Mobile health tools, sensors, and portable imaging devices: high resolution approaches for Point-of-Care assessment of structural heart disease

By Dr M Tokodi, Dr SP Bhavnani, Dr R Khedraki & Prof PP Sengupta

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.

This article summarizes a recently published study which 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).

The results showed that 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.

HIGH RESOLUTION HEALTHCARE

Due to the increasing burden of cardiovascular diseases and growing demands in healthcare, there is an emerging need for easily accessible and cost-efficient techniques for diagnosis and treatment. The rapid technological advances in the 21st century heralded by smartphone development could provide solutions to this need. The exponential increase of computing power and the progressive miniaturization of diagnostic instruments into wireless mobile health (mHealth) devices are creating a new era of data-driven and high resolution healthcare. This will enable the assessment and the management of a variety of conditions — remotely and at the point-of-care — with the potential of improving healthcare accessibility and affordability [1].

mHealth is defined as the practice of medicine supported by portable diagnostic devices including smartphone health 'apps', smartphone-connected devices, pocket-sized portable echocardiography (PPE), lab-on-a-chip devices, and miniaturized sensor-based technologies [2]. Important design features of mHealth include lower cost and high portability thereby making such devices accessible to a wide range of clinicians in different practice settings. These design factors are particularly appropriate to the health systems of resource-constrained areas of low and middle-income countries. In such areas, new technologies may bridge common healthcare inequities resulting from the low availability of traditional diagnostic devices and adequately trained healthcare practitioners [3, 4].

On the one hand, there is the promise of the transformation of healthcare delivery facilitated by advances in new technologies and data handling. However, on the other hand, several questions arise as to just how new devices should be used at the point-of-care. Such questions include: how are the new devices and sensors integrated into healthcare systems? What are the methods for data transmission? How are devices used pragmatically particularly in resource-limited areas? And finally, what is the overall impact on healthcare quality and outcomes?

AMERICAN SOCIETY OF ECHOCARDIOGRAPHY GLOBAL HEALTH INNOVATION TRIALS

To begin to answer these questions, the American Society of Echocardiography (ASE) has undertaken a series of sequential global health clinical trials – ASE-REWARD, ASE-VISION, and ASE-VALUES – to determine the usability of the new technologies and specifically the utilization of PPE devices in structural heart disease. Through these

The Authors,

Marton Tokodi, MD, Sanjeev P. Bhavnani, MD, Rola Khedraki MD, & Partho P. Sengupta, MD, DM

Author for correspondence

Partho P. Sengupta MD, DM, FACC, FASE

Professor & Chief of Cardiology

Chair of Cardiovascular Innovations

WVU Heart & Vascular Institute

West Virginia University School of Medicine

1 Medical Center Drive

Morgantown, WV, 26506, USA

email: partho.sengupta@hsc.wvu.edu

clinical trials, new methods for cloud-based image transfer and new educational modules for PPE image acquisition and interpretation have emerged. By leveraging cellular, broadband, and smartphone technologies these investigations have begun to evaluate the effectiveness of PPE used as a clinical decision support tool. In the aggregate, such efforts are creating new hierarchical structures to increase the yield of PPE and to determine its impact on healthcare access and outcomes.

PORTABLE POCKET-ECHOCARDIOGRAPHY

Pocket-sized portable echocardiography has significant potential to facilitate earlier disease detection, improving triage for high-risk patients, and enhancing the diagnostic capacity at the point-of-care [5]. The current generation of devices can provide two dimensional and color Doppler imaging in real time but are not capable of spectral Doppler or M-mode imaging [6]. The accuracy of PPE has been evaluated in various structural abnormalities such as left ventricular (LV) dysfunction, LV hypertrophy, pericardial effusion, and valvular heart disease [7-9]. Many studies have demonstrated a moderate-to-high degree of correlation between images acquired with PPE and those acquired by standard transthoracic echocardiography (TTE), especially with regards to LV function and valvular abnormalities [10-12]. Although a useful extension of clinical examination, PPE does not substitute for TTE due to its limited technical capabilities and lack of quantified findings with Doppler interrogation [6]. It should also be kept in mind that there is a learning curve for the use of these pocket-sized devices that could result in significant differences in both sensitivity and specificity of diagnostic findings and intra- and inter-observer variation between experienced and non-expert imagers [8, 13].

