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Assessing the use of a noninvasive monitoring system providing multiple cardio-pulmonary parameters following revascularization in STEMI patients

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Abstract

Background: Continuous monitoring of ECG, respiratory rate, systolic and diastolic blood pressure, pulse rate, cardiac output, and cardiac index is important in patients with ST-elevation myocardial infarction (STEMI) admitted to the intensive cardiac care unit (ICCU). However, monitoring these parameters in this setting and in these patients using noninvasive, wireless devices has not been conducted so far. We aimed to assess the use of a novel noninvasive continuous monitoring device in STEMI patients admitted to the ICCU.

Methods: Participants included STEMI patients that were admitted to the ICCU after primary percutaneous coronary intervention (PPCI). Patients were continuously monitored using a novel wearable chest patch monitor.

Results: Fifteen patients with STEMI who underwent PPCI were included in this study. The median age was 52.8 years, the majority were males, and the median body mass index (BMI) was 25.7. Monitoring lasted for 66 ± 16 hours, and included the automatic collection and recording of all vitals, freeing the nursing staff to focus on other tasks. The user experience of nurses as reflected in filled questionnaires showed high satisfaction rates in all aspects.

Conclusion: A novel noninvasive, wireless device showed high feasibility in continuously monitoring multiple crucial parameters in STEMI patients admitted to the ICCU after PPCI.

Keywords

Remote patient monitoring, noninvasive wireless device, acute coronary syndrome, ST-elevation myocardial infarction, intensive cardiac care unit

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Introduction

Heart disease is the leading cause of death worldwide.[1] Each year in the United States alone, more than one million patients are hospitalized due to myocardial infarction.[2] Primary percutaneous coronary intervention (PPCI) is the preferred reperfusion strategy in patients with ST-elevation myocardial infarction (STEMI) within 12 hours of symptoms onset.[3–5]

Following reperfusion, it is recommended to admit STEMI patients to an intensive cardiac care unit (ICCU) with

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continuous monitoring of ECG for detection of arrhythmias, assess the respiratory rate (RR), evaluate the hemodynamic status, especially for signs and symptoms of heart failure, and provide specialized care. Occasionally, invasive hemodynamic monitoring is required in critically ill patients, even though such intervention carries a risk for complications.[6,7] In this study, we assessed the use of a novel noninvasive monitor providing multiple cardio-pulmonary parameters in STEMI patients after PPCI, hospitalized in the ICCU.

Materials and methods

Study design and overview

This was an observational prospective cohort study with a retrospective analysis of the data. Adult patients (≥18 years old) with STEMI admitted to the ICCU of the Edith Wolfson Medical Center, Holon, Israel, immediately after PPCI, and capable to provide consent, were included in this study. Patients were monitored continuously using noninvasive, wireless photoplethysmography (PPG)-based chest monitors (BB-613WP, BioBeat, Petach Tikva, Israel). The monitor was attached and activated immediately after PPCI. The device automatically collected and recorded physiological parameters every 5 minutes, and transmitted them wirelessly in real-time through Bluetooth Low Energy (BLE) to a gateway device, and from there through Wi-Fi to a cloud-based medical management application available to the health care providers on a dedicated desktop computer located in the ICCU nurse station. There was no need to install any program, and any web-enabled computer can display the vital signs in real time and provide alerts. Exclusion criteria included the presence of a permanent pacemaker, pregnancy, patients under the age of 18 years, and individuals unable or unwilling to provide informed consent. The physiological data obtained by the devices were analyzed retrospectively and were crossed with the demographic and clinical data recorded in the medical center's electronic medical record (EMR). The study was approved by the local Institutional Review Board (0198-20-WOMC, NCT04635371).

Study procedures and interventions

Immediately following PPCI and signing an informed consent form, each patient was connected to the chest-patch monitor. The physiological parameters were collected in a dedicated research room within the ICCU (Figure 1). Following the collection phase, data were analyzed retrospectively by the research team, without influencing the routine of the medical staff in the ICCU. A questionnaire was provided to 12 ICCU nurses attending the patients, in order to assess the novel monitoring platform.

