

Phase 1:

The original investigation at University of Pittsburgh Medical Center (November 2006 - January 2007)

Defining the Incidence of Cardiorespiratory Instability in Patients in Step-Down Units Using an Electronic Integrated Monitoring System

- The phase 1 – The Visensia[®] Safety Index (VSI) on retrospective data
- 319 patients over 8 weeks
- 7 MET deaths
- 100% Detected by VSI in advance
- 6.3 hours mean advance detection

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Defining the Incidence of Cardiorespiratory Instability in Patients in Step-down Units Using an Electronic Integrated Monitoring System

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Background: To our knowledge, detection of cardiorespiratory instability using noninvasive monitoring via electronic integrated monitoring systems (IMSS) in intermediate or step-down units (SDUs) has not been described. We undertook this study to characterize respiratory status in an SDU population, to define features of cardiorespiratory instability, and to evaluate an IMS index value that should trigger medical emergency team (MET) activation.

Methods: This descriptive, prospective, single-blinded, observational study evaluated all patients in a 24-bed SDU in a university medical center during 8 weeks from November 16, 2006, to January 11, 2007. An IMS (BioSign; OBS Medical, Carmel, Indiana) was inserted into the standard noninvasive hardwired monitoring system and used heart rate, blood pressure, respiratory rate, and peripheral oxygen saturation by pulse oximetry to develop a single neural networked signal, or BioSign Index (BSI). Data were analyzed for cardiorespiratory instability according to BSI trigger value and local MET activation criteria. Staff were blinded to BSI data collected in 326 patients (total census).

Results: Data for 18 248 hours of continuous monitoring were captured. Data for peripheral oxygen saturation by pulse oximetry were absent in 30% of monitored hours despite being a standard of care. Cardiorespiratory status in most patients (243 of 326 [74.5%]) was stable throughout their SDU stay, and instability in the remaining patients (83 of 326 [25%]) was exhibited infrequently. We recorded 111 MET activation criteria events caused by cardiorespiratory instability in 59 patients, but MET activation for this cause occurred in only 7 patients. All MET events were detected by BSI in advance (mean, 6.3 hours) in a bimodal distribution (>6 hours and ≤ 45 minutes).

Conclusions: Cardiorespiratory instability, while uncommon and often unrecognized, was preceded by elevation of the IMS index. Continuous noninvasive monitoring augmented by IMS provides sensitive detection of early instability in patients in SDUs.

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PRESSURE TO INCREASE intensive care unit (ICU) bed availability grows as the need to streamline patient movement through acute care facilities intensifies nationally. Patients with higher illness acuity levels are transferred from ICUs to intermediate-care or step-down units (SDUs) to make room for sicker patients. Patients in SDUs are continuously monitored using noninvasive tools such as pulse oximetry, electrocardiography, and automated sphygmomanometry to give estimates of heart rate (HR), blood pressure (BP), respiratory rate (RR), and peripheral oxygen saturation by pulse oximetry (SpO₂). However, it is not known whether such SDU noninvasive monitoring identifies cardiorespiratory instability accurately and reliably. First, it is unclear how often continuous monitoring is actually used in these patients. Second, the incidence of

clinically relevant cardiorespiratory instability in this population is unknown. Third, in those patients who develop cardiorespiratory instability requiring acute intervention, it has not yet been shown in a continuously monitored population whether instability is more likely to occur rapidly or progressively. Fourth, present electronic bedside monitoring assesses and alarms for individual variable abnormalities and does not consider patterns of multiple cardiorespiratory variables in combination usually present with patient deterioration owing to sepsis, heart failure, or acute respiratory failure.

Noninvasively acquired vital signs are displayed on bedside monitors and may be forwarded to an SDU central station but are not always overseen by dedicated personnel; rather, they may be observed by nurses managing caseloads of 4 to 6 patients each. Recognizing both acute and slowly progres-

sive cardiorespiratory instability can be problematic, and marshaling the appropriate caregivers and equipment to address these situations even more so. Recently, a systematic rapid-intervention intensive care–based program has been described, the medical emergency team (MET), usually triggered by recognition of abnormality in noninvasively acquired monitoring variables, to respond early in the course of instability in non-ICU patients. MET availability can prevent adverse events.^{1,2} However, MET function requires afferent activation because staff must first perceive and then process the achievement of MET activation (triggering) criteria.³ Thus, MET use depends on accurate and reliable monitoring that enables staff to recognize and react to instability before development of severe cardiorespiratory insufficiency and associated end-organ sequelae. The subsequent efferent MET system is completely contingent on this sensing arm.

