

Trial demonstrates early Al-guided detection of heart disease in routine practice

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Heart disease can take a number of forms, but some types of heart disease, such as asymptomatic low ejection fraction, can be hard to recognize, especially in the early stages when treatment would be most effective. The ECG Al-Guided Screening for Low Ejection Fraction, or EAGLE, trial set out to determine whether an artificial intelligence (AI) screening tool developed to detect low ejection fraction using data from an EKG could improve the diagnosis of this condition in routine practice. Study findings are published in *Nature Medicine*.

Systolic low ejection fraction is defined as the heart's inability to contract strongly enough with each beat to pump at least 50% of the blood from its chamber. An echocardiogram can readily diagnose low ejection fraction, but this time-consuming imaging test requires more resources than a 12-lead EKG, which is fast, inexpensive and readily available. The AI-enabled EKG algorithm was tested and developed through a convolutional neural network and validated in subsequent studies.

The EAGLE trial took place in 45 medical

institutions in Minnesota and Wisconsin, including rural clinics, and community and academic medical centers. In all, 348 primary care clinicians from 120 medical care teams were randomly assigned to usual care or intervention. The intervention group was alerted to a positive screening result for low ejection fraction via the electronic health record, prompting them to order an echocardiogram to confirm.

"The AI-enabled EKG facilitated the diagnosis of patients with low ejection fraction in a real-world setting by identifying people who previously would have slipped through the cracks," says Peter Noseworthy, M.D., a Mayo Clinic cardiac electrophysiologist. Dr. Noseworthy is senior author on the study.

In eight months, 22,641 <u>adult patients</u> had an EKG under the care of the clinicians in the trial. The AI found positive results in 6% of the patients. The proportion of patients who received an echocardiogram was similar overall, but among patients with a positive screening result, a higher percentage of intervention patients received an echocardiogram.

"The AI intervention increased the diagnosis of low ejection fraction overall by 32% relative to usual care. Among patients with a positive AI result, the relative increase of diagnosis was 43%," says Xiaoxi Yao, Ph.D., a health outcomes researcher in cardiovascular diseases at Mayo Clinic and first author on the study. "To put it in absolute terms, for every 1,000 patients screened, the AI screening yielded five new diagnoses of low ejection fraction over usual care."

"With EAGLE, the information was readily available in the electronic health record, and care teams could see the results and decide how to use that information," says Dr. Noseworthy. "The takeaway is that we are likely to see more Al use in the practice of medicine as time goes on. It's up to us



to figure how to use this in a way that improves care and health outcomes but does not overburden front-line clinicians."

Also, the EAGLE trial used a positive deviance approach to evaluate the top five care team users and the top five nonusers of the AI screening information. Dr. Yao says this cycle of learning and feedback from physicians will demonstrate ways of improving adaptation and application of AI technology in the practice.

EAGLE is one of the first large-scale trials to demonstrate value of AI in routine practice. The low ejection fraction algorithm, which has received Food and Drug Administration breakthrough designation, is one of several algorithms developed by Mayo and licensed to Anumana Inc., a new company focusing on unlocking hidden biomedical knowledge to enable early detection as well as accelerate treatment of heart disease. The low ejection fraction algorithm was also previously licensed to Eko Devices Inc., specifically for handheld devices that are externally applied to the chest.

More information: Artificial intelligence—enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial, *Nature Medicine* (2021). DOI: 10.1038/s41591-021-01335-4

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