Abstract

Cloud Connected Non-Invasive Medical Device for Instant Left Ventricular Dysfunction Assessment via Any Smartphone

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Abstract

Background: Left Ventricular (LV) dysfunction is the inability of the heart to effectively pump blood through the circulatory system, leading to compensation and eventually heart failure (HF). Ninety-one million American adults with predisposing conditions are at risk for HF and need better screening and diagnosis to prevent disease progression, and 24 million Americans with diagnosed HF need better monitoring to reduce the high hospital readmission rates (25% within 30 days; 50% within 6 months). This epidemic of HF is causing a significant burden on our health care system, with $20 billion in direct medical cost related to HF and $1 billion in in-patient hospital costs annually. Clinical interventions based on standard measurements (blood pressure, weight, electrocardiograms) have not demonstrated a significant reduction in readmissions or all-cause mortality within 180 days after enrollment. Successful treatment may be determined from 2D transthoracic echocardiography (echo) or right heart catherization, but these gold standard methods have limitations of cost, accessibility, and availability of sonographers and cardiologists. An alternative is the HEMOTAG CardioPulmonary Assessment System (CPAS), a new cloud-connected medical device that delivers cardiac time intervals comparable to the gold standard measurements of an echo from an easy-to-use, noninvasive device accessible via any smartphone.

Objective: Given the clinical and economic impact of LV dysfunction and in view of the cost and accessibility of existing devices, there is a need for accurate, absolute, and actionable measurements, available instantly through a noninvasive and easy-to-use system. With the ability of provide rapid assessment of LV dysfunction in adults, keeping patients healthy and safe. The objective of the current study was to compare HEMOTAG to an echo for accuracy in assessment of LV dysfunction, using heart sounds and an ECG signal transduced via 3 thoracic electrodes.

Methods: One hundred twenty-three consecutive patients undergoing 2D transthoracic echocardiograms were recruited at an outpatient cardiology clinic from March 2016 through February 2017. Conventional echo variables and cardiac time intervals were assessed, and all patients were analyzed using HEMOTAG which recorded multi-channel acoustic and ECG data. LV dysfunction was assessed using the 2016 American Society of Echocardiography (ASE) standard and compared to cardiac time intervals from HEMOTAG. Patients were separated by age for comparisons. HEMOTAG indices were then assessed to identify normal/abnormal LV function.

Results: ASE diagnoses: 46 normal, 21 heart failure with preserved ejection fraction (HFpEF), 15 heart failure with reduced ejection fraction (HFrEF), and 41 indeterminate patients. HFrEF was defined as EF <53%, and systolic time ratio (STR=pre-ejection period/ejection time). 0.3 was a sensitive measure for detecting reduced EF as in HFrEF. Detecting EF <53% in patients older than 60: HEMOTAG STR sensitivity=65%, specificity=80%, AUC=.765; Echo STR sensitivity=85%, specificity=80%, AUC=0.895.

Conclusions: HEMOTAG represents a potentially widely applicable technology for the assessment of LV dysfunction via a noninvasive approach, providing absolute assessment (without requiring certified technicians to operate or interpretation of an echo) and enabling rapid, real-time, anywhere, anytime assessment of LV dysfunction.

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KEYWORDS

diabetes mellitus, type 2; left ventricular dysfunction; heart failure; Framingham index; ejection fraction

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