

Novel In-Home Cardiac Monitoring for Heart Failure Patients

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Abstract

Heart failure (HF) costs the US \$30 billion annually, and about 80% is associated with hospitalization. Reducing cost by lowering hospitalization through in-home patient monitoring is appealing. Adherence is a major challenge to in-home heart monitoring systems, especially when most high-risk patients are elderly and sick. We use a novel toilet seat, integrated with multiple sensors, as an inconspicuous monitoring system with potential for daily use. We examine initial deployment success, adherence rate to this new technology. Discharged heart failure patients are enrolled for a 90-day monitoring study. For deployment success, we examine enrollment rate and causes for failed enrollment. For adherence, we examine data missingness. For predictive analysis, we train random forest classifier with five-fold cross validation for a monitoring window of a week to predict hospitalization within 21 days. Of the 140 HF patients who consented, 35.5% were enrolled. The causes for failure to enroll were: hardware compatibility (43%), further illness (20%), loss of follow-up (17%). Of the 45 subjects analyzed, we observed maximum 71 ± 36 days of heart rate (hr), heart rate variability (hrv) and weight (sw); and minimum 37 ± 41 days of blood pressure monitoring data. Initial predictive analysis using hr, hrv, sw, resulted in an AUC of 74% (sensitivity 57%, specificity 75%) in a five-fold cross validated dataset.

1. Introduction

Cardiovascular diseases (CVD) are a health risk with around 19 million deaths attributed to CVD globally (an increase of 18.7% from 2010) [1]. The overall impacts of CVD also include adverse economic impacts to society at large. In the US, an average annual direct and indirect cost of CVD in was estimated to be \$378.0 billion in 2017 to 2018, of which 60% is considered to be in-direct costs alone [1]. Congestive heart failure (HF) is a type of CVD which is characterized by heart's inability to pump blood effectively, leading to inadequate oxygen and nutrient delivery to the body's tissues and organs. Over six million

patients in the US alone suffer from this condition, and the prevalence is rapidly growing in most countries, including the US [2]. The economic costs due to heart failure is a particular concern because of the high prevalence, which is growing [3]. The total cost associated with heart failures, was estimated to be around \$108 billion annual with the US alone accounting for \$30 billion (28.8%)[3]. Moreover, the prevalence is expected to grow to near 8 million patients by 2030 [4]. 80% of the costs related to be HF is related to hospitalizations [4].

HF has a high readmission rate, which means that patients once hospitalized for HF are at high-risk for being rehospitalized. Remote monitoring of high-risk patients is promising in reducing hospitalization rates and lengths-of-stay in hospitals, which are all directly related to the costs of treatment for the disease [5–8]. Most success in this regard has been obtained in systems such as CardioMEMS, which is an implantable device that tracks pulmonary artery pressures [5]. However, these devices are, in general, extremely invasive and expensive, which can cause their usage to be limited. In home monitoring with standard monitoring approaches of blood pressure and weight have had limited success, given that patient adherence to monitoring is a major barrier to reducing hospitalizations [6, 7].

To solve this issue with low adherence with standard in-home monitoring of high-risk individuals, in this work, we test the feasibility of a novel toilet seat called the “The Heart Seat[®]”, which is a registered trademark of Casana. These seats incorporate sensors capable of determining essential clinical variables (e.g. heart rate, blood pressures, etc.) and install directly on a standard toilet without the need for additional connections or user interaction. The seat can measure the clinical data each time the subject uses the seat and this data is transferred via Wi-Fi connection to a secure cloud database. Thus, this device is capable of capturing multiple data points for in-house monitoring without obstruction or discomfort for the subjects. This setup is ideal for patient monitoring adherence, especially for the elderly and sick population that is common to the heart failure population, as it is based on a patient's need to

regularly use the seat and does not rely on proactive patient effort to sustain data collection or monitoring.