Most METs operate using criteria established for trigger threshold changes in single variables or parameters. More recently, some MET activation systems call for nurses to amalgamate data from several physiologic sources to calculate an early warning score,^{4,5} ostensibly providing more objective evaluation and synthesis of measures identifying instability risk. If such amalgamated data were gathered continuously and synthesized electronically using an integrated monitoring system (IMS), its use could possibly activate the MET with greater sensitivity and specificity than human interface alone, which is episodic, subjective, and prone to calculation errors. However, it is unclear to what extent single-parameter threshold alarms vs IMS pooled scores identify patients with unstable cardiorespiratory function. The objectives of this study were as follows: to define the extent of continuous single-channel monitoring in a high-acuity SDU, characterize natural cardiorespiratory health in a single SDU population, define the characteristics of cardiorespiratory instability if it occurred, and evaluate the ability of an IMS index value compared with single-parameter alarms to detect clinically significant events that might trigger activation of the MET earlier than called.

METHODS

PATIENTS

The study was approved by the Patient Safety Committee as a quality improvement project. The study unit, a 24-bed adult surgical trauma SDU in a metropolitan level I trauma center hospital, is equipped with patient monitors (model M1204; Philips Medical Systems, Bothell, Washington) at every bed and a central nursing station monitor. Standard of care monitoring for this SDU included continuous 3-lead electrocardiographic HR monitoring, continuous RR monitoring using bioimpedance signaling, continuous SpO₂ monitoring by pulse oximetry (model M1191B; Philips Medical Systems, Böblingen, Germany), and intermittent noninvasive BP monitoring at a minimum cycling frequency of 2 hours. These data were also collected into an IMS (see the “Equipment and Procedures” subsection); staff were blinded to monitoring and data analysis. All bedside monitors were connected to a central station. Alarm limits were set for individual vital sign parameters, with violations causing audible alerts at the bedside and central station. No staff were dedicated to central monitor observation.

Table 1. Trigger Criteria for Medical Emergency Team (MET) Activation

Criteria
Cardiorespiratory system
Respirations <8/min or >36/min
New onset of breathing difficulty
New pulse oximeter reading <85% for >5 minutes, unless patient is known to have chronic hypoxemia
New requirement for >50% oxygen to maintain saturation level >85%
Heart rate <40 beats/min or >140 beats/min with new symptoms or any rate >160 beats/min
Blood pressure: systolic <80 or >200 mm Hg or diastolic 110 mm Hg with symptoms (neurologic change, chest pain, or breathing difficulty)
Neurologic system
Acute loss of consciousness
New onset of lethargy or difficulty in waking
Sudden collapse
Seizure (outside of seizure monitoring unit)
Sudden loss of mobility (or weakness) of face, arm, or leg
Other criteria
More than 1 stat page required to assemble MET needed to respond to a crisis
Patient report of (cardiac) chest pain (unresponsive to nitroglycerine or physician unavailable)
Color change in patient or extremity to pale, dusky, gray, or blue
Unexplained agitation for >10 min
Suicide attempt
Uncontrolled bleeding
Bleeding into airway
Naloxone hydrochloride use without immediate response
Large volume of short-term blood loss
Crash cart must be used for rapid delivery of medications

The usual ratio range of nurse to patient was 1:4 to 1:6 depending on patient census and acuity of illness (not time of day).

EQUIPMENT AND PROCEDURES

We used the BioSign IMS (OBS Medical, Carmel, Indiana). The BioSign is a Food and Drug Administration–approved nonpediatric patient monitoring system that usually integrates 5 vital signs to produce a single-parameter BioSign Index (BSI). The input variables include HR, RR, BP, SpO₂, and temperature. We were unable to record temperature continuously in this study; thus, the BSI was adjusted by the manufacturer to evaluate the remaining 4 variables using a similar proprietary probabilistic equation. The data fusion method used to calculate the BSI uses neural networking to develop a probabilistic model of normality in 4 or 5 dimensions, previously learned from a representative sample of a 150-patient training set. Variance from this data set is used to evaluate the probability that the patient-derived vital signs are considered to be in the normal range. The generated BSI ranges from 0 (no abnormalities) to 10 (severe abnormalities in all variables). A BSI of 3 or greater is deemed to reflect significant cardiorespiratory instability requiring medical attention.⁶ A BSI of 3 or greater can occur while no single vital sign parameter is outside the range of normal if their combined patterns are consistent with known instability patterns. During the evaluation, the nurses continued to activate the MET using the established institutional MET activation criteria (**Table 1**) and were blinded to the BSI values. Demographic and clinical data were obtained from the clinical record, clinical and administrative electronic databases, and the hospital MET activation records.