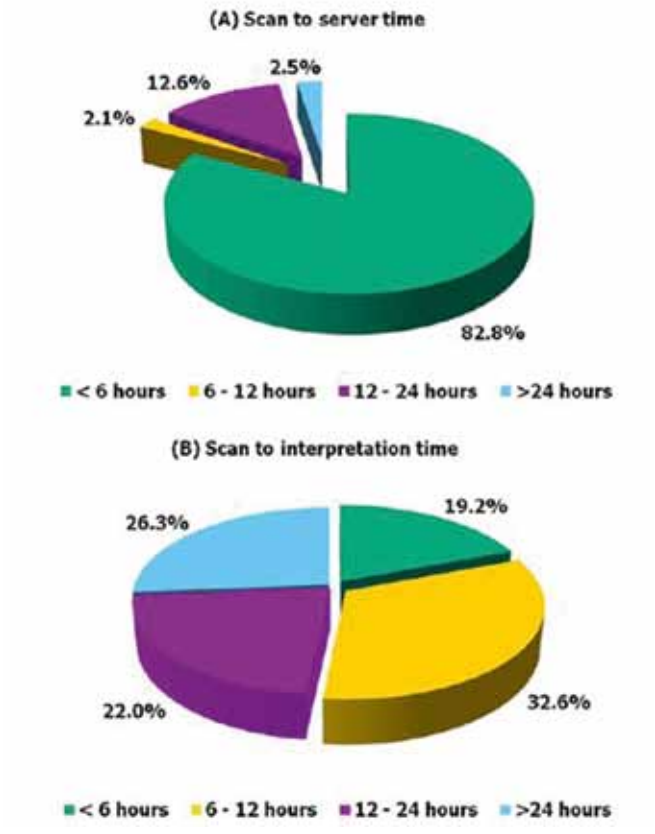

Figure 1. Time from PPE image acquisition to study upload (A) and time to study interpretation (B) via cloud-based image transfer.

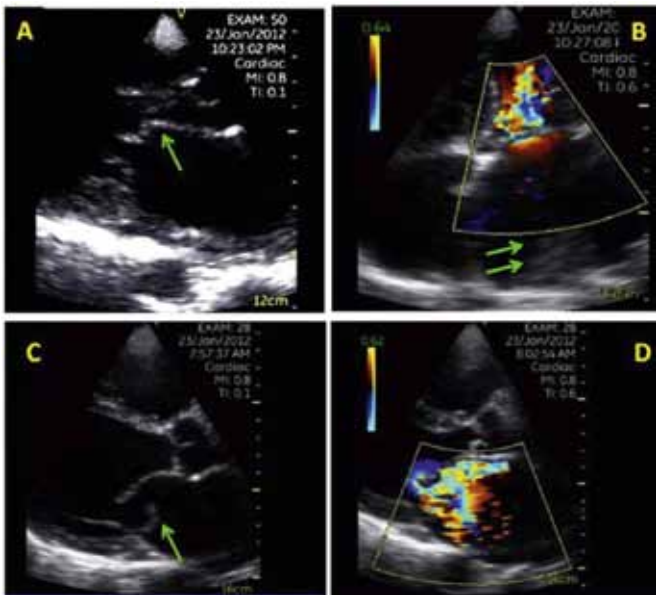

Figure 2. Results of complex SHD including systolic heart failure, and rheumatic and congenital heart disease were delivered back to local physicians for clinical decisions

