A Novel Noninvasive Device for Screening and Optimized Management to Improve Heart Failure Outcomes in Patients with Diabetes Mellitus

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Introduction

Evidence shows diabetes mellitus (DM) is major independent risk factor for several cardiovascular disorders including heart failure (HF). Large, randomized clinical trials for screening and revascularization of stable macrovascular disease in diabetics, have failed to demonstrate a significant reduction in cardiac events and HF episodes. Studies have demonstrated that early detection of left ventricular dysfunction and prevention of microvascular complications through glycemic control in diabetes patients is a critical mechanism for reducing the incidence and severity of left ventricular dysfunction and HF. There is a need for a non-invasive, affordable, accurate, absolute and actionable method to facilitate optimized management of diabetes patients across the continuity of care. HEMOTAG, is a small portable device that uses micro-sensors to capture cardiac vibrations and electrocardiogram, transduced via thoracic electrodes. It is a viable option to measure cardiac time intervals (CTIs), surrogate markers for measurements of left ventricular dysfunction.

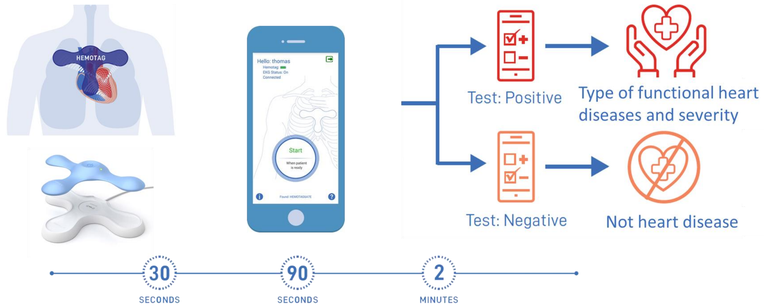

Figure 1: HEMOTAG, is a novel, intelligent, portable, non-invasive device for left ventricular dysfunction assessment, using multiple sensors (ECG and 3-axis accelerometers), one-touch mobile app acquisition, automatic cloud upload, and AI-powered accurate, actionable cardiac diagnostic reporting via secure cloud-based storage and visualization.

HEMOTAG

METHODS

In 98 diabetes patients, the predictability value of HEMOTAG-derived CTIs- systolic time ratio index (STRi) = aortic valve opening/ (aortic valve opening to aortic valve closing) normalized by heart rate, aortic valve closing (AVC) and mitral valve opening (MVO) were assessed as valid markers for left ventricular dysfunction measured simultaneously at the time of transthoracic echocardiogram; to determine reduced ejection fraction (EF) < 50%, < 35%; elevated E/e' >; 14; and elevated left atrial volume index (LAVI) > 34 ml/m2. Linear correlation analysis was performed. Sensitivity, specificity, positive, and negative predictive values were calculated.

RESULTS

Mean age was 70.3 ± 11.6 years, mean EF was 59.0 ± 12.7%, mean E/e' was 17.9 ± 8.5, mean LAVI was 35.4 ± 16.1 ml/m^2, 30.2% were women. The following was noted with a paired dichotomous interpretation; for STRi and EF <35%: sensitivity 100%, specificity 88%, AUC 0.94; for STRi and EF <50%: sensitivity 94%, specificity 87%, AUC 0.93; for MVO and E/e' >14: sensitivity 92%, specificity 45%, AUC 0.63; for AVC and LAVI>34 ml/m^2: sensitivity 92%, specificity 53%, AUC 0.65.

CONCLUSIONS

HEMOTAG detected systolic and diastolic dysfunction with high sensitivity and high specificity. This preliminary study has demonstrated the feasibility of estimating left ventricular dysfunction using a portable, non-invasive device that can facilitate screening and optimized management to improve HF outcomes in patients with DM.

Table 1. Sensitivity, specificity, and positive predictive values of HEMOTAG-Derived CTIs.

HEMOTAG CTIs	Cutoff (ms)	Sensitivity (%)	Specificity (%)	NPV (%)	PPV (%)	AUC
STRi & EF<35%	> 0.4	100	88	100	27	0.93626
STRi & EF<50%	> 0.3	94	87	99	60	0.93008
MVO & E/e'>14	> 440	92	45	74	76	0.62658
AVC & LAVI>34 ml/m^2	> 365	92	53	90	58	0.64859

Abbreviations: AUC, area under curve; CTIs, cardiac time intervals; STRi, Systolic time ratio; MVO, mitral valve opening; AVC, aortic valve closing; EF, Ejection Fraction; LAVI, Left Atrial Volume Index; PPV, positive predictive value; ROC, receiver operator characteristic.

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