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A Randomized Trial of Pocket-Echocardiography Integrated Mobile Health Device Assessments in Modern Structural Heart Disease Clinics

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ABSTRACT

OBJECTIVES This study sought to determine whether mobile health (mHealth) device assessments used as clinical decision support tools at the point-of-care can reduce the time to treatment and improve long-term outcomes among patients with rheumatic and structural heart diseases (SHD).

BACKGROUND Newly developed smartphone-connected mHealth devices represent promising methods to diagnose common diseases in resource-limited areas; however, the impact of technology-based care on long-term outcomes has not been rigorously evaluated.

METHODS A total of 253 patients with SHD were randomized to an initial diagnostic assessment with wireless devices in mHealth clinics (n = 139) or to standard-care (n = 114) in India. mHealth clinics were equipped with point-of-care devices including pocket-echocardiography, smartphone-connected-electrocardiogram blood pressure and oxygen measurements, activity monitoring, and portable brain natriuretic peptide laboratory testing. All individuals underwent comprehensive transthoracic echocardiography to assess the severity of SHD. The primary endpoint was the time to referral for therapy with percutaneous valvuloplasty or surgical valve replacement. Secondary endpoints included the probability of a cardiovascular hospitalization and/or death over 1-year.

RESULTS An initial mHealth assessment was associated with a shorter time to referral for valvuloplasty and/or valve replacement (83 ± 79 days vs. 180 ± 101 days, p <0.001) and was associated with an increased probability for valvuloplasty/valve replacement compared to standard-care (34% vs. 32%; adjusted hazard ratio: 1.54; 95% CI: 0.96 to 2.47, p = 0.07). Patients randomized to mHealth were associated with a lower risk of a hospitalization and/or death on follow-up (15% vs. 28%, adjusted hazard ratio: 0.41; 95% CI: 0.21 to 0.83; p = 0.013).

CONCLUSIONS An initial mHealth diagnostic strategy was associated with a shorter time to definitive therapy among patients with SHD in a resource-limited area and was associated with improved outcomes. (A Randomized Trial of Pocket-Echocardiography Integrated Mobile Health Device Assessments in Modern Structural Heart Disease Clinics; NCT02881398) (J Am Coll Cardiol Img 2017;■:■-■) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

ASEF = American Society of Echocardiography Foundation

BNP = brain natriuretic peptide

iECG = iPhone-electrocardiography

mHealth = mobile health

POC = point-of-care

SHD = structural heart disease

SSSIHMS = Sri Sathya Sai Institute of Higher Medical Sciences

TTE = transthoracic echocardiogram

The transformative potential for cellular technologies, expanding internet connectivity, and the development of innovative mobile health (mHealth) devices to improve health care delivery in resource-limited areas is promising (1,2). As these areas begin to leverage new digital infrastructures for health care, several key factors have emerged. These include: 1) to identify the heuristic factors and evaluative methods that lead to appropriate use of new technologies; 2) to determine the integration of device-based findings into existing informational systems and health records; 3) to demonstrate the patterns of effective use at the point-of-care; and 4) to identify those patterns that lead to earlier diagnostic and treatment decisions (3,4). In the aggregate, an emphasis on the deterministic approaches of mHealth must include pragmatic device use and outcomes-based assessments as new technology-based health care initiatives are organized (5,6).

Recent shifts in the global burden of cardiovascular diseases have led to an increasing prevalence in resource-limited areas with more than 25 million deaths in these regions predicted by 2030 (7). This problem is further compounded with resource-limited areas receiving a disproportionately low allocation of global resources ranging from the availability of appropriate diagnostic tests to sufficiently trained health care professionals (8). Portability, lower cost, and simple-to-use form factors are among the design features of mHealth that may be well suited to bridge these inequalities, and to mobilize care from hospital- and clinic-based encounters to the practitioner at the point-of-care and in remote locations (9). Although attractive from a technological perspective, the impact of mHealth used as a practitioner-based clinical-decision support tool on long-term outcomes has not been rigorously evaluated (10).

Therefore, the objective of the present study was to compare the outcomes of mHealth with smartphone-connected devices and pocket-echocardiography on medical decision making among patients with rheumatic and structural heart disease (SHD) in a health care system of a resource-limited area.

METHODS

STUDY DESIGN. The study was performed under the ASEF-VALUES (American Society of Echocardiography Foundation-Valvular Assessment Leading to Unexplored Echocardiographic Stratagems) program—a philanthropic and educational initiative to explore health care solutions for patients with SHD using new technologies. Within the program was a nested, single-site, randomized trial conducted at the Sri Satya Sai Institute of Higher Medical Sciences (SSSIHMS), a charitable, free-of-charge, tertiary-care, and teaching institution in Bangalore, India that exclusively provides care to the underserved, sees more than 20,000 SHD patients per year, and performs 1,100 percutaneous valvuloplasties and 1,000 valve replacements on an annual basis.

The primary study sponsors were the ASEF and SSSIHMS. General Electric Healthcare (Bangalore, India) provided local instruments and logistical support. Additional device support was provided by CoreSound Imaging (Raleigh-Durham, North Carolina) and iHealth (San Francisco, California). Five cardiologists and 12 sonographers from 12 academic medical centers across the United States, 15 cardiologists and cardiothoracic surgeons from SSSIHMS, and 30 cardiologists from across India participated in the study.

PARTICIPANTS. The study participants were outpatients with a new or an established diagnosis of SHD. The definition of SHD included valvular disease, left/right ventricular failure and congenital heart defects, and included adult, pediatric, and pregnant patients. We decided a priori to include SHD patients with a prior valvuloplasty or valve replacement. Exclusions included neonatal patients and those with an unstable hemodynamic status. All subjects provided written informed consent in their native language.

TRIAL ORGANIZATION, RANDOMIZATION, AND MASKING. Consecutive subjects were randomly assigned to an initial evaluation with mHealth or to standard care. Study subjects were evaluated in either 1 of 10 (5 mHealth, or 5 standard care) clinical sites all located at SSSIHMS. Each individual clinics that were used for a patient encounter after randomization. We decided to create mHealth and standard-care sites within 1 hospital to minimize variability with the initial clinical encounter (mHealth or standard care) after randomization, and separated these clinics to reduce any potential bias introduced by using mHealth devices. All mHealth clinics were equipped with the same devices and used the institutions electronic medical record to standardize workflow the data generated during the trial encounter. The standard-care clinics were designed with pragmatic intention and to mimic usual care practice patterns from a group of physicians across India. To minimize confounding resulting from the same physician participating in the clinical assessments as well as conducting procedures, physicians performing mHealth or standard care