Research yields breakthrough in mobile determination of QT prolongation

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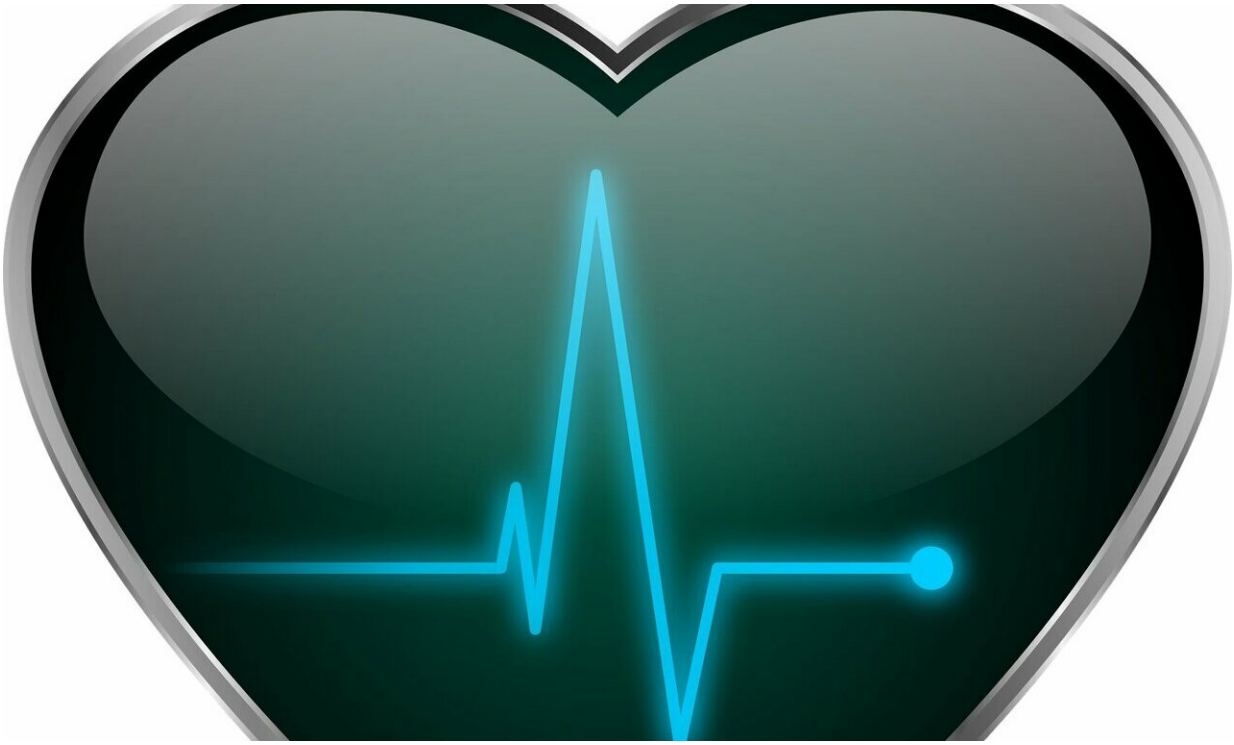

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Researchers from Mayo Clinic and AliveCor Inc. have been using artificial intelligence (AI) to develop a mobile device that can identify certain patients at risk of sudden cardiac death. This research has yielded a breakthrough in determining the health of the electrical recharging system in a patient's heart. The researchers determined that a

smartphone-enabled mobile EKG device can rapidly and accurately determine a patient's QTc, thereby identifying patients at risk of sudden cardiac death from congenital long QT syndrome (LQTS) or drug-induced QT prolongation.

The heart beats by a complex system of electrical signals triggering regular and necessary contractions. Clinicians evaluate the heart's rate-corrected QT interval, or QTc, as a vital health barometer of the heart's electrical recharging system. A potentially dangerous prolonged QTc, which is equal to or longer than 50 milliseconds, can be caused by:

- More than 100 drugs approved by the Food and Drug Administration (FDA).
- Genetics, including congenital long QT syndrome.
- Many systemic diseases, including even SARS-CoV-2-mediated COVID-19.

