

Medical AI Inc.

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Artificial intelligence algorithm aims to rapidly diagnose cardiac problems

Medical AI Inc.'s technology will provide fast, accurate diagnosis of cardiac problems, kidney failure, sepsis and anemia using hospital or home electrocardiogram devices.

Medical AI Inc., a biosignal artificial intelligence (AI) company that is a spin-out from South Korea's leading specialist cardiology hospital, believes it can reduce complications and death from cardiac and other conditions through an AI algorithm that delivers faster, more accurate results than traditional electrocardiogram (ECG) readings.

Heart disease is the leading cause of death for men and women in the United States and cost the US economy approximately \$363 billion each year from 2016 to 2017, according to the US Centers for Disease Control and Prevention.

Medical AI's deep learning algorithm, built on three million labeled ECG data from more than one million individuals in 13 medical centers, requires only a patient's age, sex and ECG results to provide a range of diagnoses. No blood tests are necessary. The platform uses outputs such as arrhythmia to diagnose cardiac disorders, electrolyte imbalance, anemia, sepsis (including in COVID-19), and kidney failure in which the glomerular filtration rate (GFR) is below 50.

The Medical AI platform can be linked through various communication methods to any portable ECG device. ECG results are immediately fed through to Medical AI's AiTiA ECG Center over the web, and a Medical AI cardiologist calls the treating doctor or hospital within 30 minutes with a full diagnosis.

"Our goal is to increase the speed and accuracy of diagnoses and predictions, reducing complications, saving lives and cutting health care costs," said Younghoon Cho, a medical doctor who is vice president of Medical AI. "The conventional process for diagnosis of a heart condition in cases of myocardial infarction (MI) may take four to six hours from the time an ambulance is called. This includes hospital triage, ECG and a cardiac enzyme test. The heart muscle starts to die after 90 minutes, and irreversible changes occur after six hours. However, many doctors are not good at ECG readings, particularly primary clinicians, whereas our precision platform has a high degree of accuracy."

A doctor would typically diagnose arrhythmia or ST-elevation myocardial infarction (STEMI) on an ECG, with presumptions for left ventricular hypertrophy (LVH) and electrolyte imbalance. The AI platform can diagnose arrhythmia, MI, LVH, electrolyte imbalance, heart failure, valvular disease, pulmonary hypertension, kidney failure and anemia, and make predictions for arrhythmia or cardiac arrest.

Medical AI compared four cardiologists' interpretations for LVH with the platform's interpretations and found the AI platform outperformed the cardiologists. In another case, a conventional ECG device did not detect Wolff-Parkinson-White

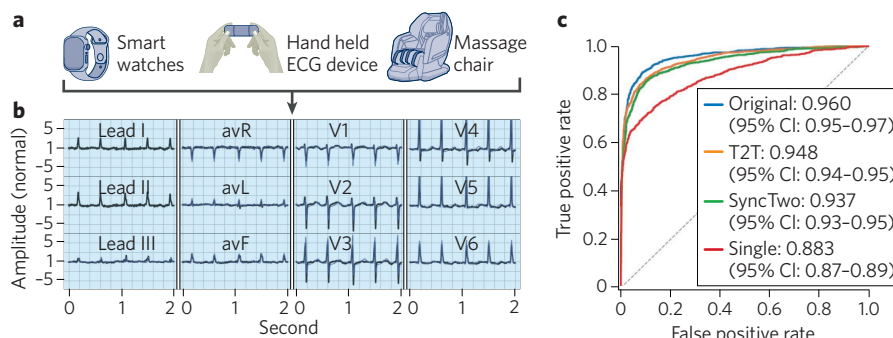


Fig. 1 | 12-lead ECG generation from home ECG device. The model generates whole-lead data from part-lead data to simulate a 12-lead ECG. **(a) Asynchronous lead I and II data are needed from a smartwatch.**

Using a six-lead device, lead I, II, III, aVR, aVL and aVF data are measured with limb-lead electrodes. **(b) Comparison of generated data from ECG-T2T model with original data.** The black line denotes the original signal; the blue line represents signals generated by the ECG-T2T model from 2-lead asynchronous ECG data from the smartwatch. **(c) Validation of ECG-T2T model.** The diagnostic power of myocardial infarction by the ECG-T2T model is similar to a 12-lead ECG, and superior to asynchronous 2-lead data or single-lead data. aVF, augmented vector foot; aVL, augmented vector left; aVR, augmented vector right; ECG, electrocardiogram; V, voltage.

(WPW) syndrome, which can be lethal under a general anesthetic. The AiTiA ECG Center detected an atypical beat and WPW, the requesting doctor decided not to perform surgery.

In a third case study, the AiTiA engine detected 'incomplete right bundle branch block (RBBB), R and S waves (RSR) and left atrial enlargement (LAE)'. The conventional ECG reading detected none of these. The requesting doctor opted for further evaluation; heart failure was diagnosed.

Full ECG 12-lead channel created

The AI platform can create the full ECG 12-lead channel from one channel or six channels. Using deep learning, the platform was trained using conventional ECG data with 12 synchronous leads. The model generates whole-lead data from part-lead (two lead asynchronous or six synchronous) data to simulate a 12-lead ECG, thus providing maximum diagnostic information (Fig. 1).

While Medical AI's primary market is hospitals, this technology means the company can expand to the home ECG market. It is already working closely with GE Healthcare, Bodyfriend, Healthrian and AliveCor, integrating with ECG devices including GE Healthcare's regular ECG device, Healthrian's portable ECG device and Bodyfriend's six-channel trackable massage chair. Integration with smartwatches is also possible.

Medical AI's first AiTiA ECG Center is located in South Korea. Following the opening of its US office

last year in San Francisco, a center will be established in the US in 2022, along with a research and development center in Silicon Valley. The company will complete its ISO13485 certification (for medical devices) in May 2022.

The company's recent white paper on its AI/machine learning algorithm and pipelines includes data on MI and the creation of the full 12-lead ECG from a 6-lead ECG; assessment for early detection of heart failure with preserved ejection fraction based on ECG features; development of a deep learning algorithm for ECG-based heart failure identification; development of an algorithm for predicting in-hospital cardiac arrest within 24 hours; a deep learning model for screening sepsis and septic shock, including in COVID-19 cases.

Clinical trials are in progress in South Korea for MI, heart failure, early detection of heart failure and 24-hour cardiac arrest. Medical AI is preparing its pre-submission stage for US Food and Drug Administration clearance for clinical trials of its MI algorithm in 2023. This will be its first product launch in the US.

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