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Evaluation of the Analytic for Hemodynamic Instability as A Prediction Tool for Early Identification of Patient Deterioration

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***Abstract*—**Unrecognized or delayed identification of patient deterioration is a key cause of in-hospitals adverse events. Clinicians rely on vital signs monitoring to recognize patient deterioration. However, due to ever increasing nursing workloads and the manual effort required, vital signs tend to be measured and recorded intermittently, and inconsistently causing large gaps during patient monitoring. Additionally, during deterioration, the body's autonomic nervous system activates compensatory mechanisms causing the vital signs to be lagging indicators of underlying hemodynamic decline. This study analyzes the predictive efficacy of the Analytic for Hemodynamic Instability (AHI) system, an automated tool that was designed to help clinicians in early identification of deteriorating patients. The lead time analysis in this retrospective observational study assesses how far in advance AHI predicted deterioration prior to the start of an episode of hemodynamic instability (HI) becoming evident through vital signs? Results indicate that of the 362 episodes of HI in this study, 308 episodes (85%) were correctly predicted by the AHI system with a median lead time of 57 minutes and an average of 4 hours (240.5 minutes). Of the 54 episodes not predicted, AHI detected 45 of them while the episode of HI was ongoing. Of the 9 undetected, 5 were not detected by AHI due to either missing or noisy input ECG data during the episode of HI. In total, AHI was able to either predict or detect 98.9% of all episodes of HI in this study. These results suggest that AHI could provide an additional 'pair of eyes' on patients, continuously filling the monitoring gaps and consequently giving the patient care team the ability to be far more proactive in patient monitoring and adverse event management.

***Keywords*—**Clinical deterioration prediction, decision support system, early warning system, hemodynamic status, physiologic monitoring.

I. Introduction

IN-hospital adverse events continue to be a major challenge for health care facilities. Management of these adverse events can be an expensive problem [1]. Between 34.3 and 83% of in-hospital adverse events are considered preventable (median: 51.2%) [2]. A key aspect to this is unrecognized or delayed identification of patient deterioration [3], [4]. Vital signs are a critical component that clinicians rely on to recognize patient deterioration. Derangement of vital signs, particularly heart rate and blood pressure, are shown to be associated with HI and emergence of shock [5]. Prolonged episodes of HI can result in serious complications including acute cerebral infarction, intracranial hemorrhage, myocardial infarctions, and renal failure [6]. Therefore, predicting or identifying signs of hemodynamic deterioration at the earliest is crucial to support appropriate pre-emptive clinical actions that are required to reduce adverse patient events and outcomes. However, vital signs are typically inadequately monitored and recorded, even in high-dependency units [7]. Measuring and recording of vital signs have been and continue to remain intermittent, inconsistent, and error-prone in practice [8], [9]. Due to ever increasing workloads and the manual effort required, vital signs measurement forms a burden to the nursing workforce [10]. Even with hourly vital sign measurement protocols, patients' health can deteriorate unnoticed during the large gaps between measurements [11]. In fact, in a large multi-site observational study, it was identified that 44% of vital signs observations were classified as missed and 53.5% of observations were delayed for high acuity patients [12]. This issue is further compounded by the fact that vital signs can be lagging indicators of hemodynamic deterioration [13]. During hemodynamic impairment, the mechanisms of the autonomic nervous system induce compensatory action in the body to maintain homeostasis, or normal vitals. These 'normal' vitals can mask the underlying deterioration until the compensatory mechanism is overwhelmed. When vital signs do fall out of normal range, unmasking the underlying progression of deterioration tends to be late in the process requiring drastic interventions to support the patient.

Early warning scores such as Shock Index, Modified Early Warning System, and National Early Warning Score have failed to achieve widespread success or adoption [14]-[16]. This is because they not only require multiple sources of data as input, including manual nursing assessments and labs, but also rely on clinician-captured vital signs. Thus, they suffer from similar issues of other lagging indicators, being intermittent, error prone, and inconsistent between hospitals.