ASE-REWARD – EXPEDITING PPE IMAGE INTERPRETATION WITH CLOUD COMPUTING

The ASE-REWARD (Remote Echocardiography with Web-Based Assessments for Referrals at a Distance) study was the first investigation to determine the feasibility of 'cloud computing' and Internet-based echocardiographic image transfer [14]. In 2012, ASE investigators, physicians, and sonographers screened >10,000 patients in rural India and imaged over 1,000 study subjects within 48 hours. The study methodology linked images obtained with PPE at the point-of-contact to the cloud with wireless broadband support brought directly to the study site. On average, each study consisted of 18 clips which were acquired according to ASE focused ultrasound guidelines. The provision of Internet-based communications in remote locations enabled upload of the digitized studies within 4 hours. The studies were then interpreted by a global consortium of 75 cardiologists scattered over four countries within the following 12 hours [Figure 1]. Results of complex structural heart disease (SHD) including systolic heart failure, and rheumatic and congenital heart disease were delivered back to local physicians for clinical decisions [Figure 2].

Readily available Internet connections and a systematic approach for image acquisition, transfer, and interpretation provided new methods for accessing expert consultation at the point-of-care.

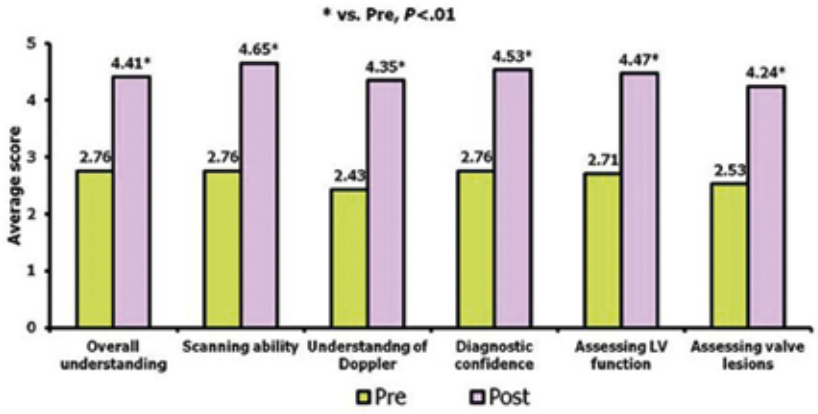

Figure 3: Overall impact of training on the self-perceived competence of the physicians in different components of PPE performance. All scores were derived using a five-point modified Likert-type scale.

ASE-VISION – INTERNET-BASED TELE-ECHOCARDIOGRAPHIC TRAINING

Recognizing that echocardiography requires expertise in both image acquisition and interpretation — common barriers limiting wider use in community settings — to standardize PPE image acquisition and reporting, the follow-up ASE-VISION (Value of Interactive Scanning for Improving Outcomes of New Learners) study was conducted in 2014 [15] and had several aims:

1) To test the feasibility of a Web-based training module for remote ultrasound training in which physicians learn from ASE-educators by transmitting their PPE images in real-time during scanning sessions;

2) To compare the Web-based trained physicians with a group of physicians trained on-site on markers of PPE efficiency and proficiency using studies performed in community settings.

After recruitment into the study a combination of 17 physicians were provided focused PPE training by ASE-sonographers on-site and remotely via a Web-based tele-echocardiography system. The remote Web-based training included live-echocardiography streaming with images accessed in real-time via Web-portals. These images were simultaneously accessed by expert sonographers in the United States who provided feedback for machine settings, transducer position, and for guideline-based image interpretation. During the trial period 900 PPE studies were performed of which 660 were used for validating physician competencies. Overall, there was adequate agreement between the two physician groups, i.e. on-site versus remotely trained, for image interpretation of major structural cardiac abnormalities obtained on PPE devices. The majority of physicians reported high satisfaction with Web-based training and significant improvements in measures of echocardiographic proficiency, including scanning ability, diagnostic confidence, and quantification of structural abnormalities on pre- and post-competency assessments [Figure 3].