In this study, we elaborate the study protocols, outlining the criteria for including and excluding participants, while also emphasizing the current enrollment and completion rates. Additionally, we examine the rate of missing values for various clinical variables, which serves as an indicator of adherence to the study. Subsequently, we evaluate the available clinical variables with a simple random forest classifier to assess their predictive capabilities.

2. Toilet seat design and clinical variables



Figure 1. An overview of the FIT toilet seat used.

The FIT toilet seat we used for the study consists of three different sensors. A single-lead electrocardiogram (ECG) is contained for measuring the electrical activity of the heart. A photoplethysmogram (PPG) placed on the seat measures blood oxygenation and pulse transit time. Similarly, the seat also contains a ballistocardiogram (BCG) for measuring the mechanical forces associated with the cardiac cycle, and a body weight sensors. Key cardiac measurement capabilities of the seats have been published in [9, 10] and are summarized below.

3. Design, Setting, and Participants

Given that the readmission rates for HF is seen to be pretty high, we recruited subjects with recent history of left ventricular heart failures and have been discharged from inpatient and cardiology departments in the University of Rochester Medical Center (URMC), with a protocol approved by URMC’s Institutional Ethics Review Board. Once recruited, the toilet seat would be used to monitor patients for a period of 90 days.

Clinical measurement	Sensors
Heart rate	ECG
Heart Rate variability	ECG
QRS duration	ECG
QTc Interval	ECG
Stroke Volume	ECG
Diastolic Blood Pressure	BCG + PPG
Systolic Blood pressure	BCG + PPG
Body Weight	Strain Gauges
Blood oxygenation	PPG
Pulse wave velocity	BCG + PPG

Table 1. Clinical variables and sensors used in determining them.

3.1. Inclusion and Exclusion criteria

We had an explicit inclusion criteria to include patients, at least 18 years old, either admitted to the hospital for HF or discharged from the hospital within the past six months. Since the study is to last for 90 days, we included only the patients who were expected to live longer than 3 months based on the clinicians suggestion. Furthermore, we enrolled only the subjects who were judged to be able to complete study procedures, i.e., independently use the toilet seat and an electronic tablet for surveys. Moreover, our enrollment criteria also was limited to patients whose care provider was within the University of Rochester Cardiology group, to ensure that the care provider could manage the subjects clinical care.

We had to explicitly exclude patients that any either of the following exclusion criteria:

- Do not have access to a landline or cellphone.
- Can not communicate over phone in English.
- Patient has a weight larger than 400 lbs
- Patient with pacemaker dependent atrial rhythm
- Patient with pacemaker dependent ventricular rhythm
- Prisoners
- Pregnant or nursing patients
- Chronic mechanical circulatory support
- Known contact allergies to plastic or stainless steel components present in the Heart Seat®
- Outpatient living situation will not support the Heart Seat®

4. Methods

4.1. Deployment rate

We examine the success rate of our deployment of toilet seats in patients considered for the study that meet all the inclusion criteria and do not fall under any exclusion criteria between the dates of Oct 1, 2021 and January 31, 2023. We also group the reason of failures in deployment.

4.2. Adherence

We examine data missingness in the completed study group. The amount of data missing for all clinical variables will give us the idea of how well the patients adhered to the study.

4.3. Predictive Analysis

We fit a random forest classifier in the available data to estimate the predictive power of the in-house monitoring system. We use data from a monitoring window of 7 days to predict for a positive hospitalization event in the next 21 days.