There is clearly a need for a simple clinical decision support system that predicts hemodynamic deterioration in patients well before it is evident through vital signs. The opportunity is to realize clinically actionable lead times for preemptive intervention. This study analyzes the AHI system [17] that was designed to help clinicians in early identification of deteriorating patients. The AHI system is a US-FDA cleared software as a medical device.

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II. Methods

A. Definition of Episodes of HI

It has been clinically recognized that a combination of hypotension (low blood pressure) and tachycardia (high heart rate) can ensue in any type of shock [5]. Requiring the simultaneous presence of both tachycardia and hypotension reflects a conservative definition of HI and requiring this state to be sustained for at least 10 continuous minutes indicates that the vital signs derangement is clinically significant [18]. Thus, this study defines an episode of HI as 10 continuous minutes or more where both hypotension and tachycardia are present; hypotension is defined as systolic blood pressure < 90 mmHg or mean arterial pressure < 70 mmHg, and tachycardia as heart rate ≥ 100 bpm. These thresholds for the vitals considered for this study are based on several contemporary medical reviews [19]-[23].

B. Analysis

The AHI system uses a single lead of ECG (Lead-II) from routinely collected ECG monitor data to generate a simple binary output (red-tall bar for HI or green-short bar for hemodynamic stability) and is automatically updated every two minutes (Fig. 1). Additionally, AHI assesses the input ECG data's quality, and produces a gray or black bar below the axis to indicate noisy or missing ECG data, respectively. A more detailed description of the AHI system can be found in [17], where its application for the rapid response team activation is explored.

The lead time analysis in this retrospective observational study assesses the following question: How far in advance (prediction) did AHI indicate signs of HI (red bar) prior to the start of an episode of HI becoming evident through vital signs? Some patients have multiple episodes of HI during a given encounter. To eliminate bias due to correlation between subsequent episodes, only lead times associated with the onset of the first episode of HI during AHI monitoring for each encounter are considered in calculating lead-time statistics. Reporting the lead time only of the first episode of HI provides a conservative measure of AHI's ability to predict the crucial onset of such episodes.

For computing the lead time, the onset of the first HI episode for a given patient encounter is first identified. Looking back in time from this onset time toward the start of AHI monitoring, the first time where AHI shows majority (> 80%) red bars is then computed. The duration between this first time and the onset time is calculated as the lead time for the given patient encounter's episode (Fig. 1 - adapted from [17]).

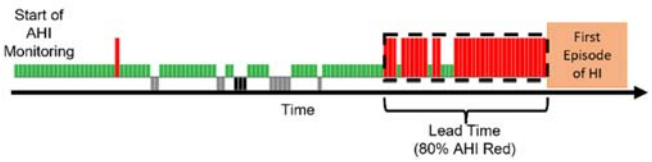

Fig. 1 AHI outputs and its lead time computation [17]

C. Study Setting

This was a pilot retrospective single-center observational cohort study conducted at Michigan Medicine, the University of Michigan's quaternary care academic health system. A waiver of patient consent was granted by the University of Michigan Institutional Review Board (IRB) as the study analysis utilized retrospective de-identified data.

D. Data

The Study Dataset included 1,180 consecutive hospitalized adult (≥ 18 years) patients' encounters between August 2019 through April 2020 who had both a continuous ECG and invasive arterial blood pressure monitoring in the Intensive Care Unit (ICU) setting. Having the arterial blood pressure monitoring data is critical because this provides continuous granular blood pressure data that are required for precisely identifying the onset of an episode of HI. The Max Harry Weil Institute for Critical Care Research and Innovation, at the University of Michigan, maintains a unique high resolution physiologic signal collection system capable of storing all continuous physiological waveform measures. For this study the following signals were stored and analyzed: ECG lead-II (120-240 Hz), heart rate (0.5 Hz), mean arterial pressure (0.5 Hz), and systolic arterial pressure (0.5 Hz). Only ECG data were used as input for the AHI algorithm, while the heart rate and blood pressure values were used to identify the onset of episodes of HI.

