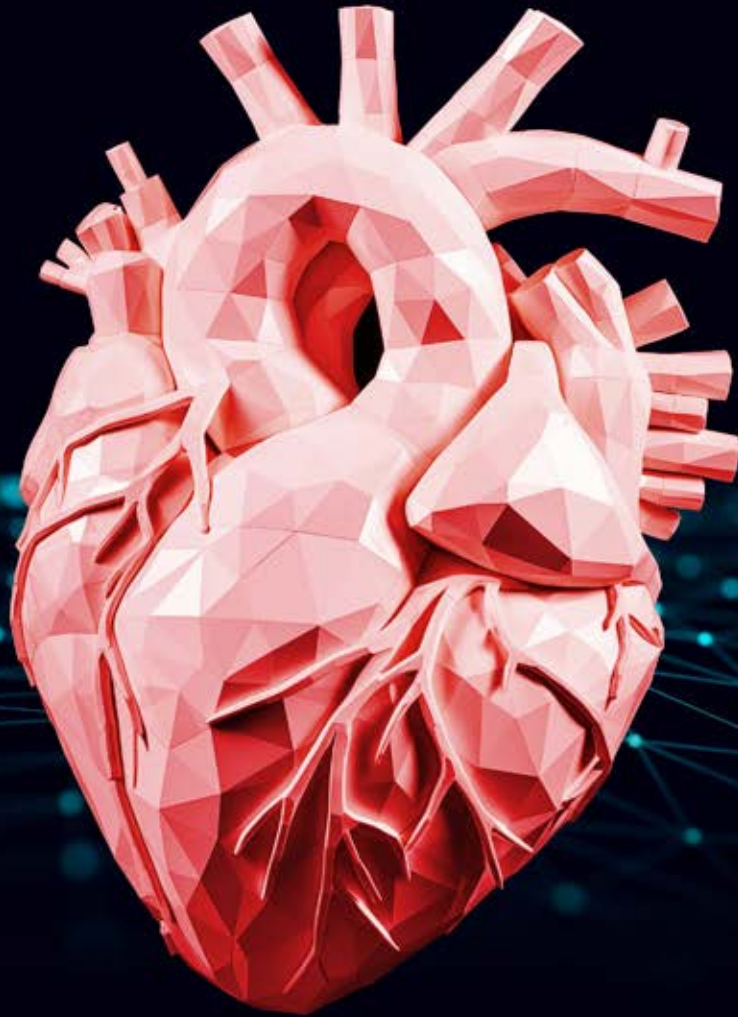


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Novel Web Tool Determines Eligibility for OTC Statin, With High Clinician Concordance

By **Grace Halsey**, Senior Editor

Using a novel web application, more than 90% of adults correctly self-selected for treatment with a nonprescription statin, closely approximating results of clinician assessment of eligibility, according to findings from TACTiC (NCT04964544), an actual use study presented during a late-breaking clinical trial session at the 2024 American College of Cardiology Scientific Sessions, held from April 6 to 8 in Atlanta, Georgia, and published simultaneously in the *Journal of the American College of Cardiology (JACC)*.

Moreover, the study investigators reported that among TACTiC participants who were eligible for access to a 5-mg dose of rosuvastatin using the web-assisted approach, nearly all (98.1%) demonstrated correct use of the medication and achieved clinically meaningful low-density lipoprotein cholesterol (LDL-C) reductions of 35.5% in 6 months after treatment was initiated. There were no safety issues reported.

The study is the first experiment with a traditionally prescribed statin medication with findings to demonstrate that, outside of a clinical setting and in the absence of a health care professional, adults could self-select, confirm eligibility, and take a statin appropriately, according to the study authors led by Steven E. Nissen, MD, chief academic officer of the Miller Family Heart, Vascular, and Thoracic Institute at Cleveland Clinic in Ohio.



“Although statins reduce adverse cardiovascular outcomes, less than half of eligible patients receive treatment,” Nissen et al wrote in *JACC*. “Multiple past attempts to address this problem through over-the-counter [OTC] statins were unsuccessful in achieving regulatory approval due to concerns about inappropriate self-selection by consumers for whom statins could be unnecessary or unsafe.” The authors point to this study’s findings as the first step in assuaging those concerns.

