type of patient? Also, what type of remote monitoring by a cardiologist? Real time based on patient demand? Once a day? Only at the end of a monitoring session?

JO: Patients with likely disease or known disease (that you are trying to quantify) are the ones that most likely benefit. Some of these devices have been marketed as “screening” devices. However, we don't really know the positive or negative predictive value of these devices for that purposes because in my opinion the right studies have not been done. For example, we don't know how these device impact appropriate or inappropriate medical care utilization (i.e., Going to the doctor because one feels fine, but their smartwatch detected a

slow heart rate or irregular rhythm). Moreover, there is indiscriminate use. For example, a young person without heart disease who is asymptomatic and has a short episode of AFib, likely does not need further treatment. Because the proper study has not been done, it is unclear whether these devices could actually lead to more harm due to inappropriate medication usage or excessive testing.

AMPS: Lastly, any preference between traditional algorithms versus the machine learning and AI. Do we have conclusive evidence that one is better than the other?

JO: The jury is still out. I think it will depend on the rhythm one is trying to diagnose and the data source quality. But as far as I know, there has not been a rigorous comparison of the techniques.

Products News

The team is progressing well on the new version of CER-S(v4.5.0) which will be finalized during 4Q22. Besides supporting several customer's projects we are also working to develop a new CER-S feature in order to allow for an easier integration into our customers tele-medicine platforms.

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