Of the 1,180 patient encounters data collected, 441 patients (37.4%) experienced at least one episode of HI. Of this subset, 79 patients (17.9%) had an episode within the first 30 minutes of when AHI monitoring began, curtailing an opportunity for lead time computation due to insufficient ECG data, and were therefore excluded. Of the remaining 362 (82.1%) Eligible Patient encounters, only their first episode of HI was considered in the lead time analysis (Fig. 2).

TABLE I
Demographic Characteristics of the Eligible Patient Set

Characteristic	Total Analysis Set (N = 362)
Gender	
Male, n (%)	216 (59.7)
Female, n (%)	146 (40.3)
Age (Years)	
Mean (SD)	61.5 (16.4)
Race, n (%)	
White	288 (79.6)
Black or African American	48 (13.2)
Asian	9 (2.5)
Unknown or not reported	9 (2.5)
Other	5 (1.4)
American Indian or Alaska Native	2 (0.5)
Native Hawaiian and Other Pacific Islander	1 (0.3)
Ethnicity, n (%)	
Hispanic	10 (2.7)
Non-Hispanic	338 (93.4)
Unknown or not reported	14 (3.9)

The Eligible Patient set (362 patient encounters) had an

average age of 61.5 years with 40% female patients. The racial and ethnic distribution of the dataset are representative of Michigan Medicine's patient population.

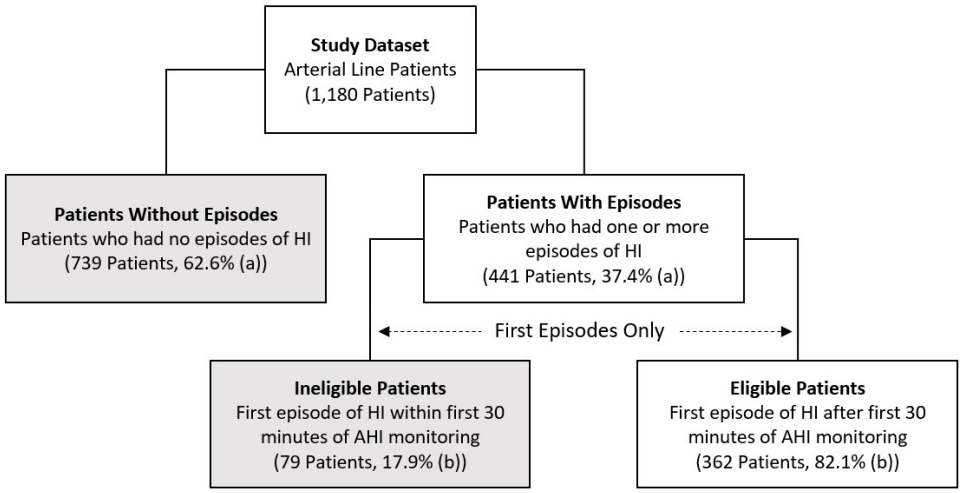

Fig. 2 Consort diagram of data used in this study: (a) Percentage based on Study Dataset (N = 1,180); (b) Percentage based on Patients with Episodes subset (N = 441)

III. Results

Table II shows the number and duration of all first episodes of HI as identified using continuous vital signs (heart rate and blood pressure) across the 362 Eligible Patient encounters.

TABLE II
ALL FIRST EPISODES OF HI

Characteristic	Statistic
All First Eligible Episodes of HI (N)	362
Episode Duration	
Median [25th, 75th] (minutes)	20 [12, 40]
Mean, Std. Dev. (minutes)	35.28, 56.99
Min, Max (minutes)	10, 816

The median duration of these episodes of HI was 20 minutes with a maximum of 13.6 hours (816 minutes). Only 25% of the episodes of HI lasted more than 40 minutes, while the rest 75% of the episodes lasted 40 minutes or less.

The ability of the AHI system to predict the first episode of HI is described in Table III.

