Feasibility and Usability of Patch-based Continuous Cardiac Rhythm Monitoring in Comparison with Traditional Telemetry in Noncritically Ill Hospitalized Patients

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ABSTRACT. Research on traditional cardiac telemetry demonstrates that excessive alarms are related to lead failures and noise-related interruptions. Patch-based continuous cardiac rhythm monitoring (CCRM) has emerged in outpatient ambulatory monitoring situations as a means to improve recording fidelity. In this study, patients hospitalized but not in the intensive care unit were simultaneously monitored via telemetry in parallel with the use of the Vital Signs Patch™ (VSP) CCRM system (LifeWatch Services, Rosemont, IL, USA), applying standardized monitoring and notifications provided by an off-site central monitoring unit (CMU). Among 11 patients (55% male; age: 66.8 ± 12.5 years), there were 42 CMU detections and 98 VSP detections. The VSP device was successfully applied by nursing with connectivity established in all 11 patients (100%). There were no VSP device–related adverse events or skin eruptions during the study. The CMU agreed with 59 (60%) of 98 VSP detections. Among those detections marked by disagreement 30 (77%) of 39 VSP detections were related to clinically meaningful arrhythmias (atrial: n = 9; ventricular: n = 7; brady-: n = 14) undetected by VSP due to noise. In two patients (18%), there were four clinically meaningful atrial fibrillation detections not recorded by the CMU. In conclusion, patch-based CCRM requires further development and review to replace traditional cardiac telemetry monitoring but could evolve into an appropriate method to detect clinically meaningful events missed by traditional methods if noise issues can be mitigated.

KEYWORDS. Alarm fatigue, cardiac telemetry, continuous cardiac monitoring, patch monitoring.

Introduction
Several hospital-based studies to date have demonstrated that routine electrocardiographic telemetry monitoring results in a high volume of alarms without immediate clinical relevance. This has led to a form of clinical desensitization, referred to as alarm fatigue, which has been attributed to several negative clinical outcomes including death. At the Cleveland Clinic, the utilization of an off-site central monitoring unit (CMU) that applies standardized cardiac telemetry indications in hospitalized patients not admitted to the intensive care unit (ICU) was associated with improved clinical outcomes. The CMU provided accurate and early notification in 79% of emergency response team (ERT) activations, with a 93% return of spontaneous circulation when CMU monitoring
technicians applied discretionary direct ERT communication in advance of an impending cardiopulmonary arrest.\(^4\) However, around 42% of CMU notifications were the result of occurrences such as lead failure and telemetry disruption.\(^4\) Such telemetry disruptions render patients vulnerable to undetected clinically relevant arrhythmias or hemodynamic events. The fidelity of electrode connections has been identified as a major contributor to telemetry disruptions in previous studies.\(^3\)\(^-\)\(^5\) Patch-based continuous cardiac rhythm monitoring (CCRM) has emerged in the outpatient setting as a useful clinical tool for the quantification and surveillance of bradyarrhythmias and tachyarrhythmias.\(^6\)\(^-\)\(^7\) These patch-based CCRM devices have been studied in the outpatient setting as an alternative to traditional Holter monitoring and have emerged as feasible and patient-friendly options for the detection of clinically meaningful arrhythmias.\(^8\)\(^-\)\(^9\) The present study sought to evaluate the feasibility and usability of the Vital Signs Patch\(^\text{TM}\) (VSP) CCRM system (LifeWatch Services, Rosemont, IL, USA) in non-ICU–hospitalized patients against the outcomes achieved with the current standard of conventional telemetry monitoring. The primary goal of this research was to elucidate early feasibility and usability characteristics of the aforementioned VSP device (including any skin-related adverse events) and to investigate its capacity to detect clinically meaningful arrhythmias while potentially decreasing the number of alarms due to telemetry interruptions by way of its novel skin fixation mechanism.

**Materials and methods**

**Patients**

Between August 2015 and December 2015, 11 non-ICU–hospitalized patients underwent CCRM simultaneously with use of the VSP device and traditional telemetry systems in parallel, applying standardized monitoring criteria and notifications provided by a monitoring technician located at an off-site CMU to bedside nursing personnel using a previously published protocol.\(^4\) The CMU is referred to as “secondary” monitoring because it does not replace “primary” monitoring alarms in the form of audible alerts occurring at the nursing station, but rather aims to ensure that clinically important alarms are not missed by bedside nursing personnel. Pediatric patients, pregnant individuals, patients with internal or external defibrillators, patients with extensive skin damage or fresh surgical incisions on the chest, and patients in critical care areas were excluded from participation in this study. The present investigation followed the relevant institutional review board policies, and written informed consent was obtained from all patients. The initial single-center study plan called for a minimum of 10 patients receiving telemetry monitoring for the early feasibility and usability assessment, followed by a larger enrollment of 25 patients; however, this latter initiative was discontinued when the manufacturer discontinued the product as a result of evolving business considerations.