The wearable monitoring devices

The monitoring devices used in the study employ reflective PPG technology, in which specific wavelengths of light are transmitted onto the skin, and the reflected light is collected by a photodiode detector positioned near the light source transmitter. The sensor tracks vital signs derived from changes in the pulse contour, following a simple offset baseline calibration process using an approved noninvasive, cuff-based device, and is based on Pulse Wave Transit Time technology combined with Pulse Wave Analysis. The device measures vital signs that include cuffless systolic and diastolic blood pressure (BP), pulse rate (PR), RR, blood oxygen saturation (SpO_2), stroke volume (SV), cardiac output (CO), cardiac index (CI), systemic vascular resistance (SVR), body temperature, single-channel ECG, and more (as previously described and validated).[8,9] The platform also provides the trends of each vital sign and alerts, including an early warning score. Patients were monitored throughout hospitalization, and sensors were replaced if hospitalization lasted longer than the 5-day battery life. The same sensors were not used to monitor different patients.

Statistical analysis

Endpoints were defined as assessing the wearable device's capability in tracking changes in physiological parameters of patients following PPCI, and the comfort of use as assessed by the ICCU health care providers (physicians and nurses).

Results

Fifteen patients with ACS-STEMI who underwent PPCI were included for assessment, with monitoring lasting for a period of 66 ± 16 hours. The majority of the patients were males (14, 93.3%), the median age was 52.8 years (41–72), and the median body mass index (BMI) was 25.7 (18.52-34.68 kg/m2). Eight of the 15 patients (53.3%) had an anterior wall STEMI and seven patients had an inferior wall STEMI. Patients' characteristics are summarized in Table 1.

There were no major adverse events while using the wearable monitor. The chest-patch monitor demonstrated high compliance among both the medical team and the patients by being noninvasive and wireless. There was no need for special training for the nursing staff on how to use and apply the wearable monitor, it was easy and simple to use, and well-accepted among our medical staff. Table 2 includes the results of the questionnaire answered by 12 nurses, showing high satisfaction rates on all aspects included, such as simplicity and ease of use (average ± SD of 1.17 ± 0.39), reduced direct contact with patients (1.83 ± 0.94), operation time (1.75 ± 1.14),