TABLE III
AHI PREDICTION OF FIRST EPISODE OF HI

Characteristic	Statistic
All First Episodes Predicted by AHI (N, %) (a)	308, 85.1%
AHI Prediction Lead Time	
Median [25th, 75th] (minutes)	57 [14, 196]
Mean, Std. Dev. (minutes)	240.5, 592.9
Min, Max (minutes)	2, 4920

(a) Percentage based on total eligible episodes (N = 362)

Of the 362 eligible episodes of HI, 308 episodes (85%) were correctly predicted by the AHI system with a median lead time of 57 minutes and a mean of 4 hours (240.5 minutes). The distribution of lead times highlighted in Fig. 3 shows that the mean lead time is skewed due to a small number of long lead times (≥ 10 hours) prior to the first episode (Fig. 3).

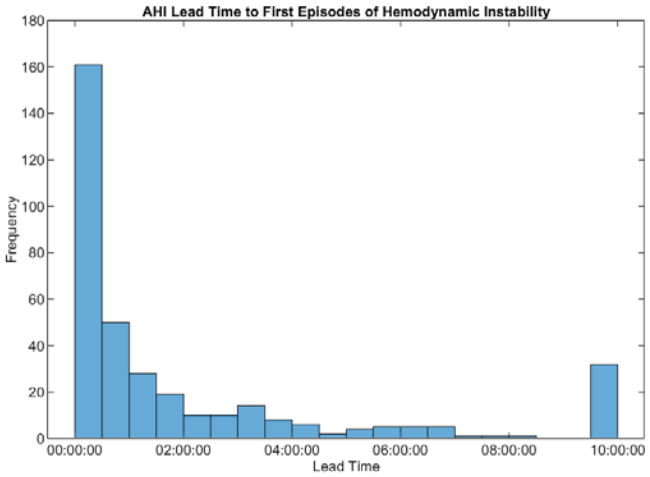

Fig. 3 Distribution of AHI lead times prior to correctly predicted first episodes of HI (N = 308). Each bar represents a 30 minute timespan. Histogram has been top-coded at 10 hours.

There were 54 episodes of HI (14.9%) that were not predicted by the AHI system. These were further assessed on whether the episodes were detected by AHI during their duration. Here, detection of an episode means AHI indicated HI (red) during the episode. Table IV shows that 45 of the 54 episodes (83.3%) that were not predicted by the AHI system were nonetheless detected at some point while the episodes of HI were ongoing (18.5%) were detected with zero delay at the onset of the episode. The remaining 35 (64.8%) episodes of the episodes of HI, were detected with some delay, i.e., AHI started consistently indicating HI (red) a few windows after the onset of the episode of HI.

Of the 362 eligible first episodes of HI, nine were neither predicted nor detected by the AHI system. Of these nine episodes, five of them were due to either noisy (gray) or missing (black) ECG data during the episodes of HI, thereby precluding

AHI from producing a hemodynamic status indication. The remaining four episodes of HI were because AHI incorrectly indicated signs of hemodynamic stability (green) during the episode of HI (false negative). Therefore, after adjusting for the cases with noisy or missing ECG data during episodes of HI, of the 362 total first episodes of HI, only four (1.1%) were neither detected nor predicted by AHI.

TABLE IV
DETECTION OF FIRST EPISODES OF HI WITH ZERO LEAD TIME

Characteristic	Statistic
First Episodes with Zero Lead Time (N, %) (a)	54, 14.9%
Episodes Detected by AHI (N, %) (b)	45, 83.3%
Episodes Detected with Zero Delay (N, %) (b)	10, 18.5%
Episodes Detected with Some Delay (N, %) (b)	35, 64.8%
Delay Median [25th, 75th] (minutes)	4 [2, 6]
Delay Mean, Std. Dev. (minutes)	4.9, 2.8
Delay Min, Max (minutes)	2, 10
Episodes Undetected (N, %(b), %(a))	9, 16.7%, 2.5%
Noisy or Missing ECG During Episode (N, %(b), %(a))	5, 9.3%, 1.3%
Episodes Neither Predicted Nor Detected (N, %(b), %(a))	4, 8.9%, 1.1%

(a) Percentage based on total eligible episodes (N = 362)
(b) Percentage based on first episodes with zero lead time (N = 54)

IV. DISCUSSION

The ability for a clinician to predict or early detect HI during the patient monitoring process is an important facet for improving the quality of patient care and reducing in-hospital adverse events and outcomes. In this study, the AHI system was analyzed for its ability to predict episodes of HI before they become observable through vital signs.