Such a prolonged QTc can predispose people to dangerously fast and chaotic heartbeats, and even sudden cardiac death. For over 100 years, QTc assessment and monitoring has relied heavily on the 12-lead electrocardiogram (EKG). But that could be about to change, according to this research.

Under the direction of Michael Ackerman, M.D., Ph.D., a genetic cardiologist at Mayo Clinic, researchers trained and validated an AI-based deep neural network to detect QTc prolongation using AliveCor's KardiaMobile 6L EKG device. The findings, which were published in *Circulation*, compared the ability of an AI-enabled mobile EKG to a traditional 12-lead EKG in detecting QT prolongation.

"This collaborative effort with investigators from academia and industry has yielded what I call a 'pivot' discovery," says Dr. Ackerman, who is director of Mayo Clinic's Windland Smith Rice Comprehensive Sudden

Cardiac Death Program. "Whereby, we will pivot from the old way that we have been obtaining the QTc to this new way. Since Einthoven's first major EKG paper in 1903, 2021 will mark the new beginning for the QT interval."

The team used more than 1.6 million 12-lead EKGs from over a half-million patients to train and validate an AI-based deep neural network to recognize and accurately measure the QTc. Next this newly developed AI-based QTc assessment ?the "QT meter" ? was tested prospectively on nearly 700 patients evaluated by Dr. Ackerman in Mayo Clinic's Windland Smith Rice Genetic Heart Rhythm Clinic. Half of these patients had congenital long QT syndrome.

The object was to compare the QTc values from a 12-lead EKG to those from the prototype hand-held EKG device used with a smartphone. Both sets of EKGs were given at the same clinical visit, typically within five minutes of each other.

The AI algorithm's ability to recognize clinically meaningful QTc prolongation on a mobile EKG device was similar to the EKG assessments made by a trained QT expert and a commercial laboratory specializing in QTc measurements for drug studies. The mobile device effectively detected a QTc value of greater than or equal to 500 milliseconds, performing with:

- 80% sensitivityThis means that fewer cases of QTc prolongation were missed.
- 94.4% specificity

This means that it was highly accurate in predicting who did not have a prolonged QTc.

"The ability to equip mobile EKG devices with accurate AI-powered

approaches capable of calculating accurately the QTc represents a potential paradigm shift regarding how and where the QT interval can be assessed," says John Giudicessi, M.D., Ph.D., a Mayo Clinic cardiology fellow and first author of the study.

"Currently, AliveCor's KardiaMobile 6L EKG device is FDA-cleared for detection of atrial fibrillation, bradycardia, and tachycardia. Once FDA clearance is received for this AI-based QTc assessment, we will have a true QT meter that can enable this emerging vital sign to be obtained easily and accurately," says Dr. Ackerman. "Akin to a glucose meter for diabetics, for example, this QT meter will provide an early warning system, enabling patients with congenital or acquired LQTS to be identified and potentially lifesaving adjustments to their medications and electrolytes to be made."

"This point-of-care application of artificial intelligence is massively scalable, since it is linked to a smartphone. It can save lives by telling a person that a specific medication may be harmful before he or she takes the first pill," says Paul Friedman, M.D., chair of the Department of Cardiovascular Medicine at Mayo Clinic in Rochester. "This allows a potentially life threatening condition to be detected before symptoms are manifest."

"Regularly monitoring for LQTS using KardiaMobile 6L allows for accurate, real-time data collection outside the walls of a hospital," says David Albert, M.D., founder and chief medical officer at AliveCor Inc. "Because LQTS can be intermittent and elusive, the ability to detect this rhythm abnormality without a 12-lead EKG—which requires the patient be in-hospital—can improve patient outcomes and save on hospital resources, while still providing the reliable and timely data physicians and their patients need."

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