**Devices and monitoring protocols**

The VSP device considered in this study was a United States Food and Drug Administration–approved multichannel [three-lead electrocardiogram (ECG)] patch-based CCRM system. It is also designed to monitor and record blood saturation, body temperature, respiration, and blood pressure, but these parameters were not assessed in the present research (Figure 1). The data from the VSP CCRM system were stored on the manufacturer’s secure server on the premises of the Cleveland Clinic and under its firewall in compliance with institutional data security policies. After the end of the study, the raw data underwent technical review for report generation and were made available to the investigators for review. The report included the specifics of arrhythmia detection and raw ECG waveforms for every instance of detection by the VSP CCRM system. The investigators compared data from the CMU flow sheet, which contained the specifics of conventional telemetry detections and included raw ECG waveforms of every detection.

**Analysis**

The data from the VSP CCRM and the CMU using traditional telemetry were first aligned according to their...
Cardiac electrophysiologist was then provided blinded rhythm strips for final approval. Adjudicated interpretations of the VSP data and CMU interpretations were subsequently evaluated for agreement.

Results

Feasibility and usability

Eleven patients were monitored simultaneously via the VSP CCRM system and conventional cardiac telemetry monitoring using notifications provided by the CMU. Table 1 shows the baseline clinical characteristics of the study cohort. The VSP device was successfully applied by nursing staff, with connectivity established in all 11 patients (100%). There were no VSP-related adverse events or skin eruptions that occurred during the period of the study. There were 42 triggered CMU detections and 98 triggered VSP detections (Figure 2 and Table 2).

In all 42 CMU detections, the real-time interpretation assigned by the monitoring technician agreed with the over-read interpretation assigned by the resident physician investigator as well as the blinded electrophysiologist over-read.

VSP detections

Out of the 98 VSP detections, agreements were established between the VSP and the CMU in 59 (60%) of the detections. The CMU did not agree with 39 (40%) of the VSP detections (Figure 3). The overwhelming majority of those disagreements were related to VSP noise artifacts, while the on-site telemetry was recording interpretable

Table 1: Baseline Clinical Characteristics for the Study Cohort (n = 11)

| Patient demographics                          |          |
|----------------------------------------------|----------|
| Age                                          | 66.8 ± 12.5 years |
| Male gender                                  | 6 (55%)  |
| Clinical characteristics                      |          |
| Hypertension                                 | 5 (45%)  |
| Diabetes                                     | 1 (9%)   |
| Coronary artery disease                      | 1 (9%)   |
| History of AF/AFL                            | 10 (90%) |
| Indication for telemetry                     |          |
| Postelectrophysiology procedure              | 6 (55%)  |
| Initiation of antiarrhythmic drug therapy    | 5 (45%)  |

AF: atrial fibrillation; AFL: atrial flutter. Values are presented as either means ± standard deviations or n (%).

Figure 2: Total number of detections on the VSP (n = 98) and the CMU (n = 59), with respective distributions of concordance (blue) and discordance (orange) when compared with one another.
Table 2: Overview of all CMU- and VSP-triggered Events for the Study Patients (n = 11) Alongside the Results of Detection from the Corresponding Modality

| Patient Number | CMU-triggered Event(s) | VSP Correlation? | VSP-triggered Event(s) | Telemetry Correlation (± CMU Notification*)? |
|----------------|------------------------|------------------|------------------------|--------------------------------------------|
| 1              | None                   | N/A              | 2 noise events         | 2 cases of normal sinus rhythm             |
|                |                        |                  | 4 noise events         | 4 cases of sinus bradycardia (no CMU notification) |
| 2              | None                   | N/A              | None                   | N/A                                        |
| 3              | None                   | N/A              | None                   | N/A                                        |
| 4              | 2 sinus bradycardia events | 2 cases of noise | 10 noise events        | 10 cases of sinus bradycardia (no CMU notification) |
| 5              | 1 asystole event        | 1 case of noise  | 1 noise events         | 1 case of normal sinus rhythm              |
| 6              | 3 sinus bradycardia events | 3 cases of noise | 3 atrial arrhythmia events | 3 cases of lead failure (no CMU notification) |
|                |                        |                  | 1 ventricular arrhythmia event | None                                      |
| 7              | 2 sinus bradycardia events | 2 cases of noise | 9 noise events         | 9 cases of atrial arrhythmia (no CMU notification) |
| 8              | None                   | N/A              | 1 noise event          | 1 case of normal sinus rhythm              |
| 9              | None                   | N/A              | None                   | N/A                                        |
| 10             | 1 ventricular arrhythmia event | 1 case of noise | 7 noise events         | 7 cases of ventricular ectopy (no CMU notification) |
| 11             | 1 lead failure event    | 1 case of normal sinus | 1 noise event       | 1 case of normal sinus rhythm              |
|                | 2 ventricular arrhythmia event | 2 cases of noise | 1 atrial arrhythmia event | 1 case of lead failure (no CMU notification) |
| Total          |                        |                  | 13                     | 39                                         |

*In the case of VSP-triggered events, the last column also indicates whether the CMU provided clinical notification for what was detected on telemetry.