The 6-month, single-arm study was designed to evaluate the safety and efficacy of the use of technology-assisted self-selection (TASS) to qualify for initial and ongoing treatment with a statin when used in an

unsupervised environment. TACTiC was conducted with only virtual visits, with no in-person contact.

According to the authors, the web app employed for the study incorporates the AHA/ACC 2018 Guideline on the Management of Blood Cholesterol, using the pooled cohort equations to determine 10-year cardiovascular risk, and includes key components of a proposed drug facts label for nonprescription rosuvastatin.

Recruitment, enrollment, end points

In response to advertising, 133 744 individuals were assessed for eligibility. Of these, 110 712 did not continue to the web app or did not meet the prescreen inclusion/

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exclusion criteria. Of the remaining 23 032 who were sent a web app link, 12 624 completed the eligibility assessment; of those, 10 332 received a “Do Not Use” outcome. Of the remaining potential participants, 1196 signed an informed consent and made up the overall study population, according to the study.

This final cohort had a median age of 63 years and was 39.6% women. Participants self-identified as White (79.3%), Black (11.7%), and Hispanic (3.2%). Approximately three-quarters had completed college or equivalent education. Median LDL-C level was 139.6 mg/dL, median systolic blood pressure was 130 mm Hg, and median calculated 10-year risk of atherosclerotic cardiovascular disease (ASCVD) was 10.1%.

After a participant entered demographic information, cholesterol values, blood pressure level, and concomitant medications, the TASS app provided 1 of 3 possible outcomes for statin use: “Do Not Use,” “Ask a Doctor,” or “OK to Use.” Participants who received an outcome of “Ask a Doctor” or “OK to Use” continued in the study and virtually met with a clinician to review their results and initiate a 6-month treatment course of low-dose (5-mg) rosuvastatin, which was delivered directly to the home. During that time, prior to each reorder of medication, participants completed an abbreviated web app assessment to ensure continued safe use of the statin; all were instructed to have LDL-C level retested at any point after starting treatment. A final virtual visit and interview with a clinician were scheduled at the end of the treatment phase.

The TACTiC investigators defined 3 coprimary end points: the percentage of participants whose self-selection corresponded to the clinician assessment, the percentage who correctly reselected for

continued use, and the mean percent change in LDL-C level over the 6-month treatment period.

Findings

Nissen and colleagues reported high concordance (90.7%; 95% CI, 88.9%-92.3%) between the TASS app outcome for initial self-selection and the initial clinician assessment. The final use assessment was similarly high, with concordance in 98.1% (95% CI, 97.1%-98.8%). The mean percentage change in LDL-C level was -35.5% (95% CI, -36.6% to -34.3%) prior to the second visit, with 84.5% of participants exceeding 20% LDL-C level lowering. Baseline LDL-C level was 139.6 mg/dL. The final LDL-C level was 88.1 mg/dL, an absolute reduction of 51.4 mg/dL.

Among the study's secondary outcomes, researchers reported high medication adherence (95%) based on pill count of direct delivery of rosuvastatin and similarly high persistence (98.5%) over the 6-month treatment period. In addition, they found adherence with retesting of LCL-D level was 83.3% for the full population and 92.9% for qualified participants at

all reassessments. The investigators said that no participants experienced a “Stop Use” warning.

Serious adverse events occurred in 27 participants (2.3%), including 1 sudden death, but none were determined to be related to the study.

TACTiC was a 6-month study, leaving uncertain whether self-selection will lead to long-term medication adherence, the authors wrote in detailing limitations of the study. Also, enrollment required the ability to read and understand English as well as access to the Internet, both criteria that would exclude potentially large populations.

