SPOTLIGHT ON CLINICAL RESEARCH

DCM-DETECT

Heather Madara
Research Regulatory and Outreach Manager
Roy S. Small, MD
Medical Director of Clinical Research
Penn Medicine Lancaster General Health Research Institute


Small


Madara

Editor's note: This is the 20th in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Members of the LG Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH *at 717-544-8004.*

The "Dilated Cardiomyopathy Detection using AI and screening with mobile Technology (DCM-DETECT)" protocol is an LG Health von Hess Grant funded study that aims to utilize artificial intelligence (AI) to analyze EKGs to screen for dilated cardiomyopathies.

Studies have shown that 10% to 20% of patients with a non-ischemic dilated cardiomyopathy (DCM) have an identifiable genetic etiology. Current American Heart Association and American College of Cardiology recommendations are that all their first-degree relatives (FDRs) undergo a screening echocardiogram to detect asymptomatic left ventricular dysfunction. Due to costs and logistical concerns, compliance with these recommendations is low even though current therapy for DCM is effective and potentially life altering.

In the DCM-DETECT study, each proband — the first family member identified with a non-ischemic DCM — will be recruited and asked to:

- Provide demographic information and family medical history.
- Complete a 6-Lead EKG using a mobile EKG device.
- Contact their FDRs to invite them to join the study.
- Encourage their FDRs to obtain cardiac screening by echocardiogram.

FDRs who choose to participate will also complete the mobile 6-Lead EKG and survey. In addition, they will be encouraged to obtain an echocardiogram through their health care provider. The primary objective of the study is to assess the impact of screening FDRs of patients with DCM using the mobile EKG device. The primary endpoint of the study will be measured by the subsequent uptake of cardiac screening in FDRs.

The study team is utilizing a mobile EKG device developed by AliveCor to show the applicability of screening tools incorporating AI technology to the general population. The Mayo Clinic has developed an FDA-approved algorithm that uses cloud-based AI to analyze the EKG recordings. This algorithm can detect an impaired ejection fraction with a high degree of sensitivity and specificity. The study will compare the AI-analyzed EKGs to echocardiogram results in both screen-positive and screen-negative participants.

Study participants will also include a cohort of Amish and old order Mennonite patients recruited from the Central Pennsylvania Clinic to clarify the barriers to care in this medically underserved population who have an elevated incidence of genetic cardiomyopathies.

This study is being done in parallel with the Mayo Clinic, Rochester. Data collection and analysis will be local, and the results will be pooled at the completion of the study at all sites. The enrollment goal at LG Health is to recruit 50 probands from The Heart Group (THG) and five from the Central Pennsylvania Clinic. We aim to further enroll approximately 120 FDRs of the probands from these two sites.

The principal investigator of this study at LG Health is Roy Small, MD (THG Advanced Heart Failure Clinic and Medical Director, Penn Medicine LG Health Research Institute). D. Holmes Morton, MD (Central Pennsylvania Clinic), Tareck Nossuli, MD, PhD (THG Advanced Heart Failure Clinic), and Douglas Gohn, MD (THG Electrophysiology) are co-investigators.

Heather Madara
Penn Medicine LG Health Research Institute
133 E. Frederick St., Lancaster, PA 17602
717-544-1777
Heather.Madara@pennmedicine.upenn.edu

Roy S. Small, MD
The Heart Group of Lancaster General Health
217 Harrisburg Ave., Lancaster, PA 17603
717-544-8300
Roy.Small@pennmedicine.upenn.edu