Validation of Left Ventricular Ejection Time (LVET) Measurement with CardioTag Wearable

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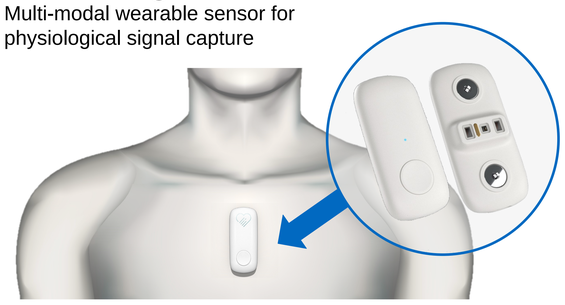
Background

- Left ventricular ejection time (LVET) is the time interval from aortic valve opening to closure and is the phase of systole when the LV ejects blood into the aorta. It is used to assess LV function and contractility. (Figure 1).[1]
- LVET is shortened in patients with heart failure with reduced ejection fraction[2] making it a provocative measure of potential therapeutic action.
- CardioTag is a sensor that measures ECG, PPG and SCG signals that can assess cardiac function parameters. In this study we sought to validate the LVET measures of the CardioTag with transthoracic echocardiography.
- Previous research has highlighted that ML algorithms leveraging the multi-modal signals derived from the CardioTag wearable can produce non-invasive estimates of hemodynamic parameters such as pulmonary capillary wedge pressure.

CardioTag
Multi-modal wearable sensor for physiological signal capture



**CardioTag is investigational and have not been cleared or approved by the United States Food and Drug Administration (FDA).*

Objective & Methods

Objective	To evaluate the accuracy of SCG-derived LVET from CardioTag compared to echocardiographic measurements
Design	Prospective, multi-site, observational study.
Recruitment	Enrolled 54 participants scheduled to undergo routine echocardiography at two sites.
LVET Data	Echocardiographic and SCG data were reviewed and annotated by two independent cardiologists. Fifteen (n=15) participants were excluded due to not completing the study or low quality data, resulting in N=39 analyzable data.

Systolic timing intervals describing cardiac function, such as LVET, can be derived from a multi-modal wearable sensor capturing SCG and ECG

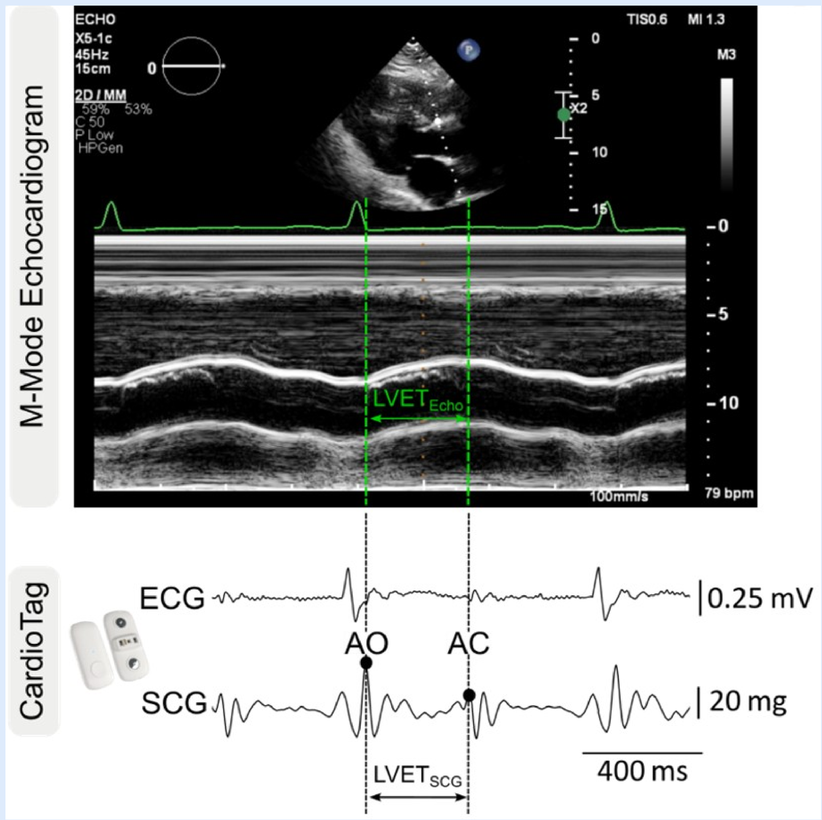


Figure 1: Simultaneous LVET Measurements via an M-Mode Echocardiogram Focused on the Aortic Valve and CardioTag SCG signal acquired from the same participant.

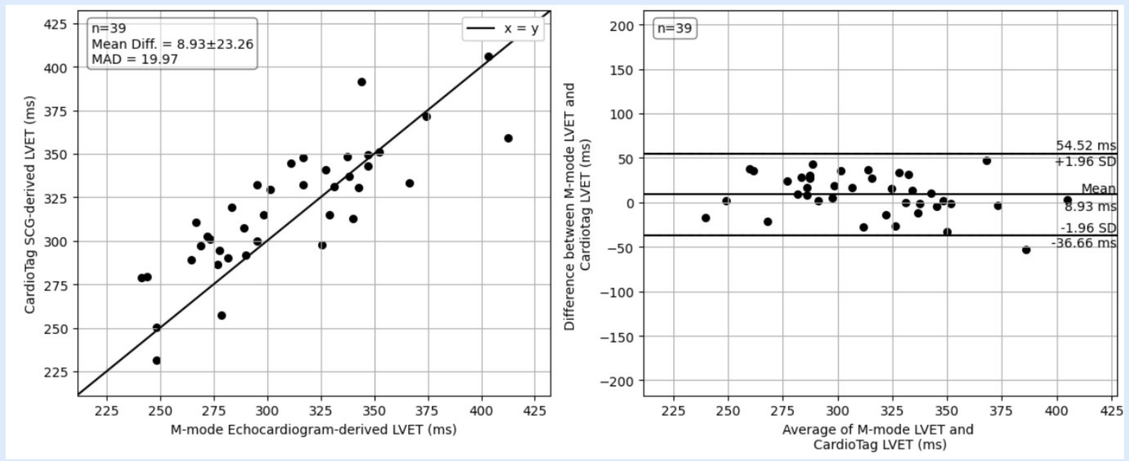


Figure 2: Correlation and Bland-Altman Plot Showing Agreement Between the LVET Measured by the CardioTag SCG and M-Mode Echocardiogram.

Table 1: Key Inclusion/Exclusion Study Criteria

Key Inclusion Criteria	Key Exclusion Criteria
• ≥ 21 years of age • Willing to wear the CardioTag device • Willing and able to provide written informed consent	• Mechanical Ventricular support • Known allergies to Ag/AgCl wet electrodes • Healing chest wall wounds • Hemodynamically unstable or otherwise inappropriate for participation • Pacemakers or Implantable Cardioverter Defibrillators (ICDs) • Pregnant women

Discussion & Conclusion

- This study explored the ability to use a wearable multi-modal sensor to derive systolic timing intervals such as LVET with accuracy comparable to an echocardiogram.
- LVET is a measure of cardiac function underappreciated as an indicator of systolic dysfunction in patients with HFrEF.[2] While accepted as a metric in echocardiography, there are no commonly used tools to assess this potentially valuable measure.
- In this study we validated CardioTag against echocardiography, showing that SCG-derived LVET matches the accuracy of existing wearable methods like impedance cardiography (ICG). Unlike echocardiography, which requires trained specialists and a specialized lab, or ICG, which is obtrusive and requires injecting current into the body, SCG offers a convenient, wearable solution.
- These findings help enable the widespread use of LVET to aid in monitoring of systolic function towards the management and diagnosis of cardiovascular diseases.

Table 2: Comparison of CardioTag and Previously Reported ICG LVET Measurements Against Echocardiography.

Method	Accuracy against Echo
ICG[3]	51.2 ± 45.8 ms
CardioTag (SCG+ECG)	8.93 ± 23.26 ms

Table 3: Participant Characteristics.

Characteristics		Study Cohort (N=39)
Age (mean ± SD)		57.7 ± 14.4
BMI (mean ± SD)		31.0 ± 10.0
Obesity Class	I	5 (12.8%)
	II	7 (17.9%)
	III	4 (10.3%)
Sex	Male	13 (33.3%)
	Female	26 (66.6%)
Race	White	20 (51.3%)
	Black	18 (46.2%)
	Other	1 (2.6%)
Fitzpatrick Skin Type	≤ Type 4	29 (78.85%)
	> Type 4	10 (25.6%)

Disclosures:
- O.I., and A.C are co-founders of Cardiosense and have significant financial interest in the company.
- V.G. and A.A. are employees of Cardiosense, Inc.
- P.M., K.M., an A.Q. do not have any relevant disclosures.

References:

1. Alhakak AS, et. al. Eur J Heart Fail. 2021; 23, 541-551.
2. Lindenfeld J et al. Lancet. 2021;398:991-1001.
3. Carvalho P, et. al. Annu Int Conf IEEE Eng Med Biol Soc. 2010; 2010:606-9.