Nonetheless, Nissen and colleagues wrote, “In the setting where ASCVD remains the leading cause of death in the US, the undertreatment of adults with elevated LDL-C [level] represents a lost public health opportunity and a motivation to consider novel approaches to therapy, including direct consumer access.”¹¹ ■

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“In the setting where ASCVD remains the leading cause of death in the US, the undertreatment of adults with elevated LDL-C [level] represents a lost public health opportunity and a motivation to consider novel approaches to therapy, including direct consumer access.”

FDA Clears First AI-Based Algorithm to Detect Heart Failure During Routine Examinations

By **Sydney Jennings**, *Editor*

The FDA granted clearance to digital health company Eko Health on April 2, 2024, for its artificial intelligence (AI) algorithm for the detection of heart failure during routine physical examinations.

Developed in partnership with Mayo Clinic to be used with Eko Health's cardiac early detection platform (SENSORA) and digital stethoscopes, the AI-based algorithm (Low Ejection Fraction [EF] AI) is designed to detect low EF in 15 seconds during a primary care examination, according to a company press release.

"The ability to identify a hidden, potentially life-threatening heart condition using a tool that primary care and subspecialist clinicians are familiar with—the stethoscope—can help us prevent hospitalizations and adverse events," Paul Friedman, MD, chair of the Department of Cardiovascular Medicine at Mayo Clinic in Rochester, Minnesota, said in the release. "Importantly, since a stethoscope is small and portable, this technology can be used in urban and remote locations and hopefully help address care in underserved areas."

The clearance was based on data from 3 studies that evaluated the effectiveness of the algorithm. First, findings from a multisite, prospective study of 3456 patients showed that Low EF AI achieved an area under the receiver operating characteristic curve (AUROC) of 0.835 for detection of left ventricle EF (LVEF) less than 40% and that the algorithm had 74.7% sensitivity and 77.5% specificity.



“The ability to identify a hidden, potentially life-threatening heart condition using a tool that primary care and subspecialist clinicians are familiar with—the stethoscope—can help us prevent hospitalizations and adverse events.”

The second study was an independent validation of the Low EF AI by the Imperial College London in the United Kingdom and was published in *The Lancet Digital Health*. Researchers reported an AUROC of 0.85 for detection of LVEF less than 40%, 84.8% sensitivity, and 69.5% specificity when used by more than 1050 patients across multiple real-world settings.

The last study was led by the Mayo Clinic and included nearly 1200 pregnant women in Nigeria. Findings showed that the Low EF AI identified twice as many cases of pregnancy-related cardiomyopathy compared with standard care. Data also showed an AUROC of 0.98, 100% sensitivity, and 79.4% specificity.

The addition of the Low EF AI to Eko's SENSORA Cardiac Early

Detection Platform enhances its capabilities, complementing existing FDA-cleared algorithms designed to detect atrial fibrillation and structural heart murmurs commonly associated with valvular heart disease, according to the company's release.

When low EF is identified during a primary care examination using SENSORA, it facilitates prompt referral to the cardiology department for comprehensive diagnostic assessments and treatment evaluation, potentially accelerating access to life-extending treatment, Eko Health added in the statement. ■

