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Listening to the Heart to Identify Liver Fibrosis: AI-Enabled ECGs as a Screening Tool for Advanced Chronic Liver Disease (The DULCE AI trial)


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LIVER

This summary reviews Simonetto DA, Rushlow D, Liu K, et al. Detection of undiagnosed liver cirrhosis via AI-enabled electrocardiogram: a pragmatic, cluster-randomized clinical trial. Nat Med. 2026 Jan;32(1):160-167.

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STRUCTURED ABSTRACT

Question: Does an artificial intelligence–enabled electrocardiogram (AI-ECG) screening strategy increase detection of previously undiagnosed advanced chronic liver disease (CLD) compared with usual care in primary care settings?

Design: Pragmatic, cluster-randomized clinical trial. Primary care teams (clusters) were randomized 1:1 to AI-ECG–enabled screening or usual care, stratified by practice location and patient volume. The intervention was clinician-facing and embedded in routine workflows without direct patient contact.

Setting: Forty-five primary care practices across Southern Minnesota and Western

Wisconsin, comprising 98 care teams within an integrated health system.

Patients: Adults aged ≥18 years undergoing routine 12-lead ECG testing for standard clinical indications, without a prior diagnosis of cirrhosis or advanced CLD.

Intervention/Exposure: A validated machine-learning AI-ECG model was applied weekly to routine ECGs. In intervention clusters, clinicians received automated notifications when the AI-ECG probability exceeded a prespecified threshold (0.51), corresponding to an anticipated ~15%–18% positivity rate. Alerts recommended targeted clinical evaluation and sequential noninvasive liver disease assessment.

Outcomes: The primary outcome was a new diagnosis of advanced CLD within 180 days of ECG testing, defined by sequential noninvasive fibrosis assessments consistent with advanced fibrosis. Secondary outcomes included a new diagnosis of any liver fibrosis and rates of downstream liver-directed evaluation.

Data Analysis: Analyses followed an intention-to-screen approach at the cluster level. The trial was prospectively powered to detect a 50% relative increase in the detection of advanced CLD. Outcomes were compared between intervention and usual-care clusters using cluster-adjusted models, with prespecified subgroup analyses among AI-ECG–positive patients.

Funding: Mayo Clinic MAX Innovation Award.

Results: In the overall cohort, AI-ECG–enabled screening significantly increased detection of advanced CLD compared with usual care (1.0% vs 0.5%; odds ratio [OR] 2.09, 95% CI 1.22–3.55; $P = 0.007$). Among AI-ECG–positive patients (positivity 17.2%–17.6% across arms), detection of advanced CLD was 4.4% vs 1.1% (OR 4.37, 95% CI 1.94–9.88; $P < 0.001$). Detection of any fibrosis was also higher overall (1.7% vs 0.5%; OR 3.17, 95% CI 1.86–5.40) and among AI-ECG–positive patients (8.4% vs 1.1%; OR 8.03, 95% CI 3.50–18.4; all $P < 0.001$).

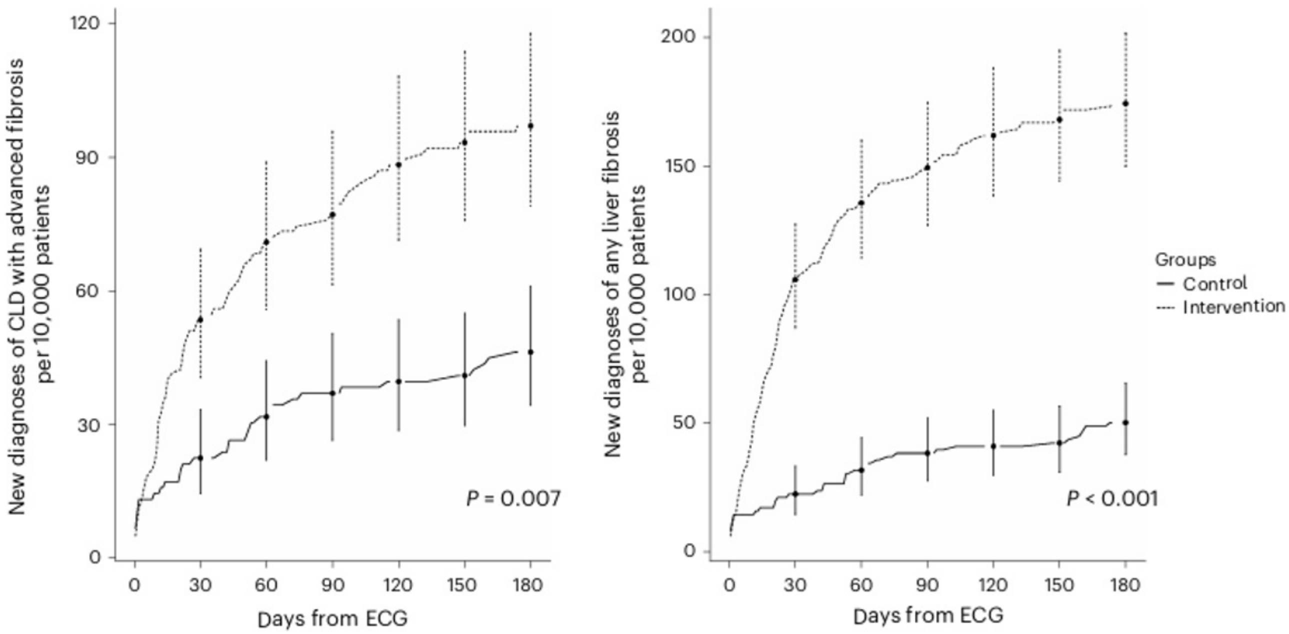

Figure 1. Cumulative diagnosis of chronic liver disease diagnosis following AI-enabled ECG screening. Cumulative incidence curves demonstrating higher rates of newly diagnosed chronic liver disease over time among patients in intervention clusters receiving AI-enabled ECG screening (dotted lines) compared with usual care (solid lines). Differences emerged early and widened over the 180-day follow-up period, supporting the role of ECG-based artificial intelligence in accelerating detection of undiagnosed liver disease.