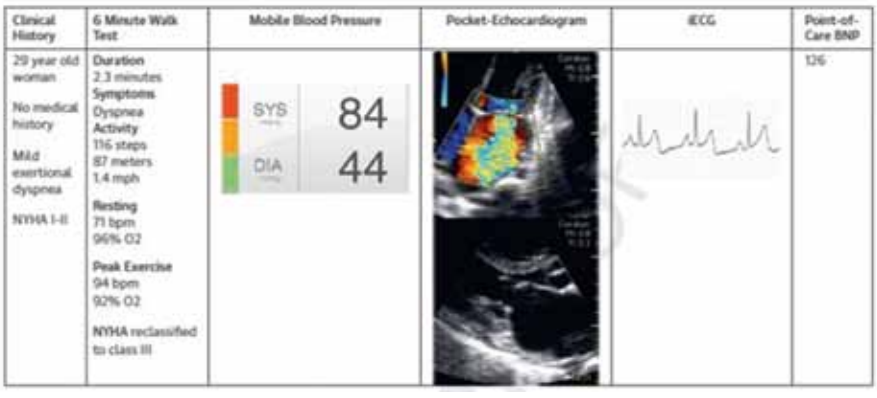

Figure 4 Comprehensive mHealth and PPE derived assessment of a 29-year old with symptomatic rheumatic mitral valve disease. Mobile diagnostics demonstrated NYHA III symptoms, hypotension, severe mitral regurgitation, and sinus rhythm. The patient was referred for mitral valve replacement.

ASE-VALUES – MHEALTH INTEGRATED PPE ASSESSMENTS & CLINICAL OUTCOMES

Using the above experiences as a foundation for the potential applications of new mHealth technologies sensors, and PPE devices, the ASE-VALUES (Valvular Assessments Leading to Unexplored Echocardiographic Stratagems) randomized clinical trial was undertaken in 2014 and completed follow-up in 2015 [16]. The primary objective of this investigation was to compare the outcomes of mHealth-derived assessments of structural heart disease with PPE and a variety of smartphone-connected devices to standard-care on medical decision making and treatment outcomes among patients with rheumatic and structural heart disease.

STUDY METHODS

To obtain comprehensive assessments of the severity of structural heart disease, 253 patients were randomized within 72 hours to either standard-care or mHealth clinics. These latter were equipped with new portable devices, including smartphone-connected iECG, activity monitors for quantification of 6-minute walk test, PPE for qualitative assessments of structural heart disease, wireless blood pressure and oximetry, and fingerstick BNP. All study subjects underwent comprehensive transthoracic-echocardiography for the quantification of valvular disease and for diagnostic comparison to PPE studies. Physician-derived mHealth assessments were conducted at the time of enrollment for point-of-care clinical decision. The primary outcome of interest was the time to treatment with valvuloplasty or valve replacement after the initial clinical evaluation with secondary outcomes being the occurrence of cardiovascular hospitalization or death over 12 months.

STUDY RESULTS

Overall, the mean age of the study population was 39±14 years. Comprehensive mHealth assessment was performed in 139 subjects and standard care evaluation in 114. The study population had a substantial burden of disease with 57%, 42%, 23%, and 32% of echocardiographic studies exhibiting mitral stenosis, mitral regurgitation, aortic stenosis, and/or aortic regurgitation, respectively. The prevalence of severe mitral and/or aortic valve disease was similar between the

