

Title: Screening for Peripartum Cardiomyopathies Using an AI Enhanced Digital Stethoscope

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""So I am Dr. Demilade Adedinsewo, I am a non-invasive cardiologist and I am at Mayo Clinic in Jacksonville, Florida.

Unmet Needs for Patients and Pregnancy-Related Cardiomyopathy

So I think that currently, with the clinical care landscape, we do not have a screening programme in place to identify cardiomyopathy during pregnancy and in the postpartum period. Even though we know that cardiovascular diseases, the leading cause of death during this time period, cardiomyopathy, is also one of the key contributors to death during this time. There's concerns about how do we effectively screen women for cardiomyopathy.

Typically, we would use an echocardiogram to detect the presence of left ventricular dysfunction, which is an ultrasound of the heart. But this test is relatively expensive, requires skill to perform, requires the cardiologist to interpret it. So it's not something that would be considered easy for screening. And so we found that, that there is a need to identify women with this condition and can we propose a simple, rapid, cost-effective means of screening women.

Patient Population and Study Design

So the study was designed as a pragmatic, randomised, controlled clinical trial, and we enrolled pregnant and postpartum women. They can be up to twelve months postpartum. In the trial, we randomised them in a one-to-one fashion to receive the intervention, which was AI guided screening, and the other arm was the control arm. The control arm received usual obstetric care, in addition to a standard twelve-lead ECG.

So during the trial, once women were randomised to the intervention arm, what happens is that a member of the study team or the clinical team would record using the digital stethoscope, and the digital stethoscope would record, like I explained earlier, a single lead ECG as well as a phonocardiogram. This is done simultaneously, so they place the device on the chest in two different locations, and we also had the handheld option for it, and it records for 15 seconds.

This device also connects to a smartphone or tablet via Bluetooth, so that you can see the results of the ECG and the phonocardiogram in real time. Once the recording is complete, the AI prediction is also available to the study team in real time and they can see it in the app, whether or not this is a low ejection fraction flag or normal ejection fraction.

Key Findings

So, in this study, we ended up with 1195 women in the final analysis. And what we found was that the AI guided intervention, which uses a digital stethoscope, the digital stethoscope records a single lead ECG as well as a phonocardiogram, and uses this to predict the likelihood of left ventricular dysfunction. We found that doing this in pregnant and postpartum women doubled the number of cases of cardiomyopathy that were detected and the odds ratio was 2.3 and this was statistically significant. And this suggests to us that about half of cases of cardiomyopathy are likely missed with usual care.

Take-Home Messages

I think the key take-home from this study was the fact that we found that we are doubling the number of cases of cardiomyopathy compared to what we currently do, which means that there is probably a number of women that are constantly being missed and the diagnosis is missed, and we know that once it's missed or delayed, they are more likely to suffer adverse outcomes.

Also, the unique thing about this study is that we use a device that is portable, battery-operated, that can be used in a variety of clinical settings, outpatient inpatient settings, as well as maybe outside even of the hospital setting. It's very easy to use, requires minimal training and or skill. Almost every healthcare professional uses a stethoscope, so it should be something that we can implement into current routine care. And it only takes 15 seconds to record with the availability of real-time AI predictions, which means that this result can be actionable at the point of care for the woman.

Next Steps

So the next steps for this study will be to evaluate it in different and diverse patient populations. So this study was done in Nigeria, which was a predominantly black population. Before rolling this out to other sites or other countries, I believe it's important that we also validate the technology in the different sites before they're rolled out. In the United States, for instance, we would need to consider doing a multicentre, larger study to evaluate how well it works to make sure that the model continues to remain robust in identifying think women will have cardiomyopathy and those who do not. Ultimately, the goal will be to have a tool that can be used globally so that we can reduce the disparities related to the identification of this condition that we know that is treatable but life-threatening when not identified early."