COMMENTARY

Why Is This Important?

Advanced CLD affects an estimated 2%–5% of the adult population, yet remains underdiagnosed, with many patients first identified only after hepatic decompensation, hepatocellular carcinoma, or a liver-related hospitalization.[1] Despite the availability of validated noninvasive fibrosis assessments,[2,3] population-level screening has not been widely adopted in primary care due to limited access to elastography, competing clinical priorities, and workflow burden—particularly among patients with cardiometabolic multimorbidity who already have frequent healthcare encounters.[2,3]

ECGs represent a uniquely scalable opportunity for opportunistic screening. ECGs are low cost, universally available, and routinely obtained in patient populations that overlap with liver disease risk phenotypes, including obesity, diabetes, hypertension, and cardiovascular disease.[4] The DULCE trial addresses a critical and previously unanswered question: can an artificial intelligence–enabled ECG, pragmatically used within routine primary care workflows, meaningfully increase detection of previously unrecognized advanced CLD?[5,6]

Importantly, this study moves beyond diagnostic accuracy to evaluate real-world clinical impact. By randomizing primary care teams and embedding AI-ECG alerts directly into clinician workflows–without additional patient contact–the trial tests a pragmatic "screen-to-diagnosis" pathway. The observed and 2-fold increase in detection of advanced CLD in the overall cohort, and more than four-fold increase among AI-ECG–positive patients, demonstrate that AI-enabled screening can shift detection upstream to a clinically actionable stage, where interventions to prevent decompensation and remain possible.

By leveraging a test already embedded in routine care, AI-ECG screening offers a pragmatic, systems-level strategy to address one of the central gaps in liver disease care: late recognition of advanced CLD. In the era of MASLD, where disease progression is often silent and referral-based strategies may miss high-risk patients, this approach provides a scalable pathway to earlier diagnosis and intervention.

Key Study Findings

Among 15,596 eligible adults (8,034 intervention; 7,562 control; mean age 63.4 ± 18.3 years; 53.6% women; mean BMI 35.3 ± 12.4 kg/m²), AI-ECG–enabled screening significantly increased detection of advanced CLD within 180 days compared with usual care (1.0% vs 0.5%; OR 2.09, 95% CI 1.22–3.55; P = 0.007).

Among AI-ECG–positive patients (17.2%–17.6%), detection of advanced CLD was substantially higher in intervention clusters than in usual care (4.4% vs 1.1%; OR 4.37, 95% CI 1.94–9.88; P < 0.001). Detection of any liver fibrosis was also increased overall (1.7% vs 0.5%; OR 3.17, 95% CI 1.86–5.40) and among AI-ECG–positive patients (8.4% vs 1.1%; OR 8.03, 95% CI 3.50–18.4; all P < 0.001). Approximately 85% of newly identified cases were detected at asymptomatic stages.

Caution

Although this was a pragmatic, cluster-randomized trial, several limitations merit consideration. Clinician adherence to AI-ECG alerts was incomplete, likely attenuating observed effect sizes and highlighting the importance of workflow integration. The primary endpoint captured diagnostic acceleration rather than downstream clinical outcomes such as hepatic decompensation, hepatocellular carcinoma, or mortality. Reliance on sequential noninvasive fibrosis assessment real-world practice but may allow misclassification near diagnostic thresholds.

Generalizability may be limited by the predominantly White cohort (~96%) and single integrated health system setting. Finally, effectiveness will likely depend on local implementation, as poorly integrated alerts or low clinician engagement may lead to alert fatigue and reduced clinical impact.

My Practice

Delayed recognition of advanced CLD, particularly among patients with cardiometabolic comorbidities, is a frequent barrier to timely intervention. We are seeing a rapid rise in steatotic liver disease, thus, identifying those patients with significant fibrosis is important to navigate appropriate specialty referrals and for consideration of early interventions. At the frontlines, in primary care settings, patients are often receiving ECGs routinely. This presents a relatively simple and scalable opportunity to identify patients with chronic liver disease. Ideally, this could be used in conjunction with other non-invasive assessments such as FIB-4. Rather than standalone tests, these could be used as structured triggers to activate a standardized evaluation pathway and hepatology referral when indicated.

For Future Research

Future studies should determine whether AI-ECG–enabled detection of advanced CLD translates into improved patient-centered outcomes, including reduced hepatic decompensation, hepatocellular carcinoma, and liver-related mortality. Longer follow-up is needed to assess the durability of detection and downstream management after initial diagnosis. Implementation research should focus on optimizing clinician engagement, refining eligibility thresholds, and integrating AI-ECG outputs with established noninvasive fibrosis pathways to maximize yield while minimizing alert fatigue. External validation across racially, ethnically, and socioeconomically diverse populations – including safety-net and resource-limited settings – will be essential to assess generalizability and equity. Finally, cost-effectiveness analyses are needed to determine whether AI-ECG screening can be sustainably scaled as a pragmatic, population-level strategy for early detection of advanced CLD. Together, these steps will determine whether AI-ECG screening can be sustainably scaled as an equitable, population-level strategy for early detection of advanced CLD.

Conflict of Interest

The authors of this summary have no conflicts of interest to disclose.

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