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Home monitoring of heart failure patients at risk for hospital readmission using a novel under-the-mattress piezoelectric sensor: A preliminary single centre experience

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Abstract

Introduction: A piezoelectric sensor (PS) converts mechanical deformations into electrical signals. We used a contactless under-the-mattress PS to monitor physiological vibrations resulting from breathing, pumping of the heart, and body movements, among individuals at home following hospitalization for heart failure (HF). Our objectives were to assess acceptability of the device in the home, to assess physiological patterns, and to determine if altered patterns correlate with readmission.

Methods: We conducted a prospective observational study of 30 patients discharged home following HF hospitalization. PS data included a continuous nightly assessment of heart rate, respiration rate, movement rate, rapid and shallow respiration duration, and a behaviour score. We utilized random forest classification to classify average nightly data by readmission status.

Results: We collected 640 nights of PS data from 29 patients. There were nine readmissions, of which four were for HF. PS monitoring was tolerated by all but one of the participants. We inspected continuous nightly physiological profiles and noted differences between patients who were and were not readmitted. Patients readmitted for HF had higher average heart and respiration rates, and more respiration variability. Average nightly respiratory rate was most predictive of readmission.

Discussion: We are the first to study nocturnal physiological patterns of HF patients at home using a contactless under-the-mattress monitoring system. We noted patterns that may be unique to patients at risk for readmission due to HF. Respiratory rate was the most important risk-adjusted associate of readmission for HF. Further studies should investigate the efficacy of home PS monitoring in HF populations.

Keywords

Remote monitoring, home monitoring, heart failure, readmissions

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Introduction

Home monitoring of physiological parameters in patients with heart failure (HF) may lead to early identification of decompensation, therefore potentially allowing for intervention before a hospital readmission occurs. Regardless, non-invasive monitoring of routine daily vital signs (weight, heart rate, blood pressure) has shown a limited ability to detect early deterioration of HF in clinical studies.[1–3] It is unknown if more frequent monitoring of vital signs, or monitoring of novel physiological parameters, may improve early identification of decompensation.

A piezoelectric sensor (PS) converts pressure into electrical signals. EverOn (EarlySense, Ramat Gan, Israel) is a novel PS that can detect subtle physiological vibrations resulting from breathing, pumping of the heart, and generalized body movements, across consumer-grade bed mattresses.[4] Mathematical algorithms convert these signals in a continuous manner to meaningful metrics including heart rate, respiratory rate and movement rate. Additionally, the technology is able to report on breathing patterns, such as rapid and shallow breathing, and on behavioural patterns, such as amount of time spent

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in bed. This sensor technology has been validated in hospitalized adults, but has not been studied in patients in their home environment.[5]

The EverOn device has multiple potential telemedicine capabilities. It is able to send signal data to a central monitoring station via local area network (LAN) or Wi-Fi (www.earlysense.com) in a hospital environment.[6] A newer model of the same device (www.myearlysense.com), which was released after the current study ended, has the ability to send information wirelessly to a smartphone app in a home environment.

We utilized this under-the-mattress PS to monitor adults who were discharged home after hospitalization for HF. Our primary objectives were to assess normal and altered physiological patterns in the home environment, and to determine if altered physiological patterns correlate with hospital readmissions.

Methods

Study design

We performed a prospective observational study of patients who were discharged to home following hospitalization for HF. The study was approved by Cleveland Clinic's Institutional Review Board. Patients were enrolled prior to hospital discharge. Patients were eligible if they were over the age of 18, had symptomatic HF as the admitting diagnosis as documented by a staff cardiologist, lived in Northeast Ohio, and slept on a mattress at home. Patients with systolic left ventricular dysfunction as well as those with preserved ejection fraction were included. Exclusion criteria included planned readmission or plans to travel out of Northeast Ohio within 30 days of discharge. Patients who shared a mattress with another person or pet were excluded from the study. We obtained written informed consent from all patients prior to study enrolment.

