

## Abstract

# Cloud Connected Noninvasive Device Correlation with Pulmonary Artery Pressure by Right Heart Catheterization: Implications for Diagnosis and Clinical Practice to Improve Outcomes for Heart Failure Patients

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## Abstract

**Background:** The management of 5-6 million Americans with heart failure (HF) is costly and problematic in part due to very high re-admission rates of 25% within 30 days, and 50% within 6 months. Clearly needed is a new way to manage these patients without relying on costly hospitalizations. Clinical interventions based on standard tele-monitoring utilizing monitoring of blood pressure, weight, electrocardiograms, or rhythm strips for review, have not demonstrated a significant reduction in all cause readmissions or all cause mortality within 180 days after enrollment. Invasive devices have demonstrated that ambulatory pulmonary artery pressures (PAPs) hemodynamic measurement allow more effective HF management leading to fewer hospitalizations. The HemoTag is a new cloud-connected medical device that captures heart sounds and an ECG signal transduced via 3 thoracic electrodes. The device measures cardiac time intervals and can potentially constitute a quick and non-invasive means of assessing patient's PAP obtained by right heart catheterization. Electromechanical Activation Time (EMAT) as one of the HemoTag indices was assessed as a marker of systolic, and mean PAPs in the right heart measurements. HemoTag indices were then assessed to identify normal/abnormal PAP using prediction models.

**Objective:** Given the clinical and economic impact of HF hospitalizations, and in view of the risk and cost of invasive monitoring, there is a need for a non-invasive, affordable, accurate, and actionable hemodynamic measurement method that can monitor HF patients in the clinic and at home. This study provides preliminary results of HemoTag as a possible solution for remote monitoring of HF patients.

**Methods:** There were 20 consecutive patients recruited at the catheterization laboratory of community affiliated academic center (JFK Medical Center) from February 1 to March 30, 2017 (WIRB approved study # 20151156). Eight patients were excluded from the study as they did not meet inclusion criteria. EMAT measurements were obtained using HemoTag within 30 minutes from the right heart catheterization. Linear regression and predictive models were employed to evaluate EMAT correlation with systolic and mean pulmonary pressure. Data was entered and analyzed on MS-Excel 2016.

**Results:** The female to male ratio was 0.58 with a mean age 69. 59 +/- 15.63 years. The mean systolic blood pressure was 130 +/- 19.42 mmHg, mean weight was 189.06 +/- 42.32 pounds. The mean of mean pulmonary atrial pressure (mPAP) was 33.09 +/- 14.27 mmHg and mean of systolic pulmonary atrial pressure (sPAP) was 55.25 +/- 23.41 mmHg. Using a linear regression approach, EMAT correlated with mPAP with R value of 0.69 whereas overall correlation between EMAT and sPAP was R=0.65. Using clinically relevant cut-off of 25mmHg for mPAP, a prediction model constructed by logistic regression with confidence interval 0.95 demonstrates a sensitivity of 100%, specificity of 100% and accuracy of 100%.

**Conclusions:** HemoTag represents a potentially widely applicable technology for the assessment of pulmonary artery pressure via a non-invasive approach which can be used in the ambulatory setting or for patients at home. This has a distinct advantage over invasive pulmonary artery monitoring with similar results. Larger studies are needed to confirm the findings of this study.

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#### KEYWORDS

heart failure; remote monitoring; hospitalization; quality of life

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