This study's Eligible Patient set consisted of the first episodes of HI from 362 patient encounters. The results demonstrate that AHI correctly predicted an impending episode of HI in 85.1% (308) of the patients. For half of these patients, AHI predicted these episodes at least 57 minutes in advance of their onset observable through vital signs. AHI's average lead time for prediction was 4 hours (240.5 minutes). Having such lead times provides clinicians with a clinically actionable amount of time to preemptively increase vigilance on these patients and, if necessary, to take precautionary actions to reduce the potential for such episodes of HI.

Of the 14.9% (54) of patient encounters where AHI did not predict (zero lead time) the episodes of HI, AHI detected the 83.3% of these episodes by indicating HI (red bars) during the episodes of HI. This is important since identification and timely notification of the first episode of HI provides clinicians an additional 'pair of eyes' on their patients in case they do not yet notice it through vital signs monitoring.

Investigating the subset of episodes of HI which were not predicted by AHI (54) showed that, in 18.5% (10) of them, AHI had no delay in recognizing the ongoing episode of HI. In other words, AHI started producing red bars, indicating the presence of HI, as soon as the episode of HI started. In 64.8% (35) of the unpredicted subset (54), AHI had a delay in indicating the presence of HI (red bars) during the episode. AHI was at most 4 minutes late for half of them. The maximum delay was 10 minutes into the episode of HI. In the remaining 16.7% (9) of the unpredicted subset (54), AHI completely missed producing any indication of HI (red bar) during the episode. Upon further investigation into these 9 cases, it was found that, in 5 of these 9 cases, AHI produced only either gray or black bars, indicating noisy or missing ECG signal, respectively. Therefore, in these 5 cases, AHI did not have an opportunity to produce any indications of hemodynamic status due to bad input data. This leaves 4 cases where AHI neither predicted nor detected the occurrence of the episode of HI. That is, of the total 362 first episodes of HI, AHI completely missed predicting and detecting only 1.1% (4) of the episodes of HI. For the remaining 98.9%, AHI was able to either predict or detect as long as the input ECG data was deemed acceptable.

This study conservatively defines an episode of HI as ≥ 10 continuous minutes of both hypotension and tachycardia being present to be a clinically significant event. Future work may use and test different definitions of HI. For example, other hemodynamic related vitals, lab results, and clinical actions (e.g., pressor initiation) may be used. Additionally, this study was performed at a single center institution, Michigan Medicine. Expansion to a multicenter study may be required in the future.

This study was conducted exclusively on patients with both a continuous ECG and invasive arterial blood pressure monitoring to accurately identify their HI episodes' onsets. While needing the invasive continuous blood pressure monitoring may be a limitation, ECG monitoring is ubiquitous across all levels of care outside of ICU and becoming more prevalent with FDA cleared wearable or portable ECG monitors. This means that the AHI system can be used on much broader groups of patients than presented in this study. Therefore, the utility of the AHI system to identify patient deterioration extends well beyond the intensive care settings and is perhaps much more applicable for patients who are not being monitored invasively. Given the lower nursing to patient ratios in lower levels of care, these units tend to have larger gaps between vital signs monitoring. Furthermore, since vital signs can be lagging in nature, AHI could potentially provide an additional 'pair of eyes' on these patients, continuously fill the monitoring gaps, and consequently provide the patient care team the ability to be far more proactive in monitoring and managing potential adverse events.

V. CONCLUSION

With the strains of overcrowding hospitals, nursing shortages, and resource constraints, now more than ever, there is a need for a simple to use, clinical decision support system that predicts hemodynamic deterioration in patients well before it is evident through vital signs. Advanced analytics like the AHI system could potentially be an important tool for the clinical care team to help identify deteriorating patients at the earliest and avoid unexpected adverse events.

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