EverOn consists of a sensor and control unit, connected by a shielded cable (Figure 1). The sensor is 300mm long, 210mm wide, and has a thickness of 6.45mm. The sensor produces an electrical signal in response to physiological stimulation. The system records information continuously when a person's chest lies on a mattress above, or within approximately 40cm of, its edges. The system initiates recording when physiological signals are noted, usually within <1 minute after a person lies down, and it stops recording immediately after a signal is lost. EverOn has been validated on a variety of mattress types including spring, foam, memory foam, and sleep number mattresses. It has not been validated on water or air mattresses. The sensor is effective with mattresses ranging in thickness from 5cm to 40cm and calibrates automatically.

In our study a technician visited the patient at home within 48 hours of hospital discharge and installed the sensor under the patient's mattress. The control unit was secured in a metal box next to the bed. The technician subsequently visited once a week to confirm that the device was functioning and was tolerated by the patient. The technician also downloaded physiological data from the control unit to a secure database. Weights and standard vital signs were collected daily at home as part of routine clinical care throughout the study period. Patients were monitored for a period of 30 to 40 days or until they were readmitted. Adverse events were collected.

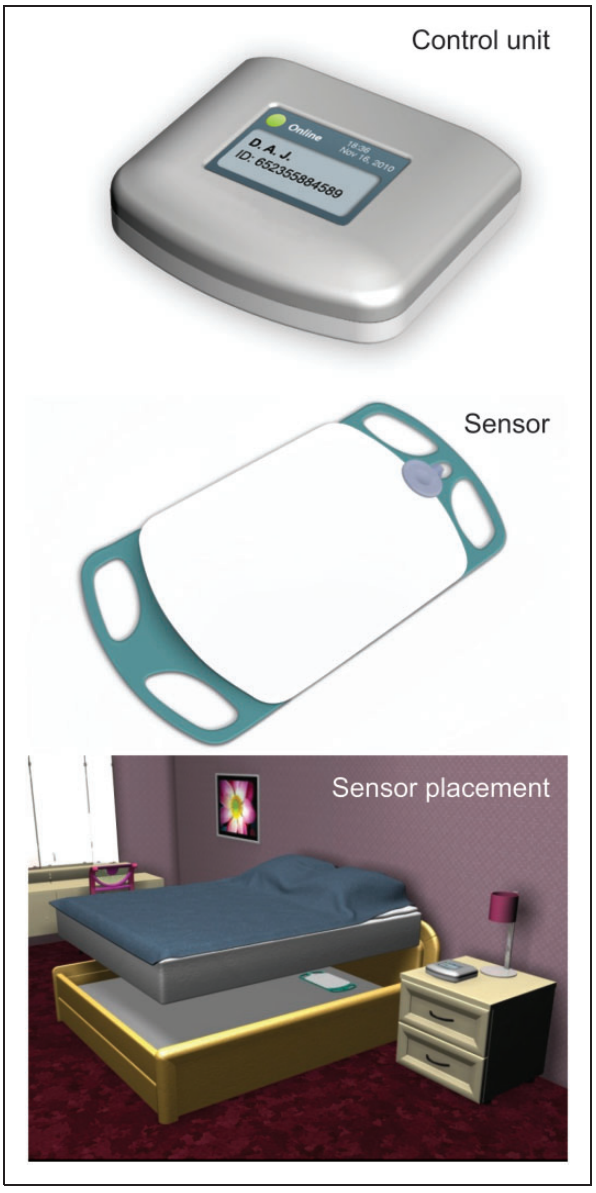

Figure 1. Piezoelectric sensor and placement.
The EarlySense piezoelectric sensor system consists of a sensor and control unit, connected by a shielded cable. The sensor is placed under the mattress. The control unit is placed in a secure metal box next to the bed.

Outcomes

The primary outcome was hospital readmission within 30 days of hospital discharge. Aetiology of readmission was determined by review of medical records.

Data analysis

Data were analysed in a case-control manner, whereby cases were patients who were readmitted and controls were patients who were not readmitted. Data are expressed as mean and standard deviation (SD). Categorical data are reported as frequency and percent. Differences in mean values were compared by a Student's *t*-test or a nonparametric method as appropriate. Data from the PS system included heart rate, respiration rate, and movement rate. Additional parameters included rapid and shallow respiration duration based on the raw signal patterns of respiration, and a behaviour score derived from bed occupancy patterns and movement while in bed. We inspected data trends among patients who were and were not readmitted, and visually identified device data patterns of interest. These patterns later informed our statistical modelling.

We utilized random forest classification (RF-C) methodology to classify data into three categories: readmission for HF exacerbation; readmission for causes other than HF; and no readmission by study end. In order to maximize our ability to detect associations between device data and readmission outcomes we analysed each patient night as an individual unit. There were 640 nights of interpretable data available for analysis. Candidate predictor variables included device output (average nightly heart rate, respiratory rate, and movement rate; standard deviation of nightly heart rate, respiratory rate, and movement rate; hours with rapid and shallow breathing; and behaviour score), as well as age, sex, race, body mass index (BMI), change in daily weight, heart rate (measured once daily), systolic and diastolic blood pressures (measured once daily), oxygen saturation (measured once daily), medication use (ACE inhibitor, beta blocker, angiotensin receptor blocker, aldosterone blocker, digoxin, nitrate, hydralazine, inotrope, calcium channel blocker, diuretic), and day number since study entry.

RF-C is a machine learning algorithmic methodology whereby a multitude of uncorrelated classification trees are constructed by computer software, and then used in concert to assess prediction. This statistical methodology has been described in detail elsewhere,[7–10] and has been used in contemporary cardiovascular literature.[10,11] In the

Table 1. Demographic and baseline clinical characteristics.

	Readmitted for HF ($n=4$)	Readmitted for other reason ($n=5$)	Not readmitted ($n=20$)	*P*-value
Age, mean (range)	72 (57–81)	69 (45–85)	74 (50–97)	0.94
Female	50% (2)	60% (3)	55% (11)	0.96
White	75% (3)	40% (2)	45% (9)	0.50
BMI	22.1	24.8	21.3	0.82
EF%	31 ± 20	41 ± 24	34 ± 17	0.70
HFpEF	25% (1)	60% (3)	25% (5)	0.31
1 hospitalization in 12 months	0	20% (1)	35% (7)	0.16
2 hospitalizations in 12 months	25% (1)	20% (1)	45% (9)	
$\geqslant 3$ hospitalizations in 12 months	75% (3)	60% (3)	20% (4)	
NYHA III or IV	100% (4)	100% (5)	100% (20)	
ICD	75% (3)	40% (2)	25% (5)	0.15
CRT-D	50 % (2)	0	20% (4)	0.18
ACE inhibitor	50 % (2)	20% (1)	50% (10)	0.47
Beta blocker	100% (4)	80% (4)	100% (20)	0.08
ARB	0	20% (1)	15% (3)	0.66
Aldosterone antagonist	25% (1)	20% (1)	35% (7)	0.78
Digoxin	25% (1)	0	20% (4)	0.52
Nitrate	25% (1)	60% (3)	15% (3)	0.11
Hydralazine	50 % (2)	60% (3)	30% (6)	0.40
Inotrope	0	0	0	
Calcium channel blocker	25% (1)	40% (2)	20% (4)	0.64
No diuretic	0	0	5% (1)	0.72
One diuretic	100% (4)	100% (5)	80% (16)	
Two or more diuretics	0 (0)	0 (0)	15% (3)	
History of lung disease	25% (1)	0	10% (2)	0.47
History of atrial fibrillation	100% (4)	40% (2)	50% (10)	0.14

HF: heart failure; BMI: body mass index; EF: ejection fraction; HFpEF: heart failure with preserved ejection fraction; NYHA: New York Heart Association class; ICD: internal cardioverter defibrillator; CRT-D: cardiac resynchronization therapy defibrillator; ARB: angiotensin II receptor blocker.

current analysis our RF-C framework included 1000 individually grown trees. We utilized this framework to identify which variables were most important in classification (a variable importance measurement quantifying change in prediction error). Analyses were performed with *R* version 3.0.2 (www.R-project.org). RF-C was implemented using Ishwaran and Kogalur's random forest Survival, Regression and Classification (SRC) library at default settings.[12]

Results

Table 1 summarizes enrolment demographics and clinical characteristics of study patients according to readmission status. One patient had missing PS data and was not included in the analysis. Nine patients in the study had HF with preserved ejection fraction (HFpEF). All study patients had either New York Heart Association (NYHA) class III or IV functional classification. There were 16 patients who had a history of atrial fibrillation. Medication use was similar among the three groups. Of the 29 patients, 22 had been hospitalized for HF twice or more in the 12 months prior to enrolment.

There were a total of 107 patient home visits by the study technician. Based on patient feedback, overall tolerance of the home monitoring experience was 97%. A single patient complained of disrupted sleep related to perceived intolerance of the monitoring device. Four patients were readmitted for HF within 30 days. Five patients were readmitted for reasons other than HF. A total of 20 patients were not readmitted during the study period.

Figure 2 shows representative PS data collected from two patients. Subject A was an elderly woman with chronic diastolic HF who had a normal heart rate that decreased in a reproducible U-shaped pattern during sleep. Subject B was a middle aged woman with advanced chronic systolic HF. Subject B had higher and more variable respiratory and movement rates as well as persistent tachycardia that did not decrease during sleep. Subject B was readmitted due to recurrent HF within nine days of index discharge.

Figure 3 shows the heart rate, respiration rate, and movement across the entire study period for each patient for the same two patients shown in Figure 2. Also shown are trends of hours with rapid and shallow breathing and behaviour score. Subject A had very few hours of rapid and shallow breathing, as well as a low behaviour score across the study period. In contrast, Subject B had many more hours of rapid and shallow breathing, as well as a behaviour score that was not only more variable than Subject A, but also trended upwards during the study period.

Table 2 summarizes standard daily vital signs and PS data during the study period. A total of 640 recorded nights of PS data were collected, as well as 625 days of standard home monitoring data, which included daily

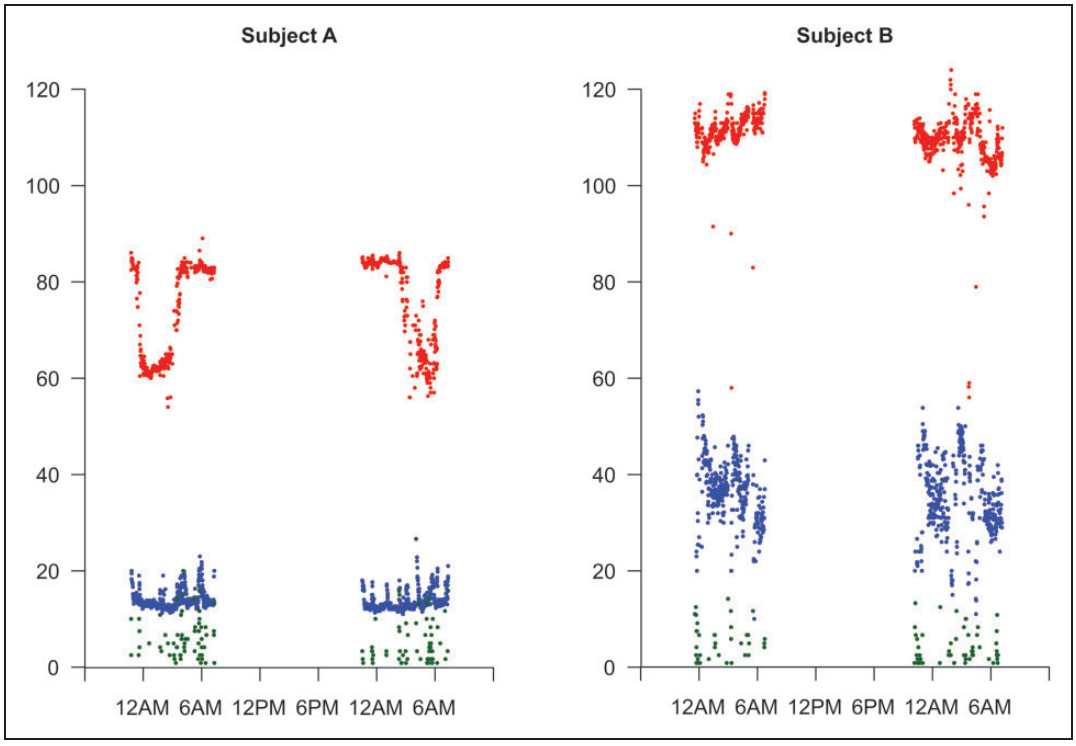

Figure 2. 48 hours of piezoelectric sensor data for two patients.
Subject A is a woman with chronic diastolic heart failure (HF), who had a heart rate that decreased in a reproducible U-shaped pattern during sleep. Subject B is a woman with chronic systolic HF, who had higher and more variable respiratory and movement rates as well as persistent tachycardia that did not decrease during sleep. Red: Heart rate. Blue: Respiratory rate. Green: Movement rate

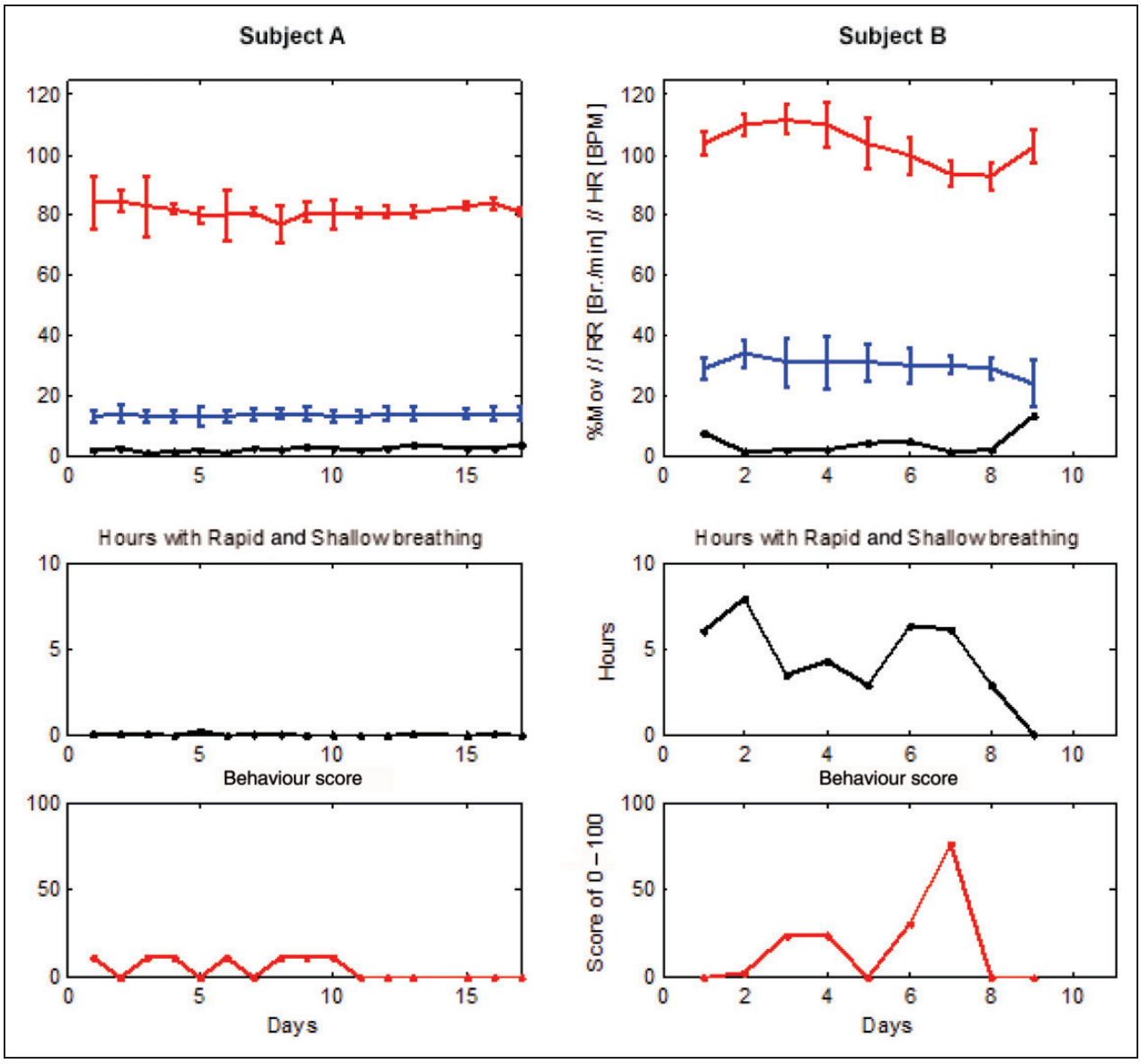

Figure 3. Piezoelectric sensor data for the entire study period for two patients.
(A) Heart rate, respiration rate, and movement across the entire study period, for each respective patient, for Subject A and Subject B. Numbers on *x*-axis represent consecutive days since study entry (i.e. time 0). Red line: heart rate. Blue line: respiratory rate. Black line: movement rate. (B) Number of hours of rapid and shallow breathing for Subject A and Subject B. (C) Daily behaviour score for Subject A and Subject B.

weight, daily blood pressure, and daily heart rate. Patients readmitted for HF or for non-HF reasons had a significantly higher average daily heart rate (75.9 bpm and 78.2 bpm versus 68.3 bpm) and a higher daily blood pressure (mean systolic pressure of 124.7 mm Hg versus 114.5 mm Hg and 111.8 mm Hg) than those not readmitted. Patients readmitted for HF gained an average of 3.3 lbs during the study, compared to a 4.8 lb weight loss for those readmitted for non-HF and a 0.2 lb weight loss for those not readmitted.

Table 2 also summarizes PS data during the study period. There was no significant difference in the nightly heart rate between patients regardless of readmission status. Patients readmitted for HF had a higher average nightly respiration rate, compared to those readmitted for reasons other than failure, and those not readmitted (21.8 versus 16.3 and 17.4). Patients readmitted for HF also had more nightly variability in respiration rate (2.8 versus 1.9 and 2.1), and a higher nightly average movement rate (5.9 versus 2.3 and 5.2). Patients readmitted for HF had more hours of rapid and shallow respiration, compared to those readmitted for reasons other than HF and those who were not readmitted (2.77 vs 0.20 and 0.31 hours, respectively). Patients readmitted for reasons other than HF had a higher nightly behaviour score compared to those readmitted for HF or those not readmitted (17.45 versus 4.9).

In an exploratory multivariable RF-C framework where each patient night was analysed as an individual unit we found that variables predictive of readmission outcome differed by type of readmission (Figure 4). Among

Table 2. Physiological parameters.

	Readmitted for HF ($n=4$)	Readmitted for non-HF ($n=5$)	Not readmitted ($n=20$)	*P*-value
Static once-daily home monitoring data				
HR (avg ± SD)	75.9 ± 14.9	78.2 ± 8.8	68.3 ± 22.4	<0.001
Systolic BP (avg ± SD)	124.7 ± 13.2	114.5 ± 0.9	111.8 ± 36.5	0.004
Diastolic BP (avg ± SD)	71.6 ± 14.1	63.6 ± 6.9	68.3 ± 21.6	<0.001
Oxygen saturation (avg ± SD)	96.1 ± 3.9	97.6 ± 1.4	89.1 ± 25.7	0.240
Change in daily weight from baseline (avg ± SD)	3.3 ± 3.8	–4.8 ± 3.4	–0.2 ± 5.9	<0.001
Continuous nightly piezoelectric sensor data				
HR (avg ± SD)	72.57 ± 14.68	72.77 ± 9.24	70.64 ± 12/01	0.619
SD of HR (avg ± SD)	4.21 ± 1.96	5.15 ± 4.45	6.00 ± 4.58	0.003
RR (avg ± SD)	21.82 ± 7.45	16.31 ± 2.59	17.41 ± 3.33	<0.001
SD of RR (avg ± SD)	2.80 ± 1.73	1.91 ± 0.35	2.12 ± 0.70	<0.001
MR (avg ± SD)	5.87 ± 2.5	2.31 ± 2.56	5.18 ± 3.47	<0.001
SD of MR (avg ± SD)	0.23 ± 0.05	0.13 ± 0.07	0.21 ± 0.07	0.046
Hours with RSB (avg ± SD)	2.77 ± 3.16	0.20 ± 0.55	0.31 ± 0.78	<0.001
Behaviour score (avg ± SD)	4.87 ± 16.90	17.45 ± 25.39	4.9 ± 12.61	<0.001

HF: heart failure; SD: standard deviation; HR: heart rate; RR: respiratory rate; MR: movement rate; RSB: rapid shallow breathing

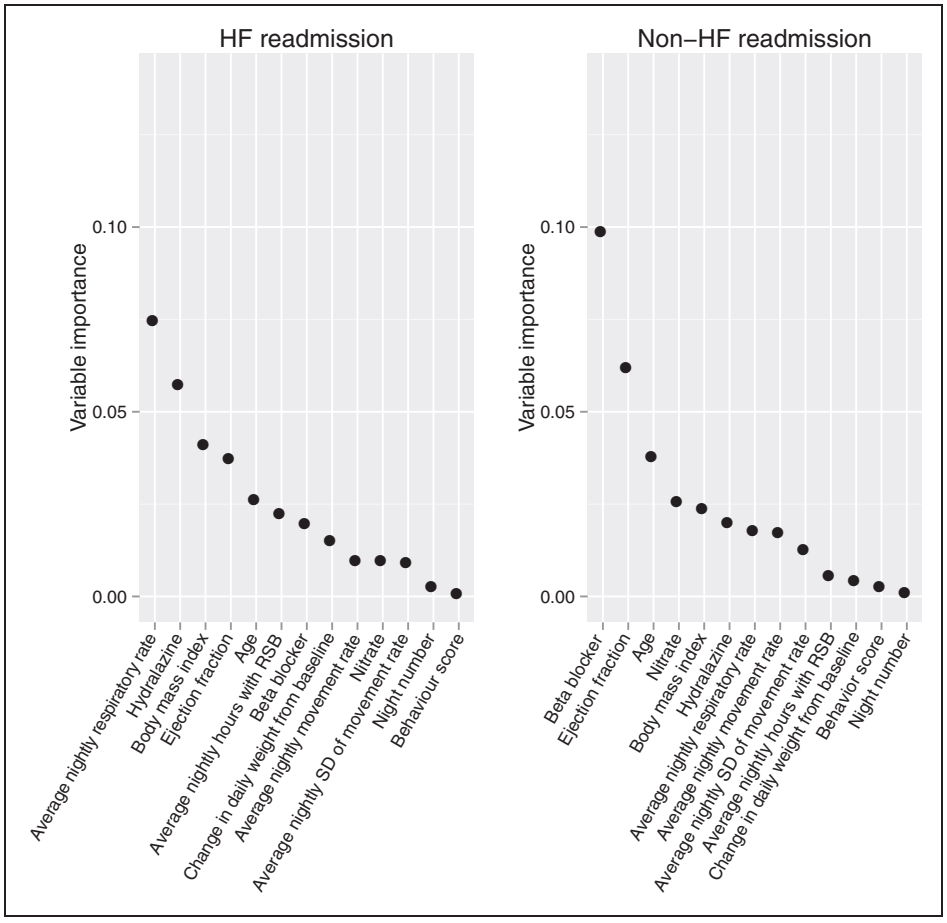

Figure 4. Variable importance for heart failure (HF) and non-HF readmissions.
Relative importance of variables predictive of HF and non-HF readmission as determined by multivariable random forest classification framework.
RSB: rapid shallow breathing; SD: standard deviation

nights of study patients who were readmitted due to HF, average respiratory rate collected by PS was the most important risk-adjusted contributor to prediction.

Discussion

To the best of our knowledge, we are the first to study recumbent nocturnal physiological patterns of older adults who were discharged to home after hospitalization for HF, using an entirely non-invasive and contactless monitoring system that requires minimal patient compliance. We found that the PS was well tolerated and reliably provided physiological data for up to 30 days in a patient population that is at high risk for readmission after hospitalization for HF. We found that it may be possible to distinguish between readmitted patients and non-readmitted patients by inspection of individual nightly a patterns and trends over time for a given individual. In our study population, we observed significant differences in respiration rate, movement rate, and behaviour score for patients readmitted for HF compared to patients not readmitted, or readmitted for reasons other than HF. Additionally, in an exploratory analysis using patient nights as individual analysis units, we found that the average nightly respiratory rate collected by PS was the variable most predictive of readmission.

PS monitoring has been previously utilized to accurately measure the respiratory and heart rates of patients in a sleep lab setting, as well as patients hospitalized in the intensive care unit.[4] Brown and colleagues used PS monitoring on a medical-surgical unit to decrease overall length of stay, decrease the number of days in the intensive care unit, and reduce adverse events for hospitalized patients.[13] PS parameters have also been tested as risk assessment tools for the development of pressure ulcers, and for early recognition of acutely deteriorating patients in non-intensive care units.[14,15]

We report the first use of PS monitoring in the home setting for HF patients. HF has a prevalence of over 6 million in the United States, and is associated with a high rate of hospitalizations, as well as substantial morbidity, mortality, and healthcare costs.[16–18] These facts underscore the need for effective home monitoring strategies in order to prevent hospitalizations in patients with chronic HF. Studies of various other monitoring approaches have found variable success.[2,19,20] Use of home-based PS monitoring may detect early decompensation of disease non-invasively, and provide an opportunity for intervention prior to hospitalization. Our findings suggest that further study in larger clinical trials is warranted. The EverOn (EarlySense, Ramat Gan, Israel) PS monitoring device used in our study has the capability to transmit signals wirelessly to a smartphone app. As such, this monitoring technology may emerge as a component of a novel home telehealth strategy for this population of patients, if found effective in further investigations.

There are several limitations to our study. We performed a non-randomized, observational study with a small sample size and short follow up period. We assessed PS monitoring at one medical centre only. The small number of patients meeting readmission endpoints limited statistical analysis. Our study was not designed to test the efficacy of PS monitoring on readmission outcomes.

In conclusion, we found that patients tolerated an under-the-mattress PS monitor placed in their home. We were able to collect physiological data and identify changes in physiological patterns that may be unique to patients at risk for hospital readmission due to HF. In an exploratory analysis using patient nights as individual analysis units, respiratory rate was the most important associate of readmission for HF. Further studies should investigate the efficacy of continuous nocturnal PS monitoring in home-based HF populations. PS monitoring may emerge as a novel telehealth home monitoring technology for this high-risk population.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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