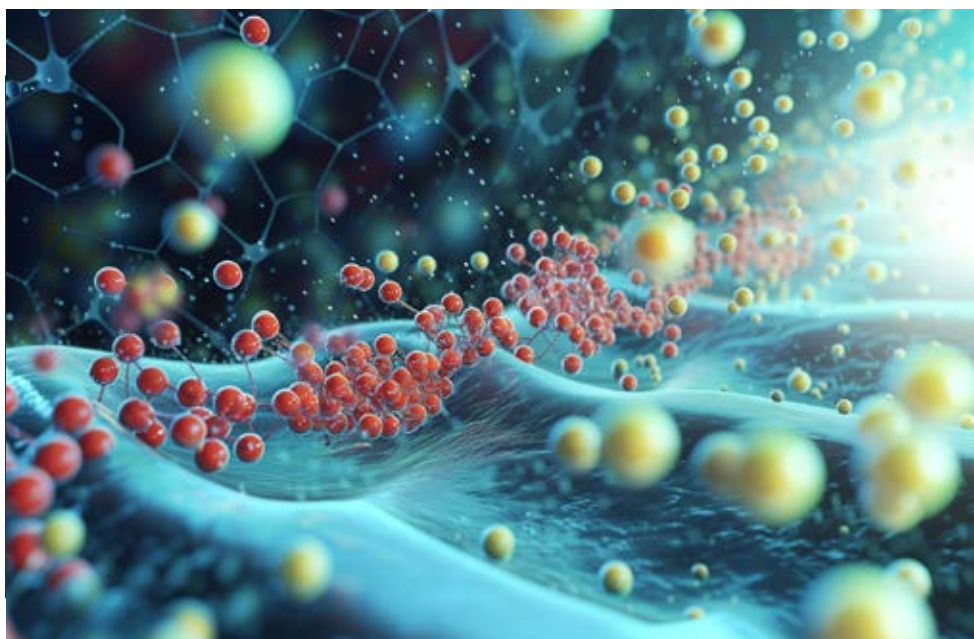
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Remotely Delivered Lipid-Lowering Program Results in Sustained Target LDL-C Levels in High-Risk Population

By **Grace Halsey**, Senior Editor

Among a diverse cohort of individuals at high risk of atherosclerotic cardiovascular disease (ASCVD) who completed a remote, algorithmically-driven lipid management program, 75.7% and 83.1% achieved target low-density lipoprotein cholesterol (LDL-C) levels at 6 and 12 months, respectively, according to an abstract presented at the American College of Cardiology 73rd Annual Scientific Sessions and Expo, held from April 6 to 8, 2024, in Atlanta, Georgia.



% participants achieving LDL-C goals at 12 months, based on ASCVD risk group, program engagement group

	Maintenance	Exited after at least 1 titration	No titration	Education only
ASCVD	85%	6%	6%	19%
Hyperlipidemia	72%	3%	2%	9%
T2D	91%	21%	17%	40%
Primary prevention	90%	16%	13%	30%

“The attenuated effect on LDL-C [level] in patients who prematurely discontinued the program highlights the need to improve patient engagement to maximize treatment plans,” the researchers concluded.

Led by Oan Unlu, MD, a master’s degree candidate at Blavatnik Institute of Biomedical Informatics at Harvard Medical School in Boston, Massachusetts, the authors cite the significant gaps in results of lipid-lowering therapy, including the failure of many individuals to reach guideline-recommended LDL-C levels. The current findings amend the researchers’ previous report of absolute LDL-C reductions as a result of participation in a remote disease management program, with analyses of the proportion of participants who achieved target LDL-C level at the completion of the program and during follow-up.

Unlu and colleagues enrolled 8294 individuals in the remote lipid management program that ran from 2018 to 2022. Of the full cohort, 2656 had known ASCVD, 2887 had LDL-C level greater than 190 mg/dL, 1388 had type 2 diabetes (T2D), and 1363 had a 10-year ASCVD risk greater than or equal to 7.5%. The majority (7079) were enrolled in medication management, whereas 1215 opted to receive education only. Target LDL-C levels were established for 6 months and 12 months across 4 ASCVD risk groups (ASCVD, hyperlipidemia, T2D, and primary prevention) and were based on the 2018 American College of Cardiology/American Heart Association

Cholesterol Guideline (LDL-C level target for ASCVD < 70 mg/dL and < 100 mg/dL for other groups), according to the abstract.

Of the patients fully completing the program, 75.7% achieved target LDL-C levels at 6 months and 83.1% achieved target levels at 12 months, with similar effects among 4 risk groups ($P < .001$ for all). Participants who discontinued the program but remained under usual care had the lowest rates of achieving target LDL-C levels.

The researchers state that the remote program was executed “with minimal physician support,” highlighting the potential for reach to extend beyond the clinical setting to medically underserved populations. Participants were able to reach target LDL-C levels through interaction with the program and to maintain those targets for at least 12 months. “The attenuated effect on LDL-C [level] in patients who prematurely discontinued the program highlights the need to improve patient engagement to maximize treatment plans,” the researchers concluded. ■

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