5. Results

5.1. Deployment rate

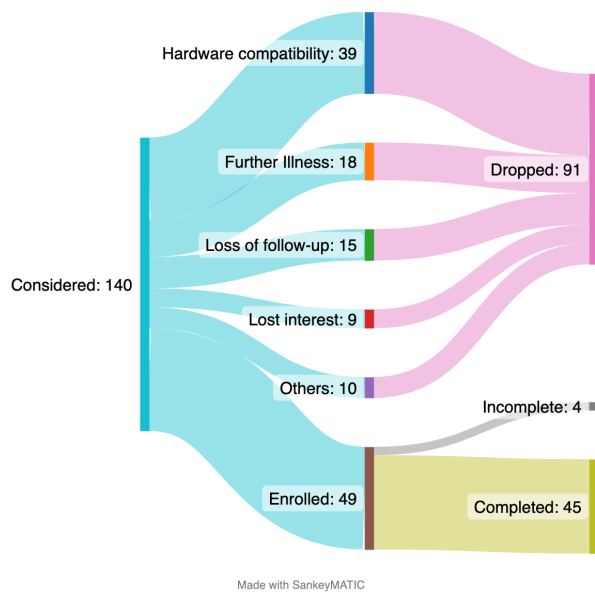


Figure 2. A sankey chart showing reasons of deployment failure in FIT toilet seat study.

140 patients consented to participate over a period of a year, of which 49 subjects (35.5%) were enrolled. 39 of the patients (43%) were dropped because the FIT toilet seat was incompatible with their existing toilet seats and therefore could not be successfully deployed. Furthermore, 18 subjects (20%) suffered from further illness, which prevented them from successfully participating in the study. 15 subjects (17%) were lost due to inability to follow-up contact, and 9 patients (10%) lost interest in the study and were therefore dropped. This number has been summarized on a sankey chart in Figure 2.

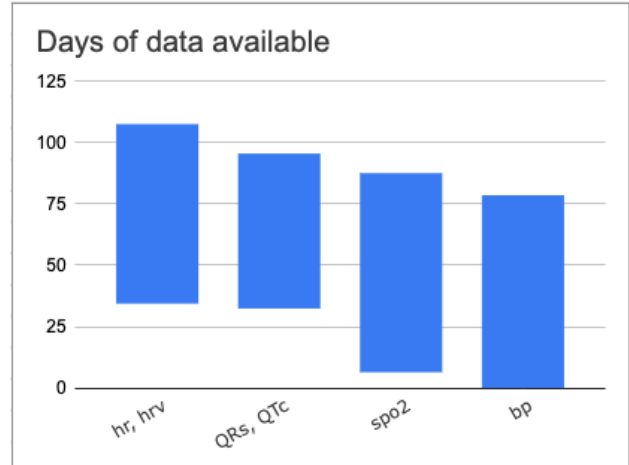


Figure 3. Number of days of available data for important clinical variables

5.2. Adherence

Of the 49 subjects enrolled, we analyzed data for 45 of them. The remaining 4 subjects were not used for this analysis due to various factors such as incomplete study. In these 45 subjects, we observed the following averaged number of days of monitoring data: 71 ± 36 days of heart rate (HR), heart rate variability (HRV) and seat weight (SW); 64 ± 31 days of QRS duration and QT corrected interval; 47 ± 40 days of SpO₂; 37 ± 41 days of blood pressure.

Figure 3 summarizes the adherence data for the different clinical variables.

5.3. Predictive analysis

Using the most frequent data variables at our disposal, namely heart rate (HR), heart rate variability (HRV), and seat weight (SW), we employed a random forest classifier to predict the likelihood of a hospitalization event occurring within the next 21 days based on a 7-day monitoring dataset. Our model achieved an Area Under the Curve (AUC) of 74%, with a sensitivity of 57% and a specificity of 75%, as assessed through a five-fold cross-validation procedure.

6. Conclusion

In the context of establishing an unobtrusive and non-invasive in-home health monitoring system, we present the data related to the system's deployment success rate and provide insights on the notable causes of deployment failures. Furthermore, we analyze and report data missingness to understand participant adherence trends in the study. Additionally, we leverage this dataset to create a prelim-

inary predictive model, which, albeit limited, offers some predictive capability based on the clinical data collected.

7. Future Works

The future work on this line is fundamentally on improving the predictive model. However, this will require better quality data, which again comes down to improving data acquisition and improving the quality of study by improving adherence as well as deployment rates. These initial results provide us with a path forward in that direction.

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