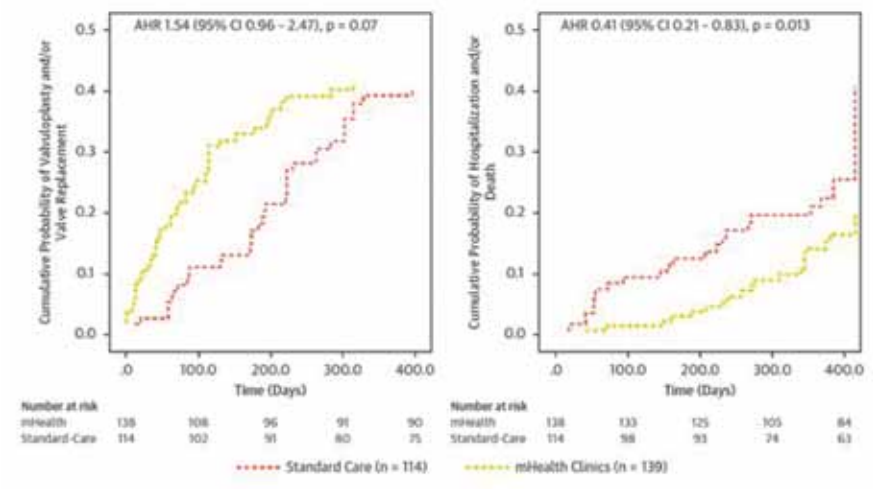

Figure 5: (A) Outcomes of percutaneous valvuloplasty or valve replacement, and (B) hospitalization and/or death stratified by mHealth with PPE or standard-care.

mHealth and standard-care randomized groups.

Ninety-six percent of PPE studies were rated to have good image quality and demonstrated adequate diagnostic correlation with transthoracic echocardiography for moderate or severe mitral or aortic valve disease (areas under the ROC curve of 0.74 and 0.79, respectively). More than one third of the study population exhibited severe mitral and/or aortic valvular disease on PPE with one in four patients having combined mitral and aortic valve pathologies. An example of an initial mHealth and PPE assessment is illustrated in Figure 4.

At 12 months, 34% of the study population underwent treatment with valvuloplasty or valve replacement. Compared to standard care, a shorter time from initial evaluation to primary outcome was observed with mHealth (83±79 days vs. 180±101 days, p<0.001) with twice as many patients in the mHealth arm receiving treatment within 90 days (20% vs 10%, p<0.01). Compared to standard-care, subjects randomized to mHealth were more likely to undergo valvuloplasty or valve replacement (AHR 1.54 [95% CI: 0.96 to 2.47], p=0.07) and were associated with a lower probability of hospitalization and/or death at on follow-up (AHR 0.41 [95% CI: 0.21 to 0.83], p=0.013. [Figure 5].

PRINCIPAL FINDINGS

Within a community cohort with advanced structural heart disease mHealth and PPE can be used as clinical decision support tools at the point-of-care to assess symptoms, structural, and functional abnormalities. Compared to standard care an initial diagnostic strategy with mHealth was associated with a shorter time to referral for valvular interventions, resulting in improved morbidity and survival.

TRANSLATIONAL PERSPECTIVES

Newly developed PPE devices and smartphone-connected mHealth technologies have emerged as potentially transformative innovations capable of reducing common health care disparities by providing diagnostic information and to support clinical decisions at the point-of-care. The ASE innovation clinical trials aimed to advance our knowledge of the potential of PPE for diagnosis, treatment, and patient-related outcomes. To do so, the key components of PPE that were evaluated included the following:

- Identification of heuristic factors and evaluation methods that lead to appropriate use of new portable imaging devices,
- Determination of the integration of PPE derived device findings into existing information systems and health records,
- Identification of patterns of utilization that lead to earlier diagnostic and treatment decisions.

CONCLUSION

Our ability to understand and longitudinally measure health parameters and cardiovascular function at high resolution with new PPE devices, coupled with new mHealth technologies that consider the multidimensional aspects of disease, accelerates medical decision-making at the point-of-care.

Demonstrating the incremental and additive value of new technologies in endemic communities with high burden of disease should remain a focus of future studies evaluating the outcomes of such technology-enabled care in resource-limited areas.

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