DATA ANALYSIS

The electronic IMS data comprising a time-activity plot of all individual measured variables plus the calculated BSI parameter were downloaded from each BioSign monitor and analyzed to identify when variable abnormalities would have triggered MET activation on the basis of our institutional criteria. We analyzed 4 specific aspects of these continuous data streams: (1) the total time in which the measured variables were within the normal physiologic range defining cardiorespiratory stability; (2) times in which the monitored variables deviated from normal enough to minimally fulfill our MET activation criteria (MET_{min}) even if occurring for brief intervals and of questionable clinical significance (eg, isolated brief tachycardia or tachypnea associated with pain or agitation); (3) those MET_{min} events that also fulfilled our MET activation criteria and should have caused MET activation (MET_{full}); and (4) total time during which MET_{full} persisted (eg, persistent hypoxemia, tachycardia, or hypotension and tachycardia). MET_{full} was determined blindly by a senior critical care medicine physician (M.R.P.) familiar with MET activation criteria. Examples of charts judged as MET_{min} and MET_{full} are shown in **Figure 1**. We further categorized whether MET_{full} events were owing to abnormalities in single or multiple vital sign abnormalities and whether the abnormalities were owing to increase or decrease beyond threshold levels for each measured variable. In all patients in whom actual MET activation occurred (MET_{actual}), we examined the temporal relationship between MET_{actual} occurrence and the time BSI history before MET activation. Data are reported as mean (SD).

RESULTS

During 8 consecutive weeks from November 16, 2006, to January 11, 2007, we obtained data for 326 monitored patients representing all patients admitted to this SDU. Defining monitoring hours as time when any electronic vital sign measurement was recorded singly or in combination, a total of 18 248 hours were captured. Data for SpO_2 monitoring were absent in 30% of monitored hours despite the care standard for continuous monitoring. We observed a lesser degree of missed variable monitoring for HR (4.8%) and RR (7.9%).

Demographic data for this total census (**Table 2**) demonstrate that about one-third of the patients were included in 1 of 3 age groups: 50 years or younger, 51 to 70 years, and 71 years or older. Racial/ethnic distribution was consistent with local demographics (74% white), and there were slightly more male patients (59%). Most patients were admitted through the general surgical service. Most had low scores on the Charlson-Deyo Comorbidity⁷ Index (69% had scores of only 0-1). The prevalence of chronic renal disease, congestive heart failure, myocardial infarction, and chronic obstructive pulmonary disease was low; the most prevalent comorbidity was diabetes mellitus (23.9%). Approximately one-fourth of the patients had been directly transferred from a higher monitoring center (ICU); the remainder were admitted directly to the SDU or from nursing units with equal or lower monitoring intensity levels. Thus, our patient population reflects a heterogeneous population of patients being actively treated because of acute cardiovascular illness, trauma, or both.

We recorded 401 events satisfying the institution's MET criteria occurring in 118 patients (36%) during the ob-

servations period (**Table 3**), which were reviewed offline. Of these events, 163 (40.6%) were determined to be associated with artifact owing to erroneous vital sign variable sensing, with the most common artifact being erroneous SpO_2 (68% of all SpO_2 events). The remaining 238 events were physiologically plausible MET criterion monitoring events (MET_{min}) occurring in 83 patients. Thus, 74.5% of our total patient sample (243 of 326 patients) did not experience plausible MET criterion cardiorespiratory events during their SDU stay. For events meeting MET_{min} requirements, on average, total MET_{min} criterion events would have occurred 4.25 times per day for the ward, or 0.17 times per day per bed. Of all the MET_{min} events, 127 such events occurring in 44 patients would not have resulted in MET_{full} . We also recorded 111 monitoring MET_{full} events occurring in 59 patients. On average, MET_{full} criterion events would have occurred 1.98 per day for the ward, or 0.08 times per day per bed. The causes of MET_{full} are summarized in Table 3. MET_{full} was due to single variable abnormalities in 94.5% of events, with low SpO_2 being the most common; 2 variable abnormalities in 4.5%; and more than 2 variable abnormalities in 0.9%.

Ten patients had MET_{actual} , representing only 17% of patients who fulfilled MET_{full} criteria. The cause for MET activation was acute mental status changes without vital sign instability in 2 patients and chest pain likely of neuromuscular origin without vital sign changes in 1 patient. In the remaining 7 patients, the cause of MET activation was cardiorespiratory events. Of these 7 MET_{actual} events, 2 were because of cardiac causes (low BP), 4 because of respiratory causes (low SpO_2 and low SPO_2 associated with RR changes in 2 patients each), and 1 because of mixed cardiorespiratory cause (both low HR and RR). The time between BSI of 3 or greater, and MET_{actual} was 6.3 (6.1) hours (range, 0.1-15 hours). **Figure 2** shows the distribution of time between the BSI of 3 or greater and MET_{actual} , with 3 occurring within 45 minutes or less and 4 occurring within 6 hours or more, which suggests that the IMS has the ability to advance clinician detection time. The single-day vital sign and BSI chart plot for 1 MET_{actual} patient is shown in **Figure 3**, and the BSI data alone for the remaining 6 patients is shown in **Figure 4**. No patient experienced cardiac arrest during the observation period.

