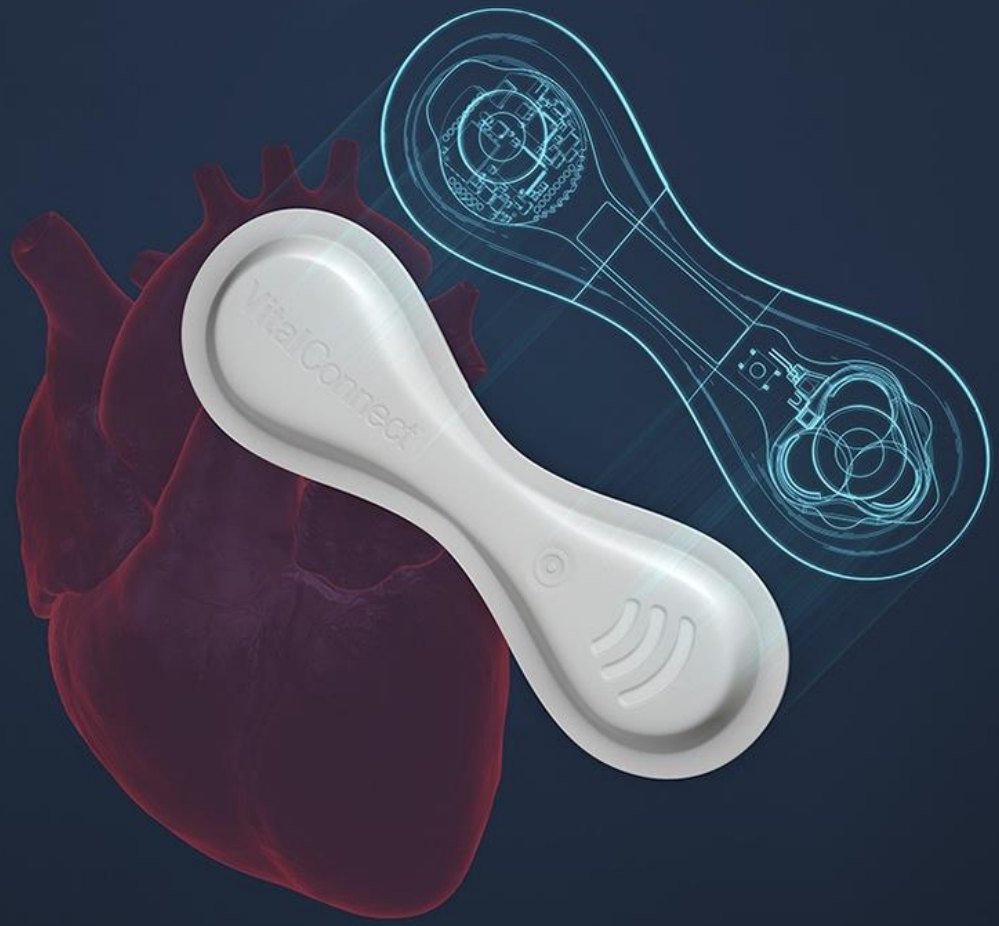
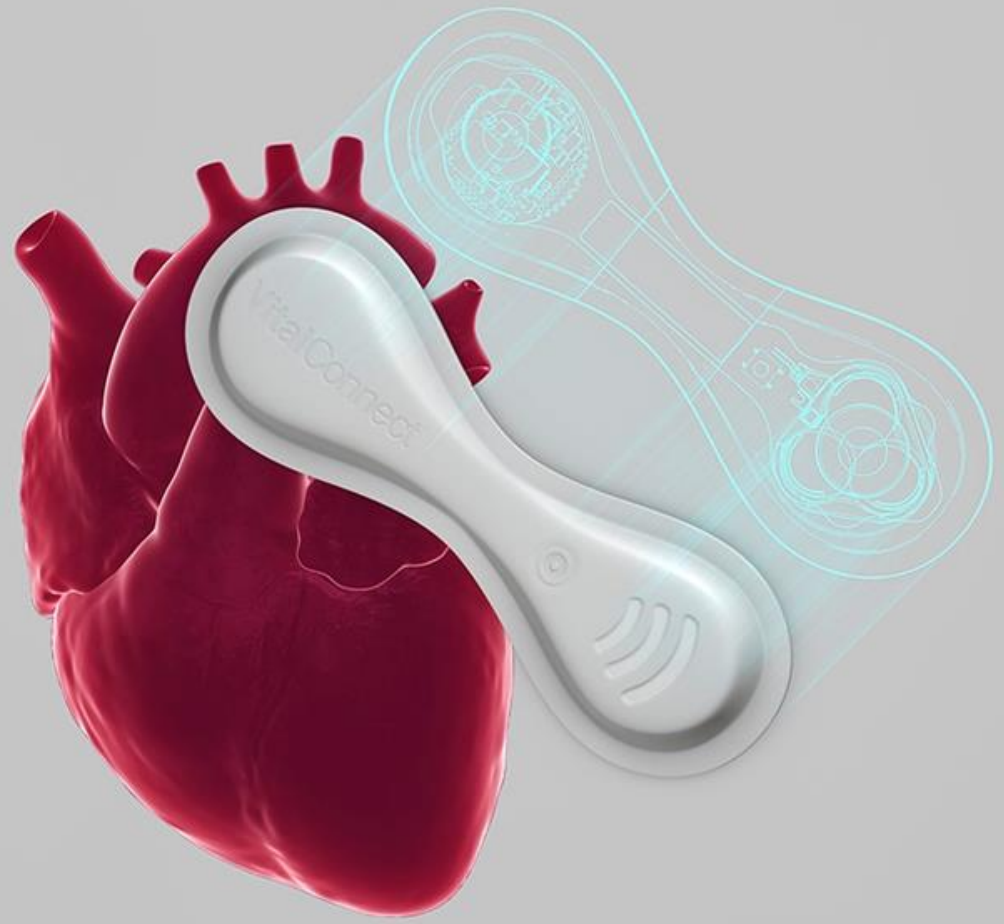
MediBioSense

VitalPatch Publications

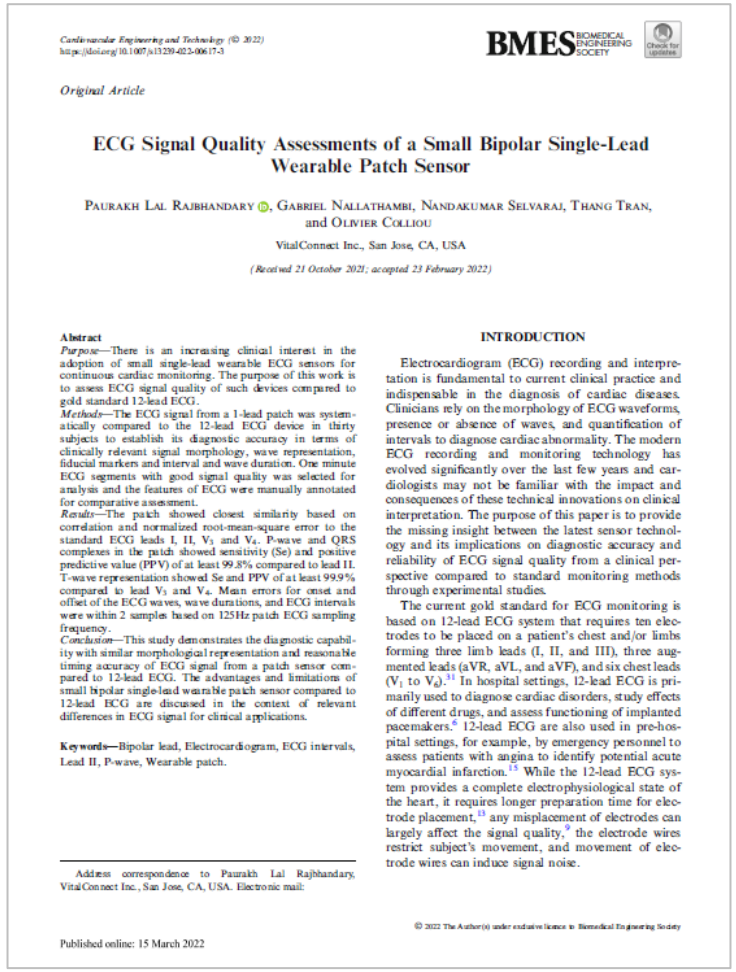


Don’t miss a beat.

Technical / Foundational



ECG Signal Quality Assessments of a Small Bipolar Single-Lead Wearable Patch Sensor



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BMES BIOMEDICAL ENGINEERING SOCIETY

Original Article

ECG Signal Quality Assessments of a Small Bipolar Single-Lead Wearable Patch Sensor

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(*Received 21 October 2021; accepted 23 February 2022*)

Abstract

Purpose—There is an increasing clinical interest in the adoption of small single-lead wearable ECG sensors for continuous cardiac monitoring. The purpose of this work is to assess ECG signal quality of such devices compared to gold standard 12-lead ECG.

Methods—The ECG signal from a 1-lead patch was systematically compared to the 12-lead ECG device in thirty subjects to establish its diagnostic accuracy in terms of clinically relevant signal morphology, wave representation, fiducial markers and interval and wave duration. One minute ECG segments with good signal quality was selected for analysis and the features of ECG were manually annotated for comparative assessment.

Results—The patch showed closest similarity based on correlation and normalized root-mean-square error to the standard ECG leads I, II, V_5 and V_6. P-wave and QRS complexes in the patch showed sensitivity (Se) and positive predictive value (PPV) of at least 99.8% compared to lead II. T-wave representation showed Se and PPV of at least 99.9% compared to lead V_5 and V_6. Mean errors for onset and offset of the ECG waves, wave durations, and ECG intervals were within 2 samples based on 125 Hz patch ECG sampling frequency.

Conclusion—This study demonstrates the diagnostic capability with similar morphological representation and reasonable timing accuracy of ECG signal from a patch sensor compared to 12-lead ECG. The advantages and limitations of small bipolar single-lead wearable patch sensor compared to 12-lead ECG are discussed in the context of relevant differences in ECG signal for clinical applications.

Keywords—Bipolar lead, Electrocardiogram, ECG intervals, Lead II, P-wave, Wearable patch.

INTRODUCTION

Electrocardiogram (ECG) recording and interpretation is fundamental to current clinical practice and indispensable in the diagnosis of cardiac diseases. Clinicians rely on the morphology of ECG waveforms, presence or absence of waves, and quantification of intervals to diagnose cardiac abnormality. The modern ECG recording and monitoring technology has evolved significantly over the last few years and cardiologists may not be familiar with the impact and consequences of these technical innovations on clinical interpretation. The purpose of this paper is to provide the missing insight between the latest sensor technology and its implications on diagnostic accuracy and reliability of ECG signal quality from a clinical perspective compared to standard monitoring methods through experimental studies.

The current gold standard for ECG monitoring is based on 12-lead ECG system that requires ten electrodes to be placed on a patient's chest and/or limbs forming three limb leads (I, II, and III), three augmented leads (aVR, aVL, and aVF), and six chest leads (V_1 to V_6).[31] In hospital settings, 12-lead ECG is primarily used to diagnose cardiac disorders, study effects of different drugs, and assess functioning of implanted pacemakers.[6] 12-lead ECG are also used in pre-hospital settings, for example, by emergency personnel to assess patients with angina to identify potential acute myocardial infarction.[15] While the 12-lead ECG system provides a complete electrophysiological state of the heart, it requires longer preparation time for electrode placement,[13] any misplacement of electrodes can largely affect the signal quality,[9] the electrode wires restrict subject's movement, and movement of electrode wires can induce signal noise.

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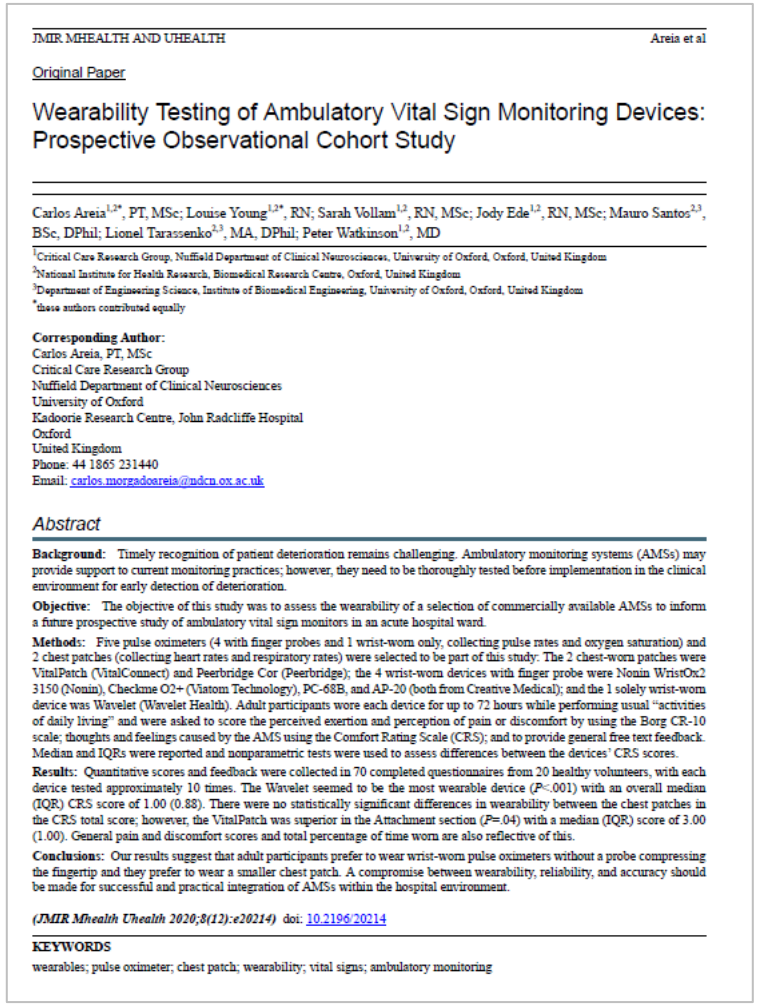
Takeaway

- This study demonstrates the diagnostic capability with similar morphological representation and reasonable timing accuracy of ECG signal from a patch sensor compared to 12-lead ECG.

Adobe Acrobat Document

Wearability Testing of Ambulatory Vital Sign Monitoring Devices: Prospective Observational Cohort Study



Original Paper

Wearability Testing of Ambulatory Vital Sign Monitoring Devices: Prospective Observational Cohort Study

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Abstract

Background: Timely recognition of patient deterioration remains challenging. Ambulatory monitoring systems (AMSs) may provide support to current monitoring practices; however, they need to be thoroughly tested before implementation in the clinical environment for early detection of deterioration.

Objective: The objective of this study was to assess the wearability of a selection of commercially available AMSs to inform a future prospective study of ambulatory vital sign monitors in an acute hospital ward.

Methods: Five pulse oximeters (4 with finger probes and 1 wrist-worn only, collecting pulse rates and oxygen saturation) and 2 chest patches (collecting heart rates and respiratory rates) were selected to be part of this study: The 2 chest-worn patches were VitalPatch (VitalConnect) and Peerbridge Cor (Peerbridge); the 4 wrist-worn devices with finger probe were Nonin WristOx2 3150 (Nonin), Checkme O2+ (Viatom Technology), PC-68B, and AP-20 (both from Creative Medical); and the 1 solely wrist-worn device was Wavelet (Wavelet Health). Adult participants wore each device for up to 72 hours while performing usual "activities of daily living" and were asked to score the perceived exertion and perception of pain or discomfort by using the Borg CR-10 scale; thoughts and feelings caused by the AMS using the Comfort Rating Scale (CRS); and to provide general free text feedback. Median and IQRs were reported and nonparametric tests were used to assess differences between the devices' CRS scores.

Results: Quantitative scores and feedback were collected in 70 completed questionnaires from 20 healthy volunteers, with each device tested approximately 10 times. The Wavelet seemed to be the most wearable device (P<.001) with an overall median (IQR) CRS score of 1.00 (0.88). There were no statistically significant differences in wearability between the chest patches in the CRS total score; however, the VitalPatch was superior in the Attachment section (P=.04) with a median (IQR) score of 3.00 (1.00). General pain and discomfort scores and total percentage of time worn are also reflective of this.

Conclusions: Our results suggest that adult participants prefer to wear wrist-worn pulse oximeters without a probe compressing the fingertip and they prefer to wear a smaller chest patch. A compromise between wearability, reliability, and accuracy should be made for successful and practical integration of AMSs within the hospital environment.

(JMIR Mhealth Uhealth 2020;8(12):e20214) doi: 10.2196/20214

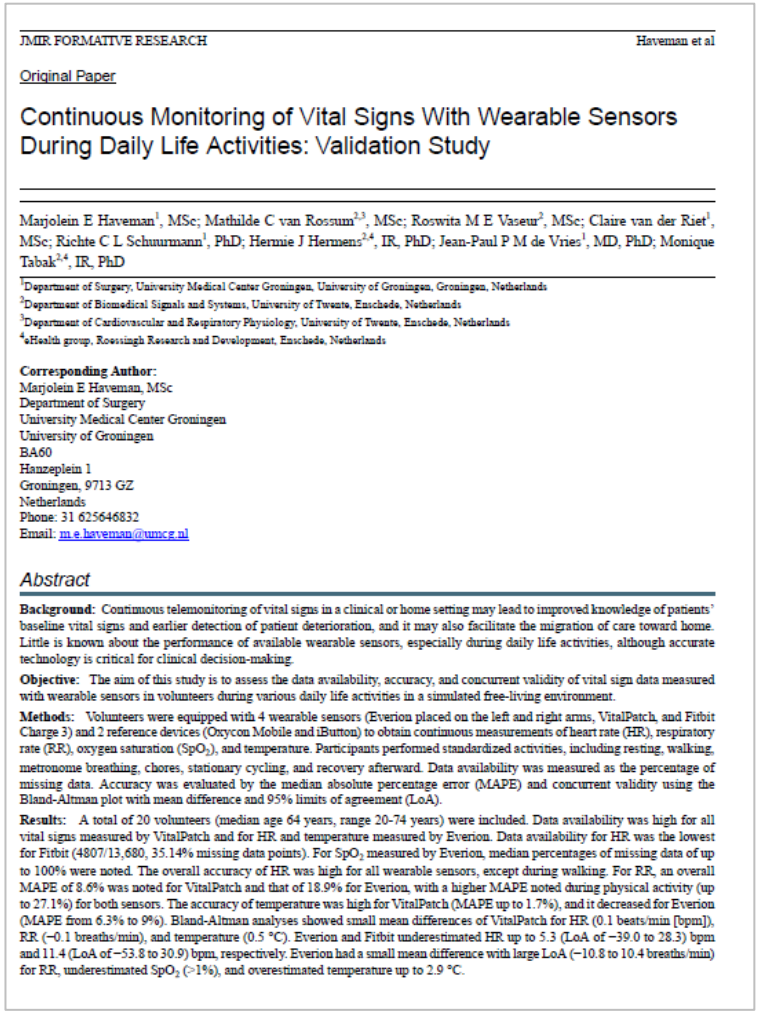
KEYWORDS
wearables; pulse oximeter; chest patch; wearability; vital signs; ambulatory monitoring

Takeaway

- The smaller chest patch (VitalPatch) was found to be less noticeable and more comfortable. These preferences were reflected in the total time participants wore the device.

Adobe Acrobat Document

Continuous Monitoring of Vital Signs With Wearable Sensors During Daily Life Activities: Validation Study



JMIR FORMATIVE RESEARCH Haveman et al

Original Paper

Continuous Monitoring of Vital Signs With Wearable Sensors During Daily Life Activities: Validation Study

Marjolein E Haveman[1], MSc; Mathilde C van Rossum[2,3], MSc; Roswita M E Vaseur[2], MSc; Claire van der Riet[1], MSc; Richte C L Schuurmann[1], PhD; Hermie J Hermens[2,4], IR, PhD; Jean-Paul P M de Vries[1], MD, PhD; Monique Tabak[2,4], IR, PhD

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Abstract

Background: Continuous telemonitoring of vital signs in a clinical or home setting may lead to improved knowledge of patients' baseline vital signs and earlier detection of patient deterioration, and it may also facilitate the migration of care toward home. Little is known about the performance of available wearable sensors, especially during daily life activities, although accurate technology is critical for clinical decision-making.

Objective: The aim of this study is to assess the data availability, accuracy, and concurrent validity of vital sign data measured with wearable sensors in volunteers during various daily life activities in a simulated free-living environment.

Methods: Volunteers were equipped with 4 wearable sensors (Everion placed on the left and right arms, VitalPatch, and Fitbit Charge 3) and 2 reference devices (Oxycon Mobile and iButton) to obtain continuous measurements of heart rate (HR), respiratory rate (RR), oxygen saturation (SpO_2), and temperature. Participants performed standardized activities, including resting, walking, metronome breathing, chores, stationary cycling, and recovery afterward. Data availability was measured as the percentage of missing data. Accuracy was evaluated by the median absolute percentage error (MAPE) and concurrent validity using the Bland-Altman plot with mean difference and 95% limits of agreement (LoA).

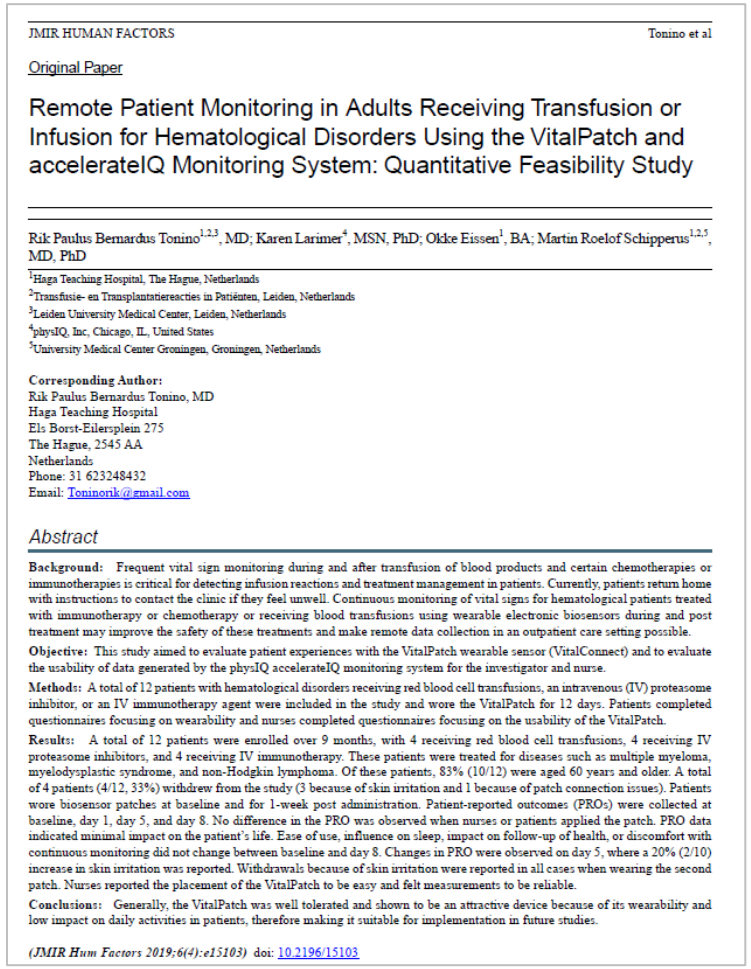
Results: A total of 20 volunteers (median age 64 years, range 20-74 years) were included. Data availability was high for all vital signs measured by VitalPatch and for HR and temperature measured by Everion. Data availability for HR was the lowest for Fitbit (4807/13,680, 35.14% missing data points). For SpO_2 measured by Everion, median percentages of missing data of up to 100% were noted. The overall accuracy of HR was high for all wearable sensors, except during walking. For RR, an overall MAPE of 8.6% was noted for VitalPatch and that of 18.9% for Everion, with a higher MAPE noted during physical activity (up to 27.1%) for both sensors. The accuracy of temperature was high for VitalPatch (MAPE up to 1.7%), and it decreased for Everion (MAPE from 6.3% to 9%). Bland-Altman analyses showed small mean differences of VitalPatch for HR (0.1 beats/min [bpm]), RR (−0.1 breaths/min), and temperature (0.5 °C). Everion and Fitbit underestimated HR up to 5.3 (LoA of −39.0 to 28.3) bpm and 11.4 (LoA of −53.8 to 30.9) bpm, respectively. Everion had a small mean difference with large LoA (−10.8 to 10.4 breaths/min) for RR, underestimated SpO_2 (>1%), and overestimated temperature up to 2.9 °C.

Takeaway

- Data availability, accuracy, and concurrent validity of the studied wearable sensors varied and differed according to activity. In this study, the accuracy of all sensors decreased with physical activity. Of the tested sensors, VitalPatch was found to be the most accurate and valid for vital signs monitoring.

Adobe Acrobat Document

Remote patient monitoring in adults receiving transfusion/infusion for hematological disorder using the VitalPatch®: Feasibility study of the physIQ accelerateIQ™ monitoring system



Original Paper

Remote Patient Monitoring in Adults Receiving Transfusion or Infusion for Hematological Disorders Using the VitalPatch and accelerateIQ Monitoring System: Quantitative Feasibility Study

Rik Paulus Bernardus Tonino[1,2,3], MD; Karen Larimer[4], MSN, PhD; Okke Eissen[1], BA; Martin Roelof Schipperus[1,2,5], MD, PhD

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Abstract

Background: Frequent vital sign monitoring during and after transfusion of blood products and certain chemotherapies or immunotherapies is critical for detecting infusion reactions and treatment management in patients. Currently, patients return home with instructions to contact the clinic if they feel unwell. Continuous monitoring of vital signs for hematological patients treated with immunotherapy or chemotherapy or receiving blood transfusions using wearable electronic biosensors during and post treatment may improve the safety of these treatments and make remote data collection in an outpatient care setting possible.

Objective: This study aimed to evaluate patient experiences with the VitalPatch wearable sensor (VitalConnect) and to evaluate the usability of data generated by the physIQ accelerateIQ monitoring system for the investigator and nurse.

Methods: A total of 12 patients with hematological disorders receiving red blood cell transfusions, an intravenous (IV) proteasome inhibitor, or an IV immunotherapy agent were included in the study and wore the VitalPatch for 12 days. Patients completed questionnaires focusing on wearability and nurses completed questionnaires focusing on the usability of the VitalPatch.

Results: A total of 12 patients were enrolled over 9 months, with 4 receiving red blood cell transfusions, 4 receiving IV proteasome inhibitors, and 4 receiving IV immunotherapy. These patients were treated for diseases such as multiple myeloma, myelodysplastic syndrome, and non-Hodgkin lymphoma. Of these patients, 83% (10/12) were aged 60 years and older. A total of 4 patients (4/12, 33%) withdrew from the study (3 because of skin irritation and 1 because of patch connection issues). Patients wore biosensor patches at baseline and for 1-week post administration. Patient-reported outcomes (PROs) were collected at baseline, day 1, day 5, and day 8. No difference in the PRO was observed when nurses or patients applied the patch. PRO data indicated minimal impact on the patient's life. Ease of use, influence on sleep, impact on follow-up of health, or discomfort with continuous monitoring did not change between baseline and day 8. Changes in PRO were observed on day 5, where a 20% (2/10) increase in skin irritation was reported. Withdrawals because of skin irritation were reported in all cases when wearing the second patch. Nurses reported the placement of the VitalPatch to be easy and felt measurements to be reliable.

Conclusions: Generally, the VitalPatch was well tolerated and shown to be an attractive device because of its wearability and low impact on daily activities in patients, therefore making it suitable for implementation in future studies.

(JMIR Hum Factors 2019;6(4):e15103) doi: 10.2196/15103

Takeaway

- Generally, the VitalPatch was well tolerated and shown to be an attractive device because of its wearability and low impact on daily activities in patients, therefore making it suitable for implementation in future studies.

Adobe Acrobat Document

A Novel Synthetic Simulation Platform for Validation of Breathing Rate Measurement

A Novel Synthetic Simulation Platform for Validation of Breathing Rate Measurement

Nandakumar Selvaraj*, Gabriel Nallathambi, and Paul Kettle

Abstract— **Validation of biosensor algorithms is paramount for regulated medical devices applied to patient monitoring. We present validation of breathing rate (BR) measurement using a patch medical device via a novel synthetic simulation platform, in-hospital data collection and controlled laboratory study. Single-lead ECG and triaxial body acceleration signals with variability and noise are synthetically generated and quantized for a constellation according to the input parameters of heart rate (HR) as a fundamental frequency(f_c) of ECG and reference BR as a modulating frequency (f_r). Synthetic signals are input to the BR algorithms and the performance of output BRs are evaluated for a region-of-interest of the constellation ($f_c/f_r \geq 3$ & $f_c/f_r \leq 8$) accounting the Nyquist and physiological varability. The performances of patch sensor's BR are also evaluated in 13 post-operative patients with reference to a clinical bedside monitor and in 57 subjects carrying out a controlled laboratory protocol with reference to capnography. The synthetic simulations revealed mean absolute error (MAE) of 0.8±0.6 brpm and standard deviation of absolute error of 0.3±0.2 brpm for the BR algorithms of patch sensor. The controlled laboratory testing revealed MAE of 1.7±0.7 brpm (n=57) for stationary conditions. The proposed simulation platform can be useful for developmental refinement or validation of BR measurement prior to testing in humans at clinical or laboratory conditions and applicable for testing other patient monitoring devices with modular modifications.**

Index Terms— **Wireless Biosensor, Respiratory Monitoring, Synthetic Simulation, Algorithms, Performance Analytics.**

I. INTRODUCTION

Accurate assessment of vital signs and timely notification of critical events are necessary for continuous patient monitoring that can help to detect infections or complications well in advance and prevent mortalities. Recent advancements in wearable medical technologies for 24-hour health monitoring may allow early detection of patient deterioration and curb the healthcare costs. The accuracy and precision of algorithms implemented in such complex embedded medical systems are paramount to earn the acceptance of clinical community; therefore, it is very important to ensure high quality of algorithmic design via rigorous testing and validation during the developmental cycles.

Synthetic simulation is common to generate surrogate data for early stages of algorithmic design, optimization of the development, and test the reliability over a wide range of a target variable [1]. Further, synthetic simulations may allow assessment of the device performance during uncommon corner cases. But a platform/system solution that allows generating synthetic signals, inputting into sensor hardware and firmware or algorithms, and evaluating performance for a constellation of input variables is not common.

Development of intelligent and efficient algorithms particularly for physiological monitoring and critical event detection necessitates a wide distribution of data belonging to both normal and abnormal conditions. However, obtaining a comprehensive continuous medical-grade data from patients is limited during in-house development and for the validation of algorithms [2]. Moreover, gold-standard reference monitors required for clinical validation of emerging wearable technologies are, in many cases, not designed for ambulatory monitoring. Thus, a synthetic simulator system may be useful to overcome many of those limitations.

We present a novel simulation platform for validation of continuous respiratory monitoring via a patch medical device that involves synthetic generation and quantization of single-lead ECG and triaxial body acceleration signals with variability and noise for a constellation of input fundamental and modulating frequencies. These synthetic signals are input to the breathing rate (BR) algorithms of patch sensor, and the performance of output BRs are evaluated for a predefined region-of-interest of the constellation accounting the Nyquist and physiological variability. Furthermore, the performances of patch sensor's BR are also evaluated in 13 post-operative patients with reference to a standard bed-side patient monitor and in 57 subjects carrying out a controlled laboratory protocol with reference to capnography.

II. MATERIALS AND METHODS

A. System under test

The system under test is a FDA cleared VitalPatch [3], a disposable adhesive patch sensor worn on chest with built-in system-on-chip processor, and associated electronics that allows continuous monitoring of single-lead ECG, tri-axial accelerometer, and thermistor data. The firmware algorithms compute and continuously transmit physiologic variables such as heart rate (HR), BR, skin temperature, body posture, fall detection, and step count among others. ECG derived R wave amplitude (RWA) that measures change of cardiac axis during breathing, triaxial accelerometer signals that measures chest wall movements of expansion and compression due to respiratory cycles, and ECG derived respiratory sinus arrhythmia (RSA) that measures respiratory modulations are combined to assess BR as described previously in detail [4].

B. Synthetic Waveform Simulation Platform

A single-lead ECG and triaxial accelerometer waveforms are synthetically generated for a range of HR (30–200

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Takeaway

- VitalPatch's BR show good correspondence
- to that of the patient monitor within 1-4 brpm.

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Fully Disposable Wireless Patch Sensor for Continuous Remote Patient Monitoring

Fully Disposable Wireless Patch Sensor
for Continuous Remote Patient Monitoring

Nandakumar Selvaraj*, Gabriel Nallathambi, Rod Moghadam, and Arshan Aga

***Abstract*— Continuous remote monitoring with convenient wireless sensors is attractive for early detection of patient deterioration, preventing adverse events and leading to better patient care. This article presents an innovative sensor design of VitalPatch, a fully disposable wireless biosensor, for remote continuous monitoring, and details the performance assessments from bench testing and laboratory validation in 57 subjects. The bench testing results reveal that VitalPatch's QRS detection had a positive predictive value of >99% from testing with ECG databases. The accuracies of HR, BR and skin temp (in mean absolute error, MAE) from bench testing were <5 bpm, <1 brpm, $< 1°C$ respectively. The laboratory testing in 57 subjects revealed the accuracy of HR and BR to be 2.2±1.5 bpm and 1.7±0.7 brpm respectively for stationary periods. The absolute percent error in detecting steps was 4.7±4.6%, and the accuracy in detecting posture was 96.4±3.1%. Meanwhile, the specificity and sensitivity of fall detection (n=20) was found to be 100% and 93.8%, respectively. In conclusion, VitalPatch biosensor demonstrated clinically acceptable accuracies for its vital signs and actigraphy metrics applicable for continuous unobtrusive patient monitoring.**

***Index Terms*— Patient Monitoring, Wireless Biosensor, Vital Signs, Actigraphy, Algorithms, Performance.**

I. INTRODUCTION

Traditional hospital patient care involves checking of vital signs manually on acute care floors and continuous monitoring with sophisticated bedside equipment in critical care units. Early detection of patient deterioration may not be possible by spot checks [1]. Intermittent symptom-based monitoring is highly inaccurate compared to continuous monitoring [2]. On the other hand, continuous monitoring can help to identify the risks of impending clinical crisis with aberrations in vital signs, improve the clinical outcomes in hospitalized patients and reduce overall cost [1]. Implementation of continuous monitoring in a 33-bed medical surgical unit led to savings of over $9 million in 5 years [3].

Contemporary continuous monitoring usually involves wired sensors on the patients such as ECG leads, a nasal cannula and a SpO2 clip connected to a bedside monitor that does not provide remote access to instantaneous/trending data, rather it is available visually only at the bedside for clinical interventions. Furthermore, patient confinement to the hospital bed combined with stress of illness, immobility and the sense of incapacitation may have negative physiological consequences including substantial decrease in stroke volume and cardiac output leading to deconditioning of the cardiovascular system [4]. Therefore, continuous remote monitoring with convenient wireless sensors is attractive for early detection of patient deterioration, preventing adverse events and leading to better patient care.

Towards this goal, we first developed a wireless sensor called as HealthPatch® consisting of a disposable adhesive patch and a reusable electronic module [5] that allows continuous monitoring of vital signs, activity and fall detection very conveniently from patient's chest. We previously reported the efficacy of HealthPatch for long-term monitoring in 76 senior subjects over 50 days at home settings [6]. This unique unobtrusive HealthPatch sensor has received FDA clearances for remote continuous monitoring in hospital and home use.

Besides clinical acceptance of our semi-disposable sensor, reuse of the electronic module with proper disinfection, sterilization and sealing inside a new disposable patch may still pose risk for cross contamination [7]. Thus, a single-use biosensor can effectively eliminate risk for contamination and improve patient safety. To this end, we have recently developed a fully disposable novel biosensors called as VitalPatch® designed for comprehensive, comfortable and continuous remote monitoring in hospital and home settings.

In this article, we first present the innovative sensor design of our disposable biosensor, associated sensing modalities, vital sign and actigraphy measurements. Secondly, the article details the performance assessments from bench testing and clinical validation from 57 subjects in laboratory settings.

II. MATERIALS AND METHODS

A. Innovative sensor design and functionalities

VitalPatch is an inexpensive fully disposable adhesive patch device ($11gm$, $115 \times 36 \times 8mm$) worn on the left chest for continuous monitoring of a patient's physiological measurements, and core body activities (Fig. 1). This medical device allows sensing of high quality single-lead bipolar ECG waveforms using a flexible electronics layer consisting of flex circuit with coated surface electrodes, skin temperature using a precision thermistor connected to the flex circuit, and core body motion using a triaxial MEMS accelerometer on a printed circuit board assembly on one end of the sensor that houses a proprietary VitalCore™ system-on-chip (SOC) processor, on board memory and Bluetooth Low Energy (BLE) transceiver for wireless communications and data transfer. The other end of the sensor flex circuit houses a zinc-air battery and actuator switch with a breathable membrane that allows diffusion of air for powering the inexpensive, high energy density zinc-air cell battery. The electronic flex circuit layer is coupled to multiple construction layers including a top foam layer with anti-static coating to reduce triboelectricity buildup due to

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Takeaway

- VitalPatch biosensor demonstrated clinically acceptable accuracies for its vital signs and actigraphy metrics applicable for continuous unobtrusive patient monitoring.

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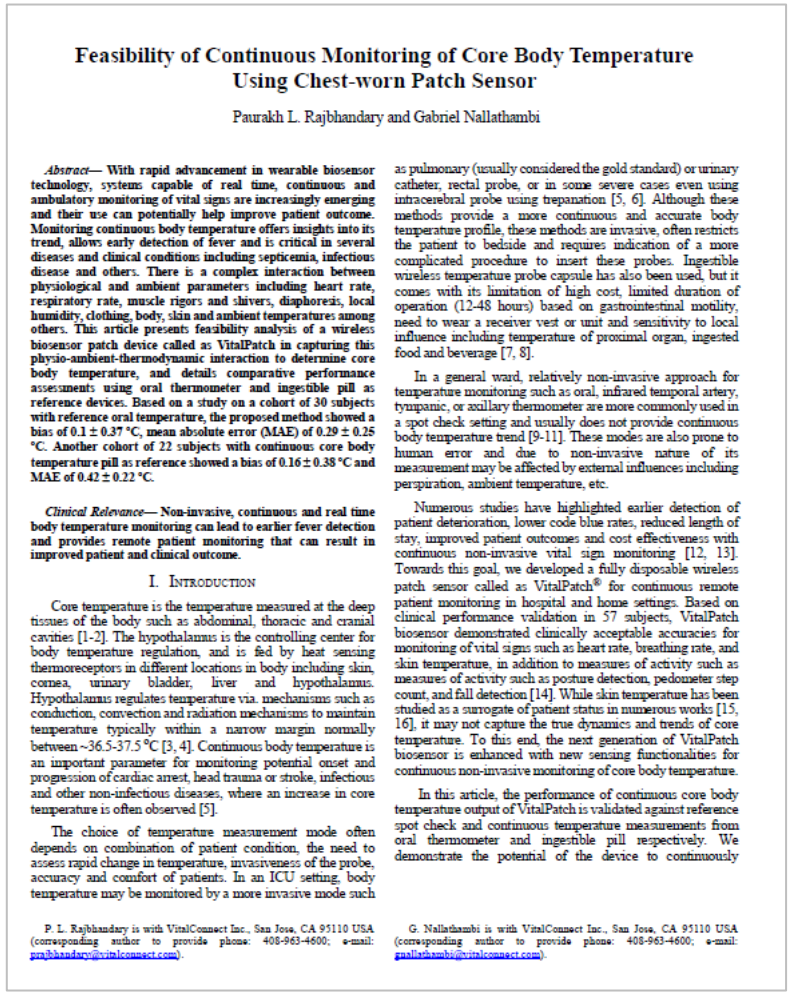
Feasibility of Continuous Monitoring of Core Body Temperature Using Chest-worn Patch Sensor



Feasibility of Continuous Monitoring of Core Body Temperature Using Chest-worn Patch Sensor

Paurakh L. Rajbhandary and Gabriel Nallathambi

Abstract— **With rapid advancement in wearable biosensor technology, systems capable of real time, continuous and ambulatory monitoring of vital signs are increasingly emerging and their use can potentially help improve patient outcome. Monitoring continuous body temperature offers insights into its trend, allows early detection of fever and is critical in several diseases and clinical conditions including septicemia, infectious disease and others. There is a complex interaction between physiological and ambient parameters including heart rate, respiratory rate, muscle rigors and shivers, diaphoresis, local humidity, clothing, body, skin and ambient temperatures among others. This article presents feasibility analysis of a wireless biosensor patch device called as VitalPatch in capturing this physio-ambient-thermodynamic interaction to determine core body temperature, and details comparative performance assessments using oral thermometer and ingestible pill as reference devices. Based on a study on a cohort of 30 subjects with reference oral temperature, the proposed method showed a bias of 0.1 ± 0.37 °C, mean absolute error (MAE) of 0.29 ± 0.25 °C. Another cohort of 22 subjects with continuous core body temperature pill as reference showed a bias of 0.16 ± 0.38 °C and MAE of 0.42 ± 0.22 °C.**

Clinical Relevance— **Non-invasive, continuous and real time body temperature monitoring can lead to earlier fever detection and provides remote patient monitoring that can result in improved patient and clinical outcome.**

I. Introduction

Core temperature is the temperature measured at the deep tissues of the body such as abdominal, thoracic and cranial cavities [1-2]. The hypothalamus is the controlling center for body temperature regulation, and is fed by heat sensing thermoreceptors in different locations in body including skin, cornea, urinary bladder, liver and hypothalamus. Hypothalamus regulates temperature via. mechanisms such as conduction, convection and radiation mechanisms to maintain temperature typically within a narrow margin normally between ~36.5-37.5 °C [3, 4]. Continuous body temperature is an important parameter for monitoring potential onset and progression of cardiac arrest, head trauma or stroke, infectious and other non-infectious diseases, where an increase in core temperature is often observed [5].

The choice of temperature measurement mode often depends on combination of patient condition, the need to assess rapid change in temperature, invasiveness of the probe, accuracy and comfort of patients. In an ICU setting, body temperature may be monitored by a more invasive mode such as pulmonary (usually considered the gold standard) or urinary catheter, rectal probe, or in some severe cases even using intracerebral probe using trepanation [5, 6]. Although these methods provide a more continuous and accurate body temperature profile, these methods are invasive, often restricts the patient to bedside and requires indication of a more complicated procedure to insert these probes. Ingestible wireless temperature probe capsule has also been used, but it comes with its limitation of high cost, limited duration of operation (12-48 hours) based on gastrointestinal motility, need to wear a receiver vest or unit and sensitivity to local influence including temperature of proximal organ, ingested food and beverage [7, 8].

In a general ward, relatively non-invasive approach for temperature monitoring such as oral, infrared temporal artery, tympanic, or axillary thermometer are more commonly used in a spot check setting and usually does not provide continuous body temperature trend [9-11]. These modes are also prone to human error and due to non-invasive nature of its measurement may be affected by external influences including perspiration, ambient temperature, etc.

Numerous studies have highlighted earlier detection of patient deterioration, lower code blue rates, reduced length of stay, improved patient outcomes and cost effectiveness with continuous non-invasive vital sign monitoring [12, 13]. Towards this goal, we developed a fully disposable wireless patch sensor called as VitalPatch® for continuous remote patient monitoring in hospital and home settings. Based on clinical performance validation in 57 subjects, VitalPatch biosensor demonstrated clinically acceptable accuracies for monitoring of vital signs such as heart rate, breathing rate, and skin temperature, in addition to measures of activity such as measures of activity such as posture detection, pedometer step count, and fall detection [14]. While skin temperature has been studied as a surrogate of patient status in numerous works [15, 16], it may not capture the true dynamics and trends of core temperature. To this end, the next generation of VitalPatch biosensor is enhanced with new sensing functionalities for continuous non-invasive monitoring of core body temperature.

In this article, the performance of continuous core body temperature output of VitalPatch is validated against reference spot check and continuous temperature measurements from oral thermometer and ingestible pill respectively. We demonstrate the potential of the device to continuously

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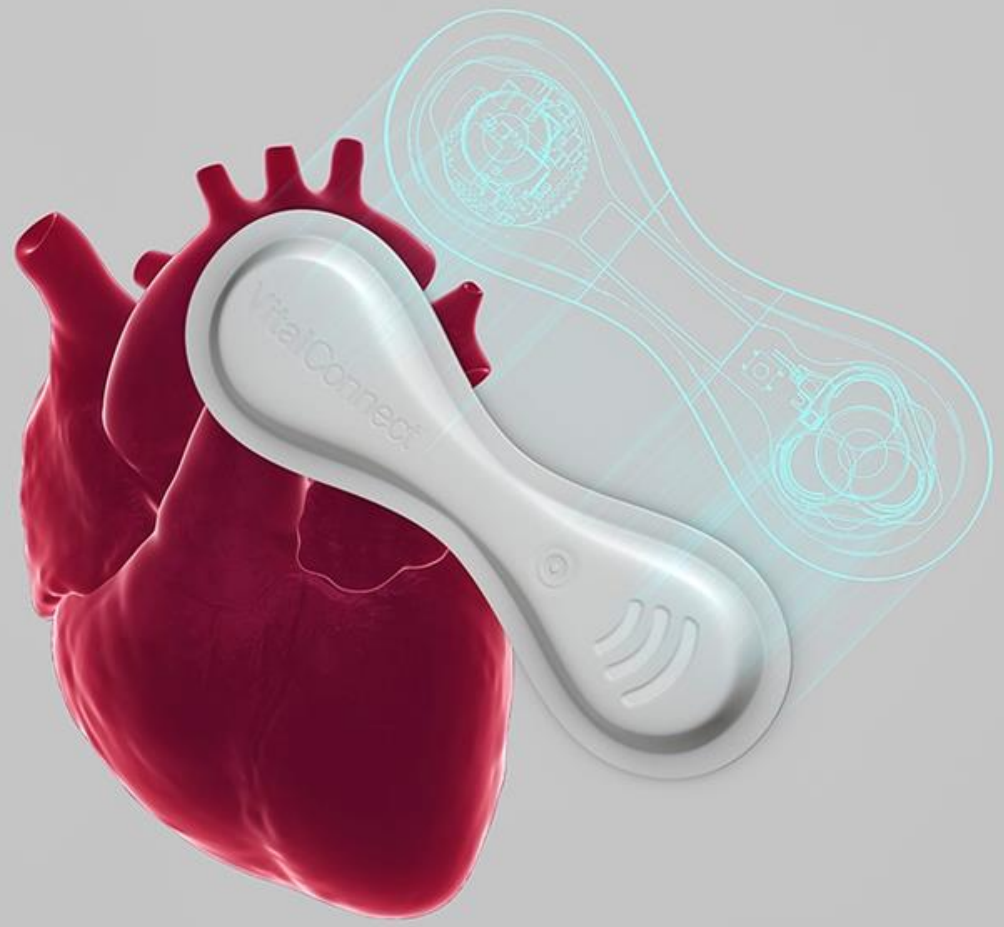
Takeaway

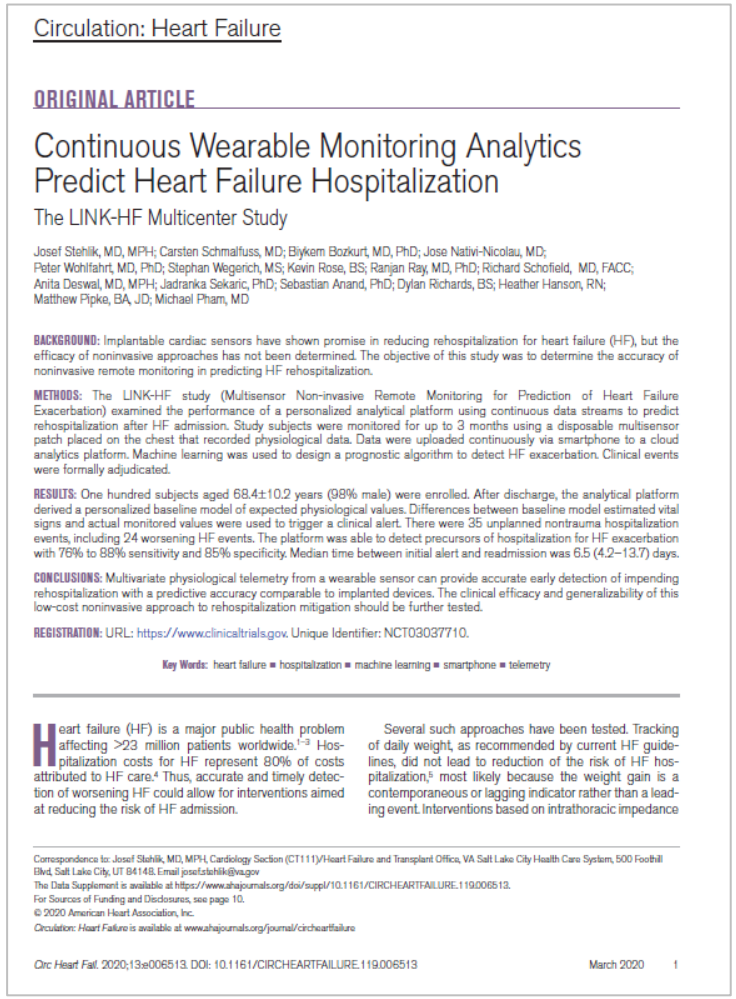
- VitalPatch is validated against reference spot check and continuous temperature measurements from oral thermometer and ingestible pill respectively.

Adobe Acrobat Document

Heart Failure



Continuous Wearable Monitoring Analytics Predict Heart Failure Hospitalization



Circulation: Heart Failure

ORIGINAL ARTICLE

Continuous Wearable Monitoring Analytics Predict Heart Failure Hospitalization

The LINK-HF Multicenter Study

Josef Stehlik, MD, MPH; Carsten Schmalfuss, MD; Bilykem Bozkurt, MD, PhD; Jose Nativi-Nicolau, MD; Peter Wohlfahrt, MD, PhD; Stephan Wegerich, MS; Kevin Rose, BS; Ranjan Ray, MD, PhD; Richard Schofield, MD, FACC; Anita Deswal, MD, MPH; Jadranka Sekaric, PhD; Sebastian Anand, PhD; Dylan Richards, BS; Heather Hanson, RN; Matthew Pipke, BA, JD; Michael Pham, MD

BACKGROUND: Implantable cardiac sensors have shown promise in reducing rehospitalization for heart failure (HF), but the efficacy of noninvasive approaches has not been determined. The objective of this study was to determine the accuracy of noninvasive remote monitoring in predicting HF rehospitalization.

METHODS: The LINK-HF study (Multisensor Non-invasive Remote Monitoring for Prediction of Heart Failure Exacerbation) examined the performance of a personalized analytical platform using continuous data streams to predict rehospitalization after HF admission. Study subjects were monitored for up to 3 months using a disposable multisensor patch placed on the chest that recorded physiological data. Data were uploaded continuously via smartphone to a cloud analytics platform. Machine learning was used to design a prognostic algorithm to detect HF exacerbation. Clinical events were formally adjudicated.

RESULTS: One hundred subjects aged 68.4±10.2 years (98% male) were enrolled. After discharge, the analytical platform derived a personalized baseline model of expected physiological values. Differences between baseline model estimated vital signs and actual monitored values were used to trigger a clinical alert. There were 35 unplanned nontrauma hospitalization events, including 24 worsening HF events. The platform was able to detect precursors of hospitalization for HF exacerbation with 76% to 88% sensitivity and 85% specificity. Median time between initial alert and readmission was 6.5 (4.2–13.7) days.

CONCLUSIONS: Multivariate physiological telemetry from a wearable sensor can provide accurate early detection of impending rehospitalization with a predictive accuracy comparable to implanted devices. The clinical efficacy and generalizability of this low-cost noninvasive approach to rehospitalization mitigation should be further tested.

REGISTRATION: URL: https://www.clinicaltrials.gov. Unique Identifier: NCT03037710.

Key Words: heart failure ■ hospitalization ■ machine learning ■ smartphone ■ telemetry

Heart failure (HF) is a major public health problem affecting >23 million patients worldwide.[1–3] Hospitalization costs for HF represent 80% of costs attributed to HF care.[4] Thus, accurate and timely detection of worsening HF could allow for interventions aimed at reducing the risk of HF admission.

Several such approaches have been tested. Tracking of daily weight, as recommended by current HF guidelines, did not lead to reduction of the risk of HF hospitalization,[5] most likely because the weight gain is a contemporaneous or lagging indicator rather than a leading event. Interventions based on intrathoracic impedance

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The Data Supplement is available at https://www.ahajournals.org/doi/suppl/10.1161/CIRCHEARTFAILURE.119.006513.
For Sources of Funding and Disclosures, see page 10.

Circulation: Heart Failure is available at www.ahajournals.org/journal/circheartfailure

Circ Heart Fail. 2020;13:e006513. DOI: 10.1161/CIRCHEARTFAILURE.119.006513 March 2020 1

Takeaway

- The platform was able to detect precursors of hospitalization for HF exacerbation with 76% to 88% sensitivity and 85% specificity. Median time between initial alert and readmission was 6.5 (4.2–13.7) days.
- Multivariate physiological telemetry from a wearable sensor can provide accurate early detection of impending rehospitalization with a predictive accuracy comparable to implanted devices.

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The Next Frontier of Remote Patient Monitoring: Hospital at Home

Published on 16.3.2023 in Vol 25 (2023)

Preprints (earlier versions) of this paper are available at https://preprints.jmir.org/preprint/42335, first published August 31, 2022.

The Next Frontier of Remote Patient Monitoring: Hospital at Home

David Whitehead [1, 2]; Jared Conley [1, 2, 3]

Article | Authors | Cited by | Tweetations (18) | Metrics

Abstract

Remote patient monitoring (RPM) has shown promise in aiding safe and efficient remote care for chronic conditions; however, its use remains more limited within the hospital at home (HaH) model of care despite a significant opportunity to increase patient eligibility, improve safety, and decrease costs. HaH could achieve these goals by further adopting the 3 primary modalities of RPM (ie, vital sign, continuous single-lead electrocardiogram, and fall monitoring). With only 2 in-person vital sign checks required per day, HaH patient eligibility is currently often limited to lower-acuity cases. The use of vital sign RPM within HaH could better match the standard clinical practice of vital sign checks every 4-8 hours and enable safe care for appropriate moderate-acuity medical and surgical floor-level patients not traditionally enrolled in HaH. Robust, efficient collection of more frequent vital signs via RPM could expand patient eligibility for HaH and create a digital health safety net that enables high quality care. Similarly, our experience at Massachusetts General Hospital has demonstrated that appropriate use of continuous single-lead electrocardiogram RPM can also expand HaH enrollment, particularly for patients with acute decompensated heart failure. Through increasing enrollment of patients in HaH, RPM stands to enable more patients to reap the potential safety benefits of home hospitalization, including decreased rates of delirium and hospital-acquired infections, and better avoid aspects of posthospital syndrome. Furthermore, instituting fall

Takeaway

- As HaH continues to advance, broader use of RPM—guided by high-quality research and operational knowledge—has significant potential to enable more patients to benefit from the demonstrated value of healing in the comfort of one's own home.

https://www.jmir.org/2023/1/e42335/

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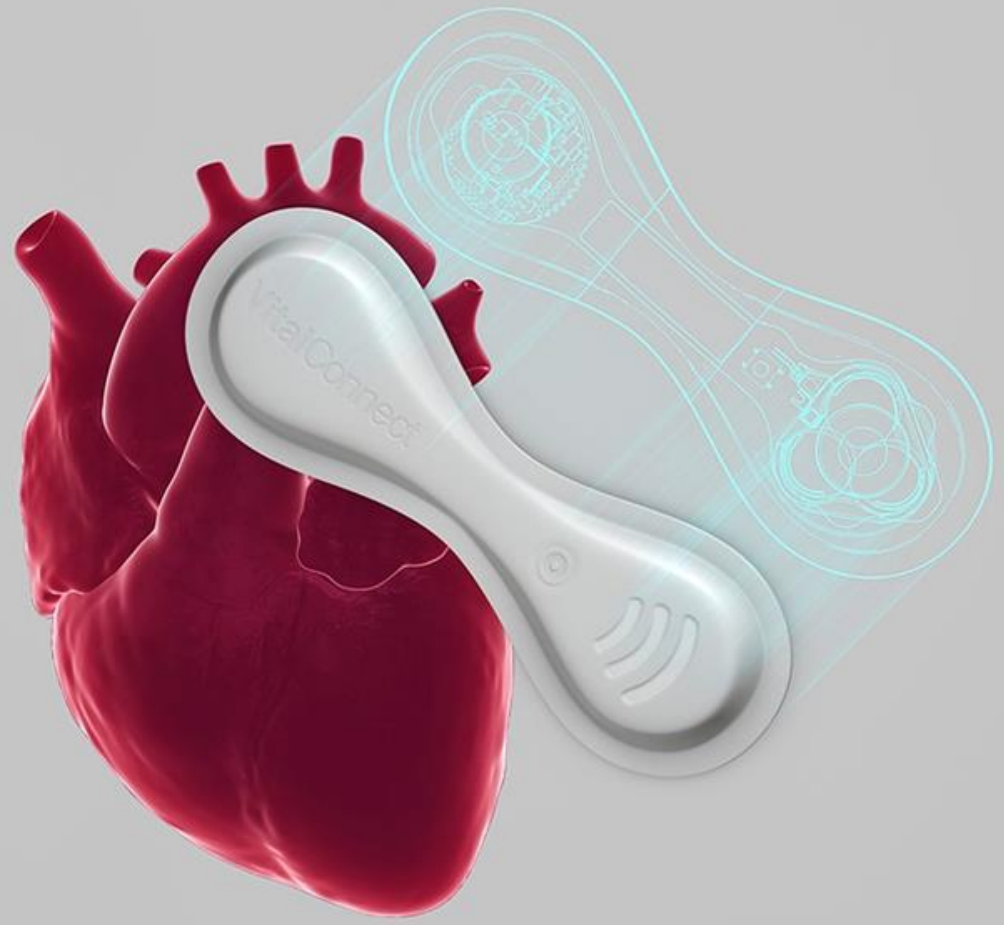
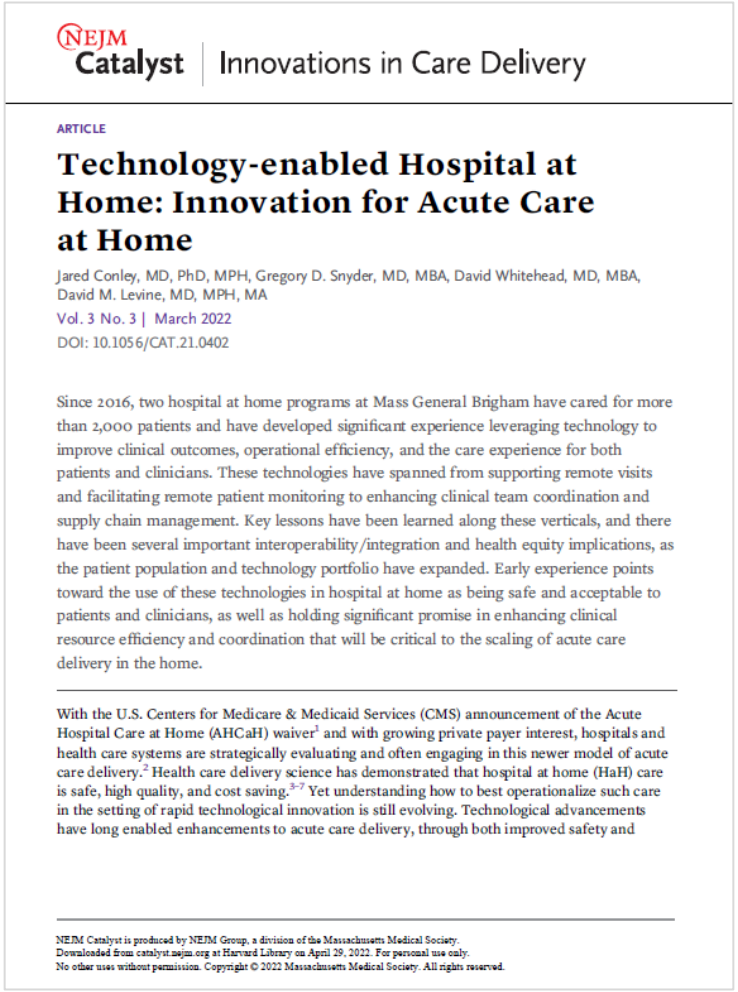
Hospital and Hospital at Home



Technology-enabled Hospital at Home: Innovation for Acute Care at Home



NEJM Catalyst | Innovations in Care Delivery

ARTICLE

Technology-enabled Hospital at Home: Innovation for Acute Care at Home

Jared Conley, MD, PhD, MPH, Gregory D. Snyder, MD, MBA, David Whitehead, MD, MBA, David M. Levine, MD, MPH, MA

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DOI: 10.1056/CAT.21.0402

Since 2016, two hospital at home programs at Mass General Brigham have cared for more than 2,000 patients and have developed significant experience leveraging technology to improve clinical outcomes, operational efficiency, and the care experience for both patients and clinicians. These technologies have spanned from supporting remote visits and facilitating remote patient monitoring to enhancing clinical team coordination and supply chain management. Key lessons have been learned along these verticals, and there have been several important interoperability/integration and health equity implications, as the patient population and technology portfolio have expanded. Early experience points toward the use of these technologies in hospital at home as being safe and acceptable to patients and clinicians, as well as holding significant promise in enhancing clinical resource efficiency and coordination that will be critical to the scaling of acute care delivery in the home.

With the U.S. Centers for Medicare & Medicaid Services (CMS) announcement of the Acute Hospital Care at Home (AHCaH) waiver[1] and with growing private payer interest, hospitals and health care systems are strategically evaluating and often engaging in this newer model of acute care delivery.[2] Health care delivery science has demonstrated that hospital at home (HaH) care is safe, high quality, and cost saving.[3–7] Yet understanding how to best operationalize such care in the setting of rapid technological innovation is still evolving. Technological advancements have long enabled enhancements to acute care delivery, through both improved safety and

Takeaway

- Since 2016, two hospital at home programs at Mass General Brigham have cared for more than 2,000 patients and have developed significant experience leveraging technology to improve clinical outcomes, operational efficiency, and the care experience for both patients and clinicians.
- Early experience points toward the use of these technologies in hospital at home as being safe and acceptable to patients and clinicians, as well as holding significant promise in enhancing clinical resource efficiency and coordination that will be critical to the scaling of acute care delivery in the home.

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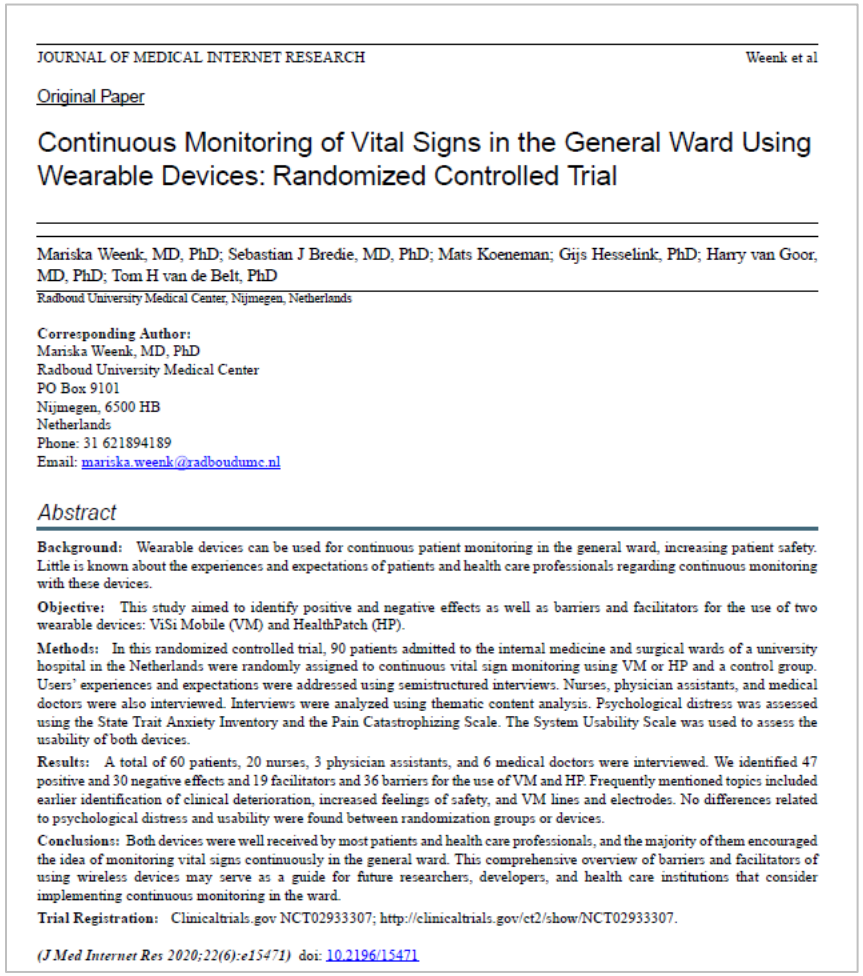
Continuous Monitoring of Vital Signs in the General Ward Using Wearable Devices: Randomized Controlled Trial



JOURNAL OF MEDICAL INTERNET RESEARCH Weenk et al

Original Paper

Continuous Monitoring of Vital Signs in the General Ward Using Wearable Devices: Randomized Controlled Trial

Mariska Weenk, MD, PhD; Sebastian J Bredie, MD, PhD; Mats Koeneman; Gijs Hesselink, PhD; Harry van Goor, MD, PhD; Tom H van de Belt, PhD

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Abstract

Background: Wearable devices can be used for continuous patient monitoring in the general ward, increasing patient safety. Little is known about the experiences and expectations of patients and health care professionals regarding continuous monitoring with these devices.

Objective: This study aimed to identify positive and negative effects as well as barriers and facilitators for the use of two wearable devices: ViSi Mobile (VM) and HealthPatch (HP).

Methods: In this randomized controlled trial, 90 patients admitted to the internal medicine and surgical wards of a university hospital in the Netherlands were randomly assigned to continuous vital sign monitoring using VM or HP and a control group. Users' experiences and expectations were addressed using semistructured interviews. Nurses, physician assistants, and medical doctors were also interviewed. Interviews were analyzed using thematic content analysis. Psychological distress was assessed using the State Trait Anxiety Inventory and the Pain Catastrophizing Scale. The System Usability Scale was used to assess the usability of both devices.

Results: A total of 60 patients, 20 nurses, 3 physician assistants, and 6 medical doctors were interviewed. We identified 47 positive and 30 negative effects and 19 facilitators and 36 barriers for the use of VM and HP. Frequently mentioned topics included earlier identification of clinical deterioration, increased feelings of safety, and VM lines and electrodes. No differences related to psychological distress and usability were found between randomization groups or devices.

Conclusions: Both devices were well received by most patients and health care professionals, and the majority of them encouraged the idea of monitoring vital signs continuously in the general ward. This comprehensive overview of barriers and facilitators of using wireless devices may serve as a guide for future researchers, developers, and health care institutions that consider implementing continuous monitoring in the ward.

Trial Registration: Clinicaltrials.gov NCT02933307; http://clinicaltrials.gov/ct2/show/NCT02933307.

(J Med Internet Res 2020;22(6):e15471) doi: 10.2196/15471

Takeaway

- According to patients and health care professionals, VM and HP have potential for continuous monitoring of vital signs in the general ward, and almost all of them encouraged the idea of monitoring vital signs continuously in the general ward.

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Hospital-Level Care at Home for Acutely Ill Adults: a Pilot Randomized Controlled Trial

CrossMark

Hospital-Level Care at Home for Acutely Ill Adults: a Pilot Randomized Controlled Trial

David M. Levine, MD MPH MA[1,2], Kei Ouchi, MD MPH[2,3], Bonnie Blanchfield, ScD[1,2], Keren Diamond, RN MBA[4], Adam Licurse, MD MHS[1,2,5], Charles T. Pu, MD[2,5,6], and Jeffrey L. Schnipper, MD MPH[1,2]

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BACKGROUND: Hospitals are standard of care for acute illness, but hospitals can be unsafe, uncomfortable, and expensive. Providing substitutive hospital-level care in a patient's home potentially reduces cost while maintaining or improving quality, safety, and patient experience, although evidence from randomized controlled trials in the US is lacking.
OBJECTIVE: Determine if home hospital care reduces cost while maintaining quality, safety, and patient experience.
DESIGN: Randomized controlled trial.
PARTICIPANTS: Adults admitted via the emergency department with any infection or exacerbation of heart failure, chronic obstructive pulmonary disease, or asthma.
INTERVENTION: Home hospital care, including nurse and physician home visits, intravenous medications, continuous monitoring, video communication, and point-of-care testing.
MAIN MEASURES: Primary outcome was direct cost of the acute care episode. Secondary outcomes included utilization, 30-day cost, physical activity, and patient experience.
KEY RESULTS: Nine patients were randomized to home, 11 to usual care. Median direct cost of the acute care episode for home patients was 52% (IQR, 28%; $p = 0.05$) lower than for control patients. During the care episode, home patients had fewer laboratory orders (median per admission: 6 vs. 19; $p < 0.01$) and less often received consultations (0% vs. 27%; $p = 0.04$). Home patients were more physically active (median minutes, 209 vs. 78; $p < 0.01$), with a trend toward more sleep. No adverse events occurred in home patients, one occurred in control patients. Median direct cost for the acute care plus 30-day post-discharge period for home patients was 67% (IQR, 77%; $p < 0.01$) lower, with trends toward less use of home-care services (22% vs. 55%; $p = 0.08$) and fewer readmissions (11% vs. 36%; $p = 0.32$). Patient experience was similar in both groups.
CONCLUSIONS: The use of substitutive home-hospitalization compared to in-hospital usual care reduced cost and utilization and improved physical activity. No significant differences in quality, safety, and patient experience were noted, with more definitive results awaiting a larger trial.
Trial Registration NCT02864420.

KEY WORDS: home hospital; hospital at home; hospital alternative; home-based care.

J Gen Intern Med
DOI: 10.1007/s11606-018-4307-z

INTRODUCTION

Hospitals are the standard of care for acute illness in the US, but hospital care is expensive and often unsafe, particularly for older individuals.[1] While admitted, 20% suffer delirium,[2] over 5% contract hospital-acquired infections,[3] and many lose functional status that is never regained.[4] Timely access to inpatient care is often poor: many hospital wards are typically over 100% capacity, and emergency department (ED) waits can be protracted. Moreover, hospital care is increasingly costly, accounting for about one-third of total medical expenditures, and is a leading cause of patient debt.[5]

A "home hospital" is home-based provision of acute services usually associated with the traditional inpatient hospital setting.[6] Prior work suggests home hospital care can reduce cost, maintain quality and safety, and improve patient experience for selected acutely ill adults who require traditional hospital-level care.[7–15] While home hospital care is familiar in several developed countries,[16] only two non-randomized studies have been conducted in the US.

We sought to demonstrate the cost, safety, quality, and patient experience of substitutive hospital-level care in the home through a pilot randomized controlled trial.

METHODS

Study Design

This investigator-initiated study was approved by the Partners HealthCare Human Research Committee as more than

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s11606-018-4307-z) contains supplementary material, which is available to authorized users.

Received May 8, 2017
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Takeaway

- The use of substitutive home hospitalization compared to in-hospital usual care reduced cost and utilization and improved physical activity.

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Hospital-Level Care at Home for Acutely Ill Adults A Randomized Controlled Trial

Annals of Internal Medicine ORIGINAL RESEARCH

Hospital-Level Care at Home for Acutely Ill Adults

A Randomized Controlled Trial

David M. Levine, MD, MPH, MA; Kei Ouchi, MD, MPH; Bonnie Blanchfield, ScD; Agustina Saenz, MD, MPH; Kimberly Burke, BA; Mary Paz, BA; Keren Diamond, RN, MBA; Charles T. Pu, MD; and Jeffrey L. Schnipper, MD, MPH

Background: Substitutive hospital-level care in a patient's home may reduce cost, health care use, and readmissions while improving patient experience, although evidence from randomized controlled trials in the United States is lacking.

Objective: To compare outcomes of home hospital versus usual hospital care for patients requiring admission.

Design: Randomized controlled trial. (ClinicalTrials.gov: NCT03203759)

Setting: Academic medical center and community hospital.

Patients: 91 adults (43 home and 48 control) admitted via the emergency department with selected acute conditions.

Intervention: Acute care at home, including nurse and physician home visits, intravenous medications, remote monitoring, video communication, and point-of-care testing.

Measurements: The primary outcome was the total direct cost of the acute care episode (sum of costs for nonphysician labor, supplies, medications, and diagnostic tests). Secondary outcomes included health care use and physical activity during the acute care episode and at 30 days.

Results: The adjusted mean cost of the acute care episode was 38% (95% CI, 24% to 49%) lower for home patients than control patients. Compared with usual care patients, home patients had fewer laboratory orders (median per admission, 3 vs. 15), imaging studies (median, 14% vs. 44%), and consultations (median, 2% vs. 31%). Home patients spent a smaller proportion of the day sedentary (median, 12% vs. 23%) or lying down (median, 18% vs. 55%) and were readmitted less frequently within 30 days (7% vs. 23%).

Limitation: The study involved 2 sites, a small number of home physicians, and a small sample of highly selected patients (with a 63% refusal rate among potentially eligible patients); these factors may limit generalizability.

Conclusion: Substitutive home hospitalization reduced cost, health care use, and readmissions while increasing physical activity compared with usual hospital care.

Primary Funding Source: Partners HealthCare Center for Population Health and internal departmental funds.

Ann Intern Med. 2020;172:77-85. doi:10.7326/M19-0600 Annals.org
For author affiliations, see end of text.
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Hospitals are the standard of care for acute illness in the United States, but inpatient care is expensive—accounting for about one third of total medical expenditures (1)—and may be unsafe, particularly for older persons (2). Timely access to inpatient care is often poor: Hospital wards are typically at capacity, and average emergency department (ED) waits can be more than 6 hours (3). After hospital discharge, many patients have "posthospital syndrome," due in part to such factors as deconditioning and sleep deprivation (4), and almost 20% of Medicare patients are readmitted within 30 days of discharge (5).

A "home hospital" is the home-based provision of acute care services usually associated with the traditional inpatient hospital (6). Prior work suggests that home hospital care can reduce cost, maintain quality and safety, and improve patient experience for selected acutely ill adults who require traditional hospital-level care (7-16). Home hospital care is already provided in several developed countries, such as Australia and Spain (17, 18), but few nonrandomized studies have been done in the United States (7, 8, 16). We published the first pilot randomized controlled trial in the United States (19). Given the strong potential for confounding and bias in nonrandomized evaluations of substitutive care, we sought to strengthen the evidence base by replicating our prior trial with more patients.

METHODS

Design Overview

We performed a parallel-design, randomized controlled trial in which participants were randomly allocated to home hospital care (intervention) or traditional hospital care (control). We enrolled participants between 12 June 2017 and 16 January 2018; follow-up ended on 17 February 2018. Patients, study staff, and physicians were not blinded to allocation status. This internally funded study was stopped early (after enrolling 91 patients) in light of local operational needs to quickly increase home hospital capacity after positive interim outcomes were presented to hospital leadership. The trial protocol (**Supplement**, available at Annals.org) was approved by the Partners HealthCare institutional review board and registered at ClinicalTrials.gov (NCT03203759). All participants provided written informed consent before randomization.

Setting and Participants

Adult participants were recruited in the ED at Brigham and Women's Hospital (an academic medical

See also:
Editorial comment 145
Web-Only Supplement

Takeaway

- Substitutive home hospitalization reduced cost, health care use, and readmissions while increasing physical activity compared with usual hospital care.

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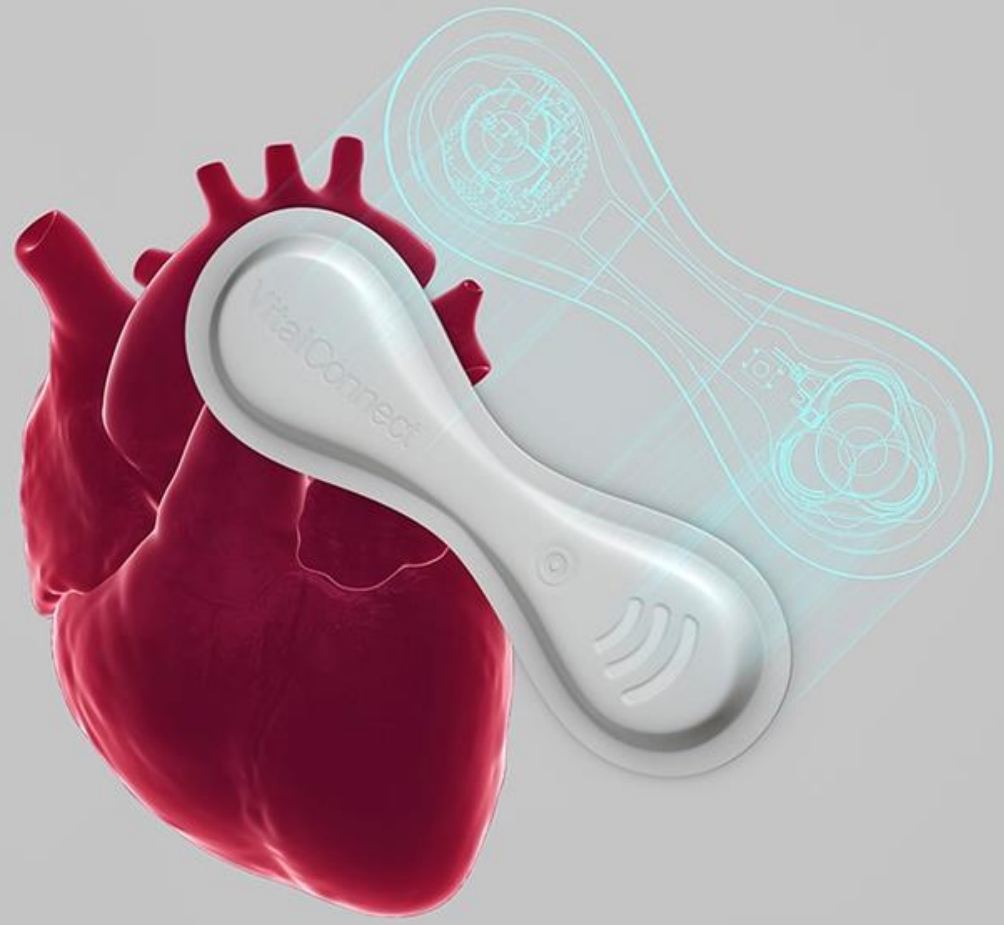
Experimental Applications



Automated Prediction of the Apnea-Hypopnea Index using a Wireless Patch Sensor

Automated Prediction of the Apnea-Hypopnea Index using a Wireless Patch Sensor

Nandakumar Selvaraj* and Ravi Narasimhan

Abstract— **Polysomnography (PSG) is the gold standard that manually quantifies the apnea-hypopnea index (AHI) to assess the severity of sleep apnea syndrome (SAS). This study presents an algorithm that automatically estimates the AHI value using a disposable HealthPatch™ sensor. Volunteers (n=53, AHI: 0.1–85.8) participated in an overnight PSG study with patch sensors attached to their chest at three specified locations and data were wirelessly acquired. Features were computed for 150-second epochs of patch sensor data using analyses of heart rate variability, respiratory signals, posture and movements. Linear Support Vector Machine classifier was trained to detect the presence/absence of apnea/hypopnea events for each epoch. The number of epochs identified with events was subsequently mapped to AHI values using quadratic regression analysis. The classifier and regression models were optimized to minimize the mean-square error of AHI based on leave-one-out cross-validation. Comparison of predicted and reference AHI values resulted in linear correlation coefficients of 0.87, 0.88 and 0.92 for the three locations, respectively. The predicted AHI values were subsequently used to classify the control-to-mild apnea group (AHI<15) and moderate-to-severe apnea (AHI≥15) with an accuracy (95% confidence intervals) of 89.4% (77.4–95.4%), 85.0% (70.9–92.9%), and 82.9% (67.3–91.9%) for the three locations, respectively. Overnight physiological monitoring using a wireless patch sensor provides an accurate estimate of AHI.**

Index Terms— **Apnea-Hypopnea Index, Heart rate variability, Actigraphy, Respiration, Machine Learning.**

I. INTRODUCTION

Sleep apnea syndrome (SAS) is a chronic sleep disorder highly prevalent worldwide. SAS disorder affects health and quality of life, and also leads to serious health consequences such as cardiovascular disease, neurocognitive dysfunction, and respiratory failure. Overnight polysomnography (PSG) is the gold standard that quantifies the apnea-hypopnea index (AHI) to assess the severity of SAS disorder. However, overnight PSG performed in a sleep laboratory involves many challenges for SAS screening. The laboratory-testing environment might significantly affect normal sleep patterns and may cause more apnea/hypopnea events in some patients as compared to their home environments. The patients might also be more apprehensive and suffer from sleeplessness due to the first night effect [1]. Furthermore, the PSG may not be suitable for SAS screening due to its high operating costs, requirement of dedicated facilities, equipment and personnel, inadequate availability, and limited repeatability.

Home sleep tests using portable monitors have been gaining attention for screening of moderate-to-severe sleep apnea. However, failure rates for home testing are significantly high, leading to inconclusive studies with no interpretable data [2]. Reasons for such failures include the complex sensor attachments, obtrusiveness, compliance issues (such as failure to turn on the monitor), and detachment of sensors during tosses and turns. The costs of home sleep tests vary greatly with inconsistent coding, billing, and coverage [3]. The patient is required to return the monitor to the clinician's office either by drop-off or mail after the home sleep test. Additionally, a waiting period of at least couple of weeks after the sleep test is commonly required to obtain the results, since the algorithms on PSG and home-based monitors predict AHI based on the laborious sleep physician's visual analysis of events using oxygen saturation and airflow signals.

Given the limitations of currently available tools, we present a novel SAS screening tool that estimates the AHI value automatically by epoch-by-epoch analysis of the HealthPatch™, a disposable wireless patch biosensor.

II. MATERIALS AND METHODS

A. Study Group

The study population consists of 53 volunteers of healthy and untreated SAS patients (29 males and 24 females) with age range of 22–73 years. The inclusion criterion to participate in the study was the age limit of ≥18 years. The exclusion criteria included surgical treatment for SAS and major behavioral and neurological disorders. The AHI had a range of 0.1–85.8 among these subjects.

B. Polysomnography System

The Sapphire 22-channel PSG system (CleveMed, Inc., Cleveland, OH, USA) was used to collect the standard PSG data. Sleep physicians performed sleep scorings in accordance with American Academy of Sleep Medicine (AASM) guidelines. Hypopneas were identified as ≥50% reduction in airflow lasting for ≥10 s with a 3% desaturation or an arousal. Apneas were identified as the absence of airflow (≥90% of baseline) for ≥10 s. Apnea-hypopnea index (AHI) is calculated as the average number of apnea/hypopnea events per hour to quantify the SAS severity.

C. HealthPatch™ Sensor

The HealthPatch™ sensor is a disposable adhesive patch biosensor worn on the chest that incorporates two surface electrodes with hydrogel on the bottom, a battery, an electronic module with the embedded processor, micro-electromechanical system (MEMS) tri-axial accelerometer and Bluetooth Low Energy (BLE) transceiver. The patch sensor facilitates continuous monitoring of ECG and actigraphy signals at a sampling rate of 125 Hz and 62.5

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978-1-4244-7929-0/14/$26.00 ©2014 IEEE

Takeaway

- Overnight physiological monitoring with an adhesive HealthPatch™ sensor provides an accurate estimate of AHI values compared to the gold-standard of PSG.

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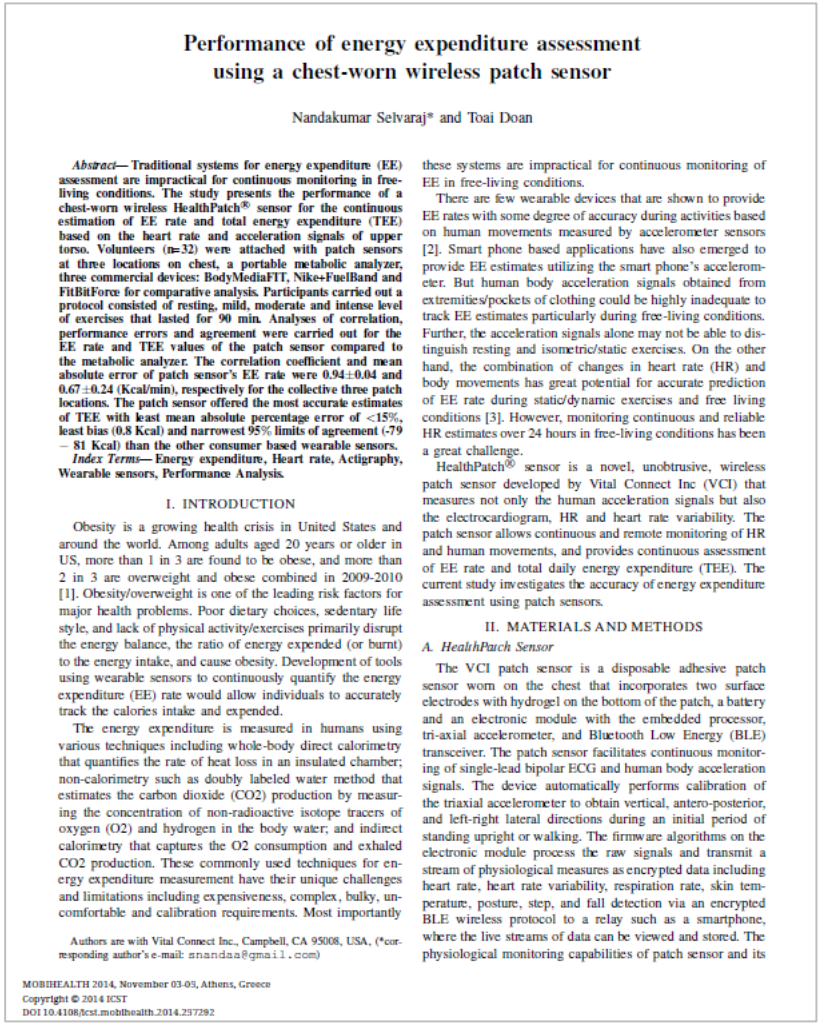
Performance of energy expenditure assessment using a chest-worn wireless patch sensor



Performance of energy expenditure assessment using a chest-worn wireless patch sensor

Nandakumar Selvaraj* and Toai Doan

Abstract— **Traditional systems for energy expenditure (EE) assessment are impractical for continuous monitoring in free-living conditions. The study presents the performance of a chest-worn wireless HealthPatch® sensor for the continuous estimation of EE rate and total energy expenditure (TEE) based on the heart rate and acceleration signals of upper torso. Volunteers (n=32) were attached with patch sensors at three locations on chest, a portable metabolic analyzer, three commercial devices: BodyMediaFIT, Nike+FuelBand and FitBitForce for comparative analysis. Participants carried out a protocol consisted of resting, mild, moderate and intense level of exercises that lasted for 90 min. Analyses of correlation, performance errors and agreement were carried out for the EE rate and TEE values of the patch sensor compared to the metabolic analyzer. The correlation coefficient and mean absolute error of patch sensor's EE rate were 0.94±0.04 and 0.67±0.24 (Kcal/min), respectively for the collective three patch locations. The patch sensor offered the most accurate estimates of TEE with least mean absolute percentage error of <15%, least bias (0.8 Kcal) and narrowest 95% limits of agreement (-79 – 81 Kcal) than the other consumer based wearable sensors.**

Index Terms— **Energy expenditure, Heart rate, Actigraphy, Wearable sensors, Performance Analysis.**

I. INTRODUCTION

Obesity is a growing health crisis in United States and around the world. Among adults aged 20 years or older in US, more than 1 in 3 are found to be obese, and more than 2 in 3 are overweight and obese combined in 2009-2010 [1]. Obesity/overweight is one of the leading risk factors for major health problems. Poor dietary choices, sedentary life style, and lack of physical activity/exercises primarily disrupt the energy balance, the ratio of energy expended (or burnt) to the energy intake, and cause obesity. Development of tools using wearable sensors to continuously quantify the energy expenditure (EE) rate would allow individuals to accurately track the calories intake and expended.

The energy expenditure is measured in humans using various techniques including whole-body direct calorimetry that quantifies the rate of heat loss in an insulated chamber; non-calorimetry such as doubly labeled water method that estimates the carbon dioxide (CO2) production by measuring the concentration of non-radioactive isotope tracers of oxygen (O2) and hydrogen in the body water; and indirect calorimetry that captures the O2 consumption and exhaled CO2 production. These commonly used techniques for energy expenditure measurement have their unique challenges and limitations including expensiveness, complex, bulky, uncomfortable and calibration requirements. Most importantly these systems are impractical for continuous monitoring of EE in free-living conditions.

There are few wearable devices that are shown to provide EE rates with some degree of accuracy during activities based on human movements measured by accelerometer sensors [2]. Smart phone based applications have also emerged to provide EE estimates utilizing the smart phone's accelerometer. But human body acceleration signals obtained from extremities/pockets of clothing could be highly inadequate to track EE estimates particularly during free-living conditions. Further, the acceleration signals alone may not be able to distinguish resting and isometric/static exercises. On the other hand, the combination of changes in heart rate (HR) and body movements has great potential for accurate prediction of EE rate during static/dynamic exercises and free living conditions [3]. However, monitoring continuous and reliable HR estimates over 24 hours in free-living conditions has been a great challenge.

HealthPatch® sensor is a novel, unobtrusive, wireless patch sensor developed by Vital Connect Inc (VCI) that measures not only the human acceleration signals but also the electrocardiogram, HR and heart rate variability. The patch sensor allows continuous and remote monitoring of HR and human movements, and provides continuous assessment of EE rate and total daily energy expenditure (TEE). The current study investigates the accuracy of energy expenditure assessment using patch sensors.

II. MATERIALS AND METHODS

A. HealthPatch Sensor

The VCI patch sensor is a disposable adhesive patch sensor worn on the chest that incorporates two surface electrodes with hydrogel on the bottom of the patch, a battery and an electronic module with the embedded processor, tri-axial accelerometer, and Bluetooth Low Energy (BLE) transceiver. The patch sensor facilitates continuous monitoring of single-lead bipolar ECG and human body acceleration signals. The device automatically performs calibration of the triaxial accelerometer to obtain vertical, antero-posterior, and left-right lateral directions during an initial period of standing upright or walking. The firmware algorithms on the electronic module process the raw signals and transmit a stream of physiological measures as encrypted data including heart rate, heart rate variability, respiration rate, skin temperature, posture, step, and fall detection via an encrypted BLE wireless protocol to a relay such as a smartphone, where the live streams of data can be viewed and stored. The physiological monitoring capabilities of patch sensor and its

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Takeaway

- The current study investigated the performance of chestworn wireless HealthPatch sensor for the continuous assessment of energy expenditure (EE) rate and total energy expenditure (TEE). The results showed excellent accuracy and agreement for the prediction of EE rates and TEE in a group of 32 individuals that represented balanced gender, and wide range of age and BMI.

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Psychological acute stress measurement using a wireless adhesive biosensor

Psychological acute stress measurement using a wireless adhesive biosensor

Nandakumar Selvaraj

Abstract— **Stress management is essential in this modern civilization to maintain one's stress level low and reduce health risks, since stress is one of the primary causes leading to major chronic health disorders. The present study investigates the validity of stress index (SI) metric that objectively quantifies the psychological acute stress using a disposable adhesive biosensor worn on the chest called as HealthPatch®. Eleven healthy volunteers (n=11) were attached with one HealthPatch sensor at left pectoralis major muscle along the cardiac axis to record modified Lead-II ECG. The subjects carried out a standard Trier Social Stress Test (TSST) protocol. During the study, the subjects filled out state anxiety form-Y1 of the State Anxiety Inventory questionnaire (sSTAI); salivary samples were obtained for salivary alpha-amylase (sAA) and salivary cortisol (sC) measurements; and the HealthPatch sensor data were wirelessly acquired. The data analyses revealed that sSTAI scores were significantly increased (P<0.001) due to TSST compared to the baseline. But, the changes in both sAA and sC measurements were not significant (P=0.281 and P=0.792, respectively). On the other hand, SI metric of HealthPatch showed significant (P<0.001) increase (~50%) during TSST, and shown to be sensitive to objectively track acute changes in psychological stress. Thus, HealthPatch biosensor can be valuable for continuous monitoring of psychological health and effective management of stress leading to healthy life.**

Index Terms— **Psychological stress, Heart rate variability, Trier Social Stress Test, State-Trait Anxiety Inventory.**

I. INTRODUCTION

Human body regulates its internal environment by various physiological processes, and maintains at a certain state of equilibrium called as homeostasis. Stress is referred to the disruption of homeostasis leading to a perturbed state of the human body. Stress can be triggered by various factors known as stressors including physical (e.g. diseases/illness, allergy, fatigue and poor sleep), psychological (e.g. conflicts, trauma, financial state and work/educational demands) and environmental (e.g. noise, crowd, disasters and pollution) influences. The human body's reaction to the stressors is called as stress response, which is predominantly regulated by hypothalamic-pituitary-adrenocortical (HPA) and sympathetic-adrenal-medullary (SAM) systems [1]. These systems interact by releasing stress hormones (glucocorticoids and catecholamines), and cause physiological changes including vasomotor tones, heart rate variability (HRV), blood pressure and sweat production at the body peripherals.

Stress is beneficial to manage the demands in work/education, drives to accomplish the goals/tasks efficiently, and generate fight-or-flight response in danger. On the other hand, stress is one of the primary causes leading to major chronic health disorders including diabetes, obesity, heart disease, gastrointestinal conditions, depression and anxiety problems [2]. Therefore, stress management is essential in this modern civilization to maintain one's stress level low, and reduce health risks.

Though there is no specific "Gold Standard" reference measurement has been established for stress, stress levels are generally assessed based on self-assessment using questionnaires e.g., State-Trait Anxiety Inventory (STAI), and perceived stress scale. Self-assessment is highly impractical for continual assessment, and it is also less reliable due to bias, random responding, and social compulsion to falsify the questionnaire responses to project a positive self-image.

Salivary-based noninvasive measurements such as salivary alpha-amylase (sAA) and salivary cortisol (sC) have been employed to objectively quantify the psychosocial stress response in individuals [1, 3]. The sensitivity and reliability of salivary measurements are limited due to number of factors including the sample volume [4], type of cotton rolls/swabs, and methodological issues such as time of sampling, assay conditions, storage and compliance to the protocol [5].

Stress can also be objectively detected using the physiological changes in blood pressure, heart rate (HR), HRV, galvanic skin response and pupil diameter [6]. Wearable smart sensors are widely used nowadays to capture the physiological and behavioral data in our day-to-day lives to correlate with stress. But, there are hardly any clinical-grade physiological monitors that can accurately quantify stress levels across individuals.

HealthPatch® is a clinically validated disposable medical device worn on the chest that remotely monitors single lead ECG, HR, HRV, breathing rate, skin temperature, step count, posture and fall detection [7, 8].

HealthPatch sensor also provides continuous assessment of changes in acute psychological stress levels as Stress Index (SI). The validity of SI metric for acute stress measurement is presently investigated compared to the standard self-assessment questionnaires and salivary-based biometrics.

II. MATERIALS AND METHODS

A. Study Group

The study recruited 11 volunteers (age: 47±17 years, body mass index: 24±4.6 and female/male: 6/5) from the local community of Palo Alto, CA, USA, through online and print media. The inclusion criteria included the age limits of 21−85 years and medical insurance coverage. The exclusion criteria included severe skin reaction to adhesives, current

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Takeaway

- In conclusion, HealthPatch's biometrics including vital signs and SI can provide feedback about the patient's stress levels, offer awareness about his/her state of mind, and has implications for prevention and detection of cardiac and stress related diseases. The study reveals that HealthPatch biosensor can be valuable for continuous monitoring of psychological health and effective management of stress leading to healthy life.

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Assessing fatigue and sleep in chronic diseases using physiological signals from wearables: A pilot study

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Assessing fatigue and sleep in chronic diseases using physiological signals from wearables: A pilot study

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Problems with fatigue and sleep are highly prevalent in patients with chronic diseases and often rated among the most disabling symptoms, impairing their activities of daily living and the health-related quality of life (HRQoL). Currently, they are evaluated primarily *via* Patient Reported Outcomes (PROs), which can suffer from recall biases and have limited sensitivity to temporal variations. Objective measurements from wearable sensors allow to reliably quantify disease state, changes in the HRQoL, and evaluate therapeutic outcomes. This work investigates the feasibility of capturing continuous physiological signals from an electrocardiography-based wearable device for remote monitoring of fatigue and sleep and quantifies the relationship of objective digital measures to self-reported fatigue and sleep disturbances. 136 individuals were followed for a total of 1,297 recording days in a longitudinal multi-site study conducted in free-living settings and registered with the German Clinical Trial Registry (DRKS00021693). Participants comprised healthy individuals (N = 39) and patients with neurodegenerative disorders (NDD, N = 31) and immune mediated inflammatory diseases (IMID, N = 66). Objective physiological

Takeaway

- The patch measures correlated with fatigue and sleep PROs, while demonstrating reasonable signal quality. Furthermore, analysis of heart rate recovery estimated during activities of daily living showed significant differences between healthy and patient groups. This work underscores the promise and sensitivity of novel digital measures from multimodal sensor time-series to differentiate chronic patients from healthy individuals and monitor their HRQoL. The presented work provides clinicians with realistic insights of continuous at home patient monitoring and its practical value in quantitative assessment of fatigue and sleep, an area of unmet need.

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