Figure 3: Pie graph characterizing the VSP detections that were discordant with the CMU (n = 39; 40%). The majority resulted from VSP noise detection during CMU detection of sinus rhythm (13%), atrial arrhythmia (23%), ventricular arrhythmia (18%), and sinus bradycardia (36%). However, four VSP detections (10%) resulted from atrial arrhythmias undetected by the CMU.

waveform data (n = 35; 90%) (Figure 3). Accordingly, the telemetry captured normal sinus rhythm (13%), atrial arrhythmia (23%), ventricular arrhythmia (18%), and sinus bradycardia (36%) during VSP noise (Table 2). Significantly, none of the above telemetry detections resulted in a CMU detection and notification. The CMU essentially learned to ignore baseline rhythm abnormalities with the help of feedback from the nursing staff. However, in 10% (four detections) of the discordance, the VSP recorded atrial arrhythmias that were not also detected by the CMU due to lead failure at the time of arrhythmia detection.

CMU detections (traditional telemetry)

Out of the 42 CMU detections, there was discordance between the VSP and the CMU in the case of 13 (31%) (Figure 4). Most of the instances of discordance (n = 12/13;
the status quo of traditional telemetry monitoring again
fidelity of waveform recording, not worsen it. However,
to continue to see opportunities to challenge the gold standard
receiving telemetry monitoring was achieved, but the
principal aim of assessing the early feasibility and
usability of patch-based monitoring for non-ICU patients
monitoring. Thus, these preliminary findings suggest that a
better patch monitor could potentially detect arrhythmia
events missed by the status quo and also have recorded
interpretable ECG data during the interruption of tradi-
tional telemetry detection.

To our knowledge, this is the first study to evaluate patch-

based monitors in the inpatient setting. In a study by
Barrett et al. comparing a 14-day monitoring protocol
with the Zio patch (iRhythm Technologies, San Francisco,
CA, USA) and conventional 24-hour Holter monitoring in
the outpatient setting, the former detected 57% more clini-
cally significant events but was found to be less sensitive
in the detection of events during the first 24 hours of dual
monitoring, when the multilead Holter connections were
still very robust. In our study, the number of VSP detec-
tions was higher than the number of CMU detections
because the VSP detected baseline rhythm abnormalities
that were not generally clinically meaningful. Meanwhile,
the CMU employed reprogrammed patient-specific alarm
thresholds as determined by the nursing staff to mitigate
the number of unactionable alarms, which is a routine care
protocol in our institution. For example, one of the study
patients experienced an elevated burden of premature
ventricular contractions (PVCs) at baseline that did not
require clinical action. Communication between the nurs-
ing and the CMU had resulted in a higher patient-spe-
cific threshold of 20 PVCs/minute or more for the alarm,
which resulted in a marked alarm reduction for the CMU
as compared with the VSP system for that patient, which
used its nominal settings. It should be noted that this
reflects the standard workflow of the CMU and could per-
haps be judged to be unfair to the VSP given the locked-in
nature of its nominal settings. A similar patient-specific
alarm parameter detection method could be applied to
future-state patch monitors in the instance of live patient
monitoring. Thus, this barrier could be easily overcome.

Study limitations

Our study has several limitations that are important to
bring up. The first limitation was the feasibility sample
size. This study could be completed only in 11 patients
instead of the proposed 25 patients because the VSP
device was withdrawn from the market by the manu-
facturer. The second limitation is that the study was con-
ducted in a single center, which limits the generalizability
of its findings.

Conclusion

The principal aim of assessing the early feasibility and
usability of patch-based monitoring for non-ICU patients
receiving telemetry monitoring was achieved, but the
overall results were quite disappointing. The authors con-
tinue to see opportunities to challenge the gold standard
of conventional cardiac telemetry monitoring. However,
it is abundantly clear that patch-based CCRM requires
further development and refinement to replace tradi-
tional cardiac telemetry monitoring, with a focus on better
fidelity of ECG recording. Still, the technology could one day evolve to detect clinically meaningful events missed by traditional methods if noise issues are mitigated. With the ongoing novel advances in both the areas of hardware and software in wireless cardiac monitoring technology, we believe that an opportunity to improve the existing telemetry infrastructure exists. An ideal patch monitor should have a high degree of recording fidelity, allow for real-time analysis of ECG waveforms, and be patient- and nursing-friendly. As patch monitoring–based technology continues to evolve, more large-scale trials are required to validate device safety, efficacy, and cost-effectiveness in relation to conventional monitoring.

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