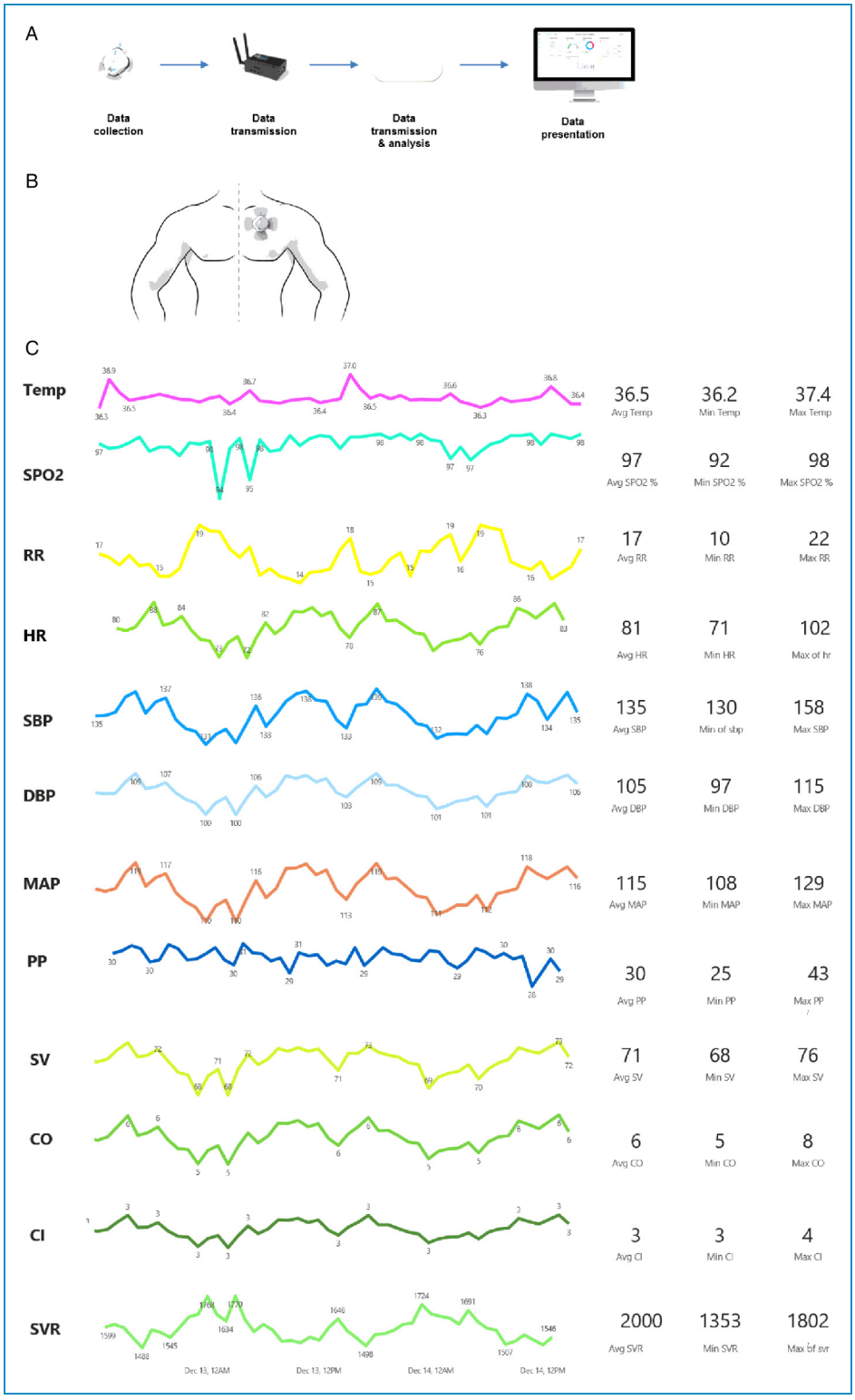

Figure 1. The remote patient monitoring system used in the study. (A) The architecture of the wearable monitoring system; (B) a figure showing the device and its positioning on a patient's chest; (C) a monitoring sample of the photoplethysmography-based device with mean values in a single patient.
Abbreviations: Temp, temperature; SPO2, blood oxygen saturation; RR, respiratory rate; HR, heart rate; SBP, systolic blood pressure; MAP, mean arterial pressure; DBP, diastolic blood pressure; SV, stroke volume; CO, cardiac output; SVR, systolic vascular resistance.

Table 1. Demographic data of the participants.

Patient	Age	Sex	BMI	Infarct location
1	72	Male	18.52	Lateral STEMI
2	58	Male	26.73	Inferior STEMI
3	45	Male	24.76	Anterior STEMI
4	44	Male	26.23	Inferior-posterior STEMI
5	60	Male	20.38	Anterior STEMI
6	54	Male	27.00	Anterior STEMI
7	65	Female	34.2	Anterior STEMI
8	47	Male	25.82	Inferior-lateral STEMI
9	56	Male	19.0	Inferior STEMI
10	52	Male	28.7	Inferior STEMI
11	56	Male	26.0	Inferior STEMI
12	41	Male	24.69	Anterior-lateral STEMI
13	45	Male	31.35	Anterior STEMI
14	58	Male	34.68	Anterior-lateral STEMI
15	66	Male	24.16	Inferior STEMI

STEMI, ST elevation myocardial infarction; BMI, body mass index.

and the willingness to replace currently-used legacy devices (2.00 ± 0.60). Importantly, the wearable monitor permitted noninvasive, wireless, continuous monitoring of multiple parameters in real-time transmitted to the nursing station and shared by the medical team, enabling them to monitor the hemodynamic status of the patients. Furthermore, we found that the wearable monitor had the capability of allowing the medical team to recognize the trend, detect, and follow changes in various parameters (Figure 1).