COMMENT

To our knowledge, our study provides information on the largest continuous collection of cardiorespiratory variables in the non-ICU patient population in the literature to date. The study produced 3 major findings. First, although it is the policy of the SDU to have continuous SpO_2 monitoring, this was realized only 70% of the time. Second, most patients were stable during their entire SDU stay, and even those who had episodes of instability were stable most of the time. Third, cardiorespiratory instability that reached MET activation thresholds occurred in different patterns. Clinically significant cardiorespiratory instability in an SDU frequently is unnoticed, and in those 7 patients in whom the MET was activated because of cardiorespiratory reasons, the mean time that a BSI of 3 or

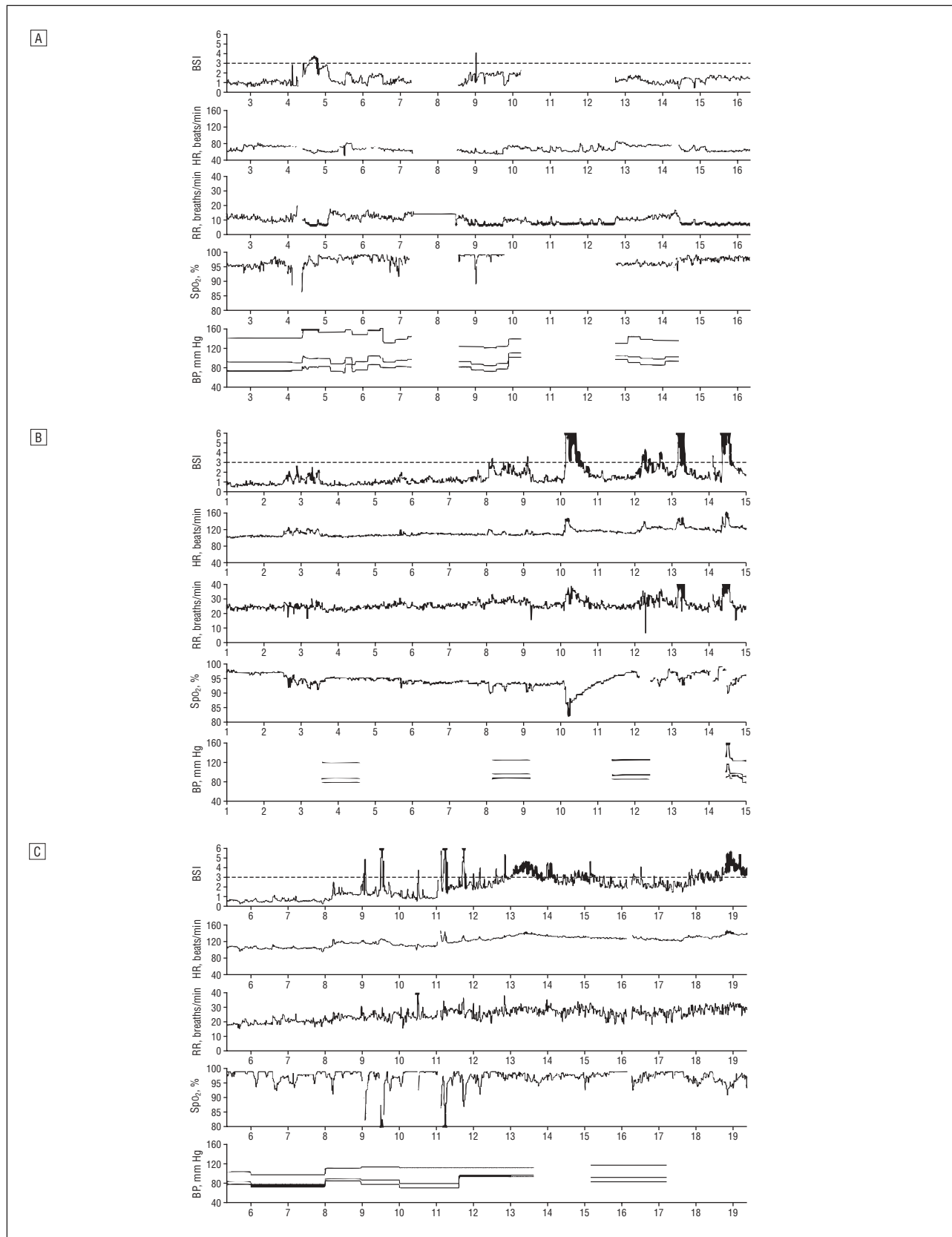


Figure 1. Examples of charts of patