Non-invasive Assessment of Elevated LVEDP Using a Small Portable Device: Design for Telemonitoring

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Introduction

Left ventricular end-diastolic pressure (LVEDP) provides crucial information on the LV operating compliance and is a key marker for congestive heart failure and pulmonary hypertension. The diagnosis and monitoring of the left-sided filling pressure often requiring invasive procedures. HEMOTAG, is a small portable device that uses micro-sensors to capture cardiac vibrations and electrocardiogram (ECG), transduced via thoracic electrodes. It is a viable option to measure cardiac time intervals (CTIs), surrogate markers of hemodynamics and intracardiac pressure. In this study, diastolic-to-systolic time ratio (DSR) and systolic time ratio (STR) along with the patient's age, height, and weight were assessed as valid markers for elevated LVEDP, compared against left heart catheterization LVEDP measurement.

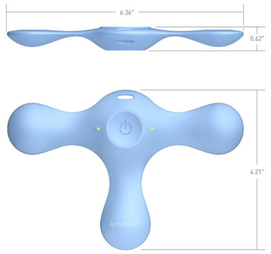


Figure 1: Shape and dimensions of the HEMOTAG sensor.

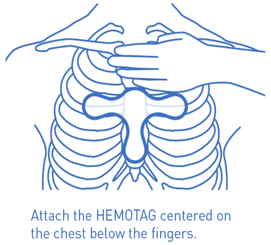


Figure 2: Placement of HEMOTAG at 2nd intercostal space, centered on mid-sternal line.

METHODS

In 44 female and 49 male patients, mean LVEDP was measured during cardiac catheterization. Simultaneously, Hemotag generated CTIs including systolic time (ST): mitral valve closure (MVC) to aortic valve closure (AVC), diastolic time (DT): AVC to MVC, STR: Aortic valve opening/(Aortic valve opening to Aortic valve closing), and DSR: DT/ST. The predictability value of non-invasively HEMOTAG-derived CTI ratios – diastolic time normalize by heart rate (DT/HR), DSR, and STR – plus biological information of age, height, and weight were assessed to determine elevated LVEDP (> 15 mmHg). Logistic regression analysis between the markers and LVEDP was performed. Sensitivity, specificity, correlation, and p-values were calculated.

HEMOTAG

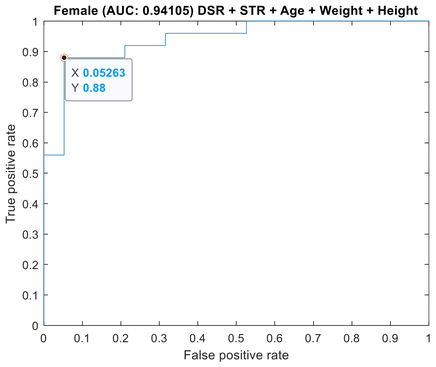
RESULTS

Mean age for the female (male) patients was 69.41 ± 11.84 (63.12 ± 10.80) and mean LVEDP was 17.20 ± 6.17 (16.57 ± 5.42). Using logistic regression with DSR, STR, age, height, and weight as features, sensitivity of 88.00%, specificity of 94.74%, AUC of 0.94, r = 0.74, p-value = 4.31e-06, were obtained for female patients; using DT/HR, STR, age, height, and weight, a sensitivity of 89.29%, specificity of 71.43%, AUC of 0.79, r = 0.40, and p-value = 0.0419 were obtained in the male patients.

Table 1. Clinical and Demographic Characteristics of the Patients.

Female	Age (year)	BP_Sys (mmHg)	BP_Dias (mmHg)	HR (bpm)	Weight (lb)	Height (inches)	LVEDP (mmHg)
Mean	69.41	125.12	71.56	72.07	157.94	62.88	17.20
± std	11.84	16.72	10.90	13.83	42.71	2.54	6.17
Min	32	90	47	46	82	57	7
Median	68	123	71	70	154.5	63	17.5
Max	89	175	100	99	285	69	29

Male	Age (year)	BP_Sys (mmHg)	BP_Dias (mmHg)	HR (bpm)	Weight (lb)	Height (inches)	LVEDP (mmHg)
Mean	63.12	133.33	81.35	71.52	196.21	68.43	16.57
± std	10.80	17.00	12.62	14.13	40.77	3.18	5.42
Min	40	103	58	44	120	61	6
Median	64	132	83	67.5	192	68.4	16
Max	86	185	114	104	299	76.8	29



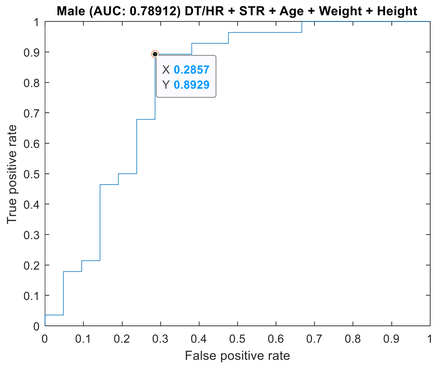


Table 2. Performance of HEMOTAG-Derived CTIs plus Age, Height, and Weight for Assessment of Elevated LVEDP (> 15 mmHg).

Patient	HEMOTAG CTIs	Sensitivity (%)	Specificity (%)	AUC	r	p-value
Female	DSR, STR	88.00	94.74	0.94	0.74	4.31e-06
Male	DT/HR, STR	89.29	71.43	0.79	0.40	0.0419

Abbreviations: AUC, area under the curve; CTIs, cardiac time intervals; DSR, diastolic to systolic time ratio; DT/HR, diastolic time normalize by heart rate; LVEDP, (left ventricular end-diastolic pressure); r, correlation coefficient, STR, systolic time ratio.

CONCLUSIONS

HEMOTAG detected elevated LVEDP with high sensitivity and high specificity for both female and male patients. This preliminary study has demonstrated the feasibility of estimating LVEDP using a portable, non-invasive device that empowers patients to transmit such data from home instantaneously to providers. Further studies are required to validate HEMOTAG as a point-of-care non-invasive assessment for heart failure and pulmonary hypertension patients.

ACKNOWLEDGMENTS

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