Discussion

The concept of having a coronary care unit phase, which began in the mid-1960s, emphasizes the importance of early detection and management of cardiac arrhythmias in ACS patients based on the development of monitoring and defibrillation capabilities. The later introduction of the pulmonary artery balloon flotation catheter allowed for bedside hemodynamic monitoring and direct invasive hemodynamic management.[10]

The novel noninvasive PPG-based chest-patch monitor presented in this article has the advantage of providing frequent intermittent monitoring of multiple parameters, showing its safety and simplicity without the need for extensive medical training. The device is applied to the upper left chest and requires a single baseline calibration of BP using a cuff-based device.

This is the first case series performed in the ICCU, enrolling STEMI patients and revealing the feasibility of such a novel noninvasive monitor to provide remote patient

Table 2. The questionnaire filled by the ICU nurses, working with the novel monitoring device.

Question/nurse	1	2	3	4	5	6	7	8	9	10	11	12	Average ± SD
Ease and simplicity of use?	2	1	1	1	1	1	1	2	1	1	1	1	1.17 ± 0.39
Ease of connecting and attaching the device?	2	1	1	1	1	1	2	2	2	2	1	1	1.42 ± 0.51
Satisfaction with the time it takes to connect the device?	1	1	1	1	1	1	2	2	2	2	2	1	1.42 ± 0.51
Does the device provide less contact time with the patient?	2	1	3	2	4	1	2	1	2	2	1	1	1.83 ± 0.94
Does the device have a relevant amount of operation time?	1	2	1	1	1	1	2	2	4	4	1	1	1.75 ± 1.14
Willingness to replace other currently used devices with this device?	2	2	3	2	2	3	1	2	2	2	1	2	2.00 ± 0.60
What was your overall satisfaction with the device?	2	2	2	1	1	2	2	2	2	2	1	1	1.67 ± 0.49
Was the device safe for use?	1	1	1	1	1	1	1	1	2	2	1	1	1.17 ± 0.39

12 nurses completed the questionnaire.
1–very high satisfaction/agreement; 5–very poor satisfaction/agreement.

monitoring, and allow the practitioner to see various physiological parameters at the same time. The monitor has the advantage of providing advanced monitoring capabilities in a variety of clinical settings, including the ICCU setting and cardiogenic shock while using only a single chest patch monitor. The device monitors BP, PP, MAP, HR, SpO2, RR, SV, CO, CI, SVR, Temp, and single channel ECG, while using a wireless, simple and friendly-operated form factor with no need for multiple cables and additional monitors surrounding the patients, thus ensuring the STEMI patient a calm and relaxing environment when compared with the standard devices used today. The major benefits of continuous measurements of vital signs are the ability to track hemodynamic changes as compared with the standard measurement devices, allowing early detection and recognition of instability and deterioration, and leading to prompt intervention in critically ill patients including cases with cardiogenic shock. Hemodynamic monitoring by noninvasive methods could reduce the morbidity and mortality seen with invasive devices such as the arterial line and Swan Ganz catheters, which despite being the gold standard measurement technique within ICCUs, are associated with a high prevalence of infection and local vascular damage. The wearable monitor provides alerts and an early warning score system. It reduces the involvement needed by health care providers. This has the potential to decrease the number of nurses per shift where there is a lack of medical staff and in highly-active departments, thus helping to reduce the economic burden. Hemodynamic monitoring of SV, CO, CI, and SVR is useful in STEMI patients, allowing early detection of deterioration, potentially improving prognosis, and increasing in-hospital safety for this patient population.[11–14]

The monitor has a major impact on reducing infection transmission, especially with the current SARS-CoV-2 pandemic, emphasizing the importance of wireless and noninvasive devices for remote patient monitoring, requiring minimal contact by the medical teams while keeping continuous hemodynamic monitoring.

The use of such advanced monitoring devices could be implemented not only in the ICCU but also in the general ward, in which it would be of value due to the workforce shortage and high burden of work. Further studies are being considered to compare standard monitoring devices and noninvasive chest patch monitoring devices in STEMI patients.

The main limitation of the study is the small number of patients included. However, as this was a preliminary proof of concept study, it still achieved all of the goals set forth.

Conclusions

In this preliminary proof of concept study, we have evaluated for the first time a noninvasive, wireless monitoring device in STEMI patients admitted to the ICCU. We found this strategy to be feasible and well accepted by nursing staff, and it provided valuable information above and beyond the routinely monitored parameters.

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