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Even though the ECG is the standard screening tool used by physicians to detect heart disease, existing ECG technology has limited effectiveness in detecting structural heart disease and coronary artery disease.

HeartSciences Inc. is working on offering just that proposition in cardiovascular disease. By applying signal processing and machine learning (a type of artificial intelligence) to the signals gathered by conventional 12-lead electrocardiography, HeartSciences can pick up signs of left ventricular early diastolic dysfunction, an early marker of many heart diseases including heart failure with preserved ejection fraction, valve disease, and coronary artery disease (CAD) associated with diastolic dysfunction.

HeartSciences began in 2008 as Heart Test Laboratories, to improve the capabilities of the resting ECG, which is the frontline tool for heart disease. There has been a lack of innovation in the ECG segment, apart from making it available in new form factors such as smartphones, notes CEO Mark Hilz, who says “It seemed to me ridiculous, after 100 years, to be only looking at an analog waveform.” The start-up’s focus was on advancing the clinical effectiveness of ECG technology so that it would be a more effective screening tool for patients, in order to reduce the large number of patients with heart disease who remain undiagnosed until an adverse event occurs. Currently, 50% of men and 64% of women who die suddenly of a heart attack had no prior symptoms.

Even though the ECG is the standard screening tool used by physicians to detect heart disease, existing ECG technology has limited effectiveness in detecting structural heart disease and coronary artery disease. For example, current 12-lead resting ECG technology detects CAD less than 50% of the time. The lack of low cost, effective frontline tools for cardiac testing has also led to expensive diagnostic testing with low yields that may put patients at unnecessary risk. A study by
Duke University of 400,000 patients in the United States undergoing invasive catheterization testing found that only 38% of patients without previously known heart disease had blockages that required treatment.

From 2008 to 2013, HeartSciences focused on fundamental research and proof-of-concept using signal processing techniques known as wavelet transform mathematics to transform the ECG’s analog waveform into a larger dataset of wavelets that could be analyzed to capture the energy kinetics of the heart throughout its cycle. In early 2013, the company had some insights and an early prototype called the MyoVista ECG, but ran out of money. Hilz and Chairman Andrew Simpson, both previous investors in Heart Test Laboratories, stepped in to fund the company, continue R&D and move the technology forward to commercialization. The company name was changed to HeartSciences.

Neither Hilz nor Simpson had previous medtech experience, but Hilz says, “We are adding technology to the ECG, and I have been in the technology industry for 30 years. Mr. Simpson’s background is in investment banking and running billion-dollar operational companies. Those two things combined make us well suited to understand technology and to be able to finance it.” To date, HeartSciences has raised more than $32 million from high net worth individuals and family offices.

Upon taking the helm, the new leadership enlisted the help of Partho Sengupta, MD, currently Chief of Cardiology at West Virginia University, Heart and Vascular Institute, as well as the director of Cardiovascular Imaging, and now a clinical advisor to the company. Sengupta led a clinical study at the Icahn School of Medicine at Mount Sinai (New York, NY) to provide further understanding of MyoVista’s capabilities and to determine what further refinements were needed. A total of 188 patients referred for CT angiography (who would thus ultimately get a definitive diagnosis) received a baseline 12-lead surface ECG, which was processed by the MyoVista wavelet transform mathematics. Patients also underwent a complete echocardiography evaluation and CT angiogram.

In analyzing the study results, Sengupta found that although MyoVista correctly identified coronary artery disease in 82% of the cases, it could also detect abnormal myocardial relaxation, a sign of an even more impactful harbinger of heart disease: diastolic dysfunction. “That’s important,” Hilz says, “because diastolic dysfunction is one of the first detectable effects that heart disease has on the heart tissue, for almost all types of heart disease; including structural, ischemic, and severe arrhythmias. If we can insert this kind of capability into a regular 12-lead resting ECG, it would significantly improve risk stratification.”

The study, which was recently published in the Journal of the American College of Cardiology, found that abnormal mechanical relaxation was seen in 70% of the patients upon echocardiographic assessment; MyoVista predicted abnormal myocardial relaxation with a sensitivity of 80% and a specificity of 84% (“Prediction of Abnormal Myocardial Relaxation from Signal Processed Surface ECG,” Sengupta, Kulkarni et al, JAAC, April 17, 2018).

For the study, MyoVista signal processing provided 370 data variables for analysis, extracted from the T wave of each patient’s ECG test. (Now the company is analyzing approximately 650 variables, not including the traditional variables, and is also starting to work with QRS parameters; through machine-learning, the platform con-
continues to evolve). “I give Dr. Sengupta a lot of credit for guiding the company,” says Hilz, “for recognizing that the large multi-variable problem called for artificial intelligence and machine learning.” Because HeartSciences was initially looking at coronary stenosis, Sengupta recommended that each patient in the study also undergo a thorough echocardiography evaluation along with CT angiography. “It was Sengupta who realized the implications of picking up abnormal cardiac relaxation, a surrogate for diastolic dysfunction,” Hilz says.

To further train the machine-learning algorithm for the clinical device, Hilz estimates that the company needs to test 1200 patients of diverse ages and health statuses. To that end, HeartSciences has collaborations with Mount Sinai, West Virginia University, the Windsor Cardiac Centre in Ontario, Canada, and UCLA (University of California Los Angeles). Data has been collected on 900 patients so far, Hilz reports. “Once we get to 1200, we will install the final version of the machine-learning algorithm into the product.”

Upon market clearance (the company plans to submit to the FDA in late 2018), the initial commercial strategy is to prove the clinical effectiveness in the marketplace. The company has received CE Mark and it launched the product in Europe in late 2017. No marketing partnerships are currently in place, but Hilz notes there is a great breadth of companies that would be logical partners for a technology like 

“It is very intentional to offer a very low cost, improved, frontline tool,” Hilz says, since, as noted, the vast majority of patients with heart disease are not being diagnosed. MyoVista, from the ECG manufacturers, to cardiovascular device companies that don’t currently have a foothold in the ECG market, to information tech companies like Google.

The commercial version of the product, for which two utility patents have been issued and others are pending, is a full-featured 12-lead ECG with the addition of the MyoVista wavelet ECG functionality. The user gets a touch screen that displays the conventional ECG tracing annotated by the accepted Glasgow Analysis, as well as additional graphics in which colors represent the energy distribution during the cardiac cycle and the energy frequency during the heart’s repolarization cycle. A specific energy detection algorithm is displayed to indicate diastolic dysfunction (see Figure 1).

Pricing of the MyoVista systems is currently comparable to that of the fully functional ECG devices sold by General Electric Co. or Royal Philips Electronics NV. “It is very intentional to offer a very low cost, improved, frontline tool,” Hilz says, since, as noted, the vast majority of patients with heart disease are not being diagnosed. It’s estimated that left ventricular diastolic dysfunction affects 20-30% of the general adult population.

At the same time, the goal is to avoid paying for a series of tests—stress tests, stress echo, and combinations thereof—for patients who don’t need it. “We need improved risk stratification tools,” says Hilz. “Today, a primary care physician has a regular ECG and a questionnaire. We need to enhance that frontline tool to say who should go on for further testing, and diastolic dysfunction is the right thing to detect. If the system identifies diastolic dysfunction while patients are still asymptomatic, we could treat them sooner, before they have a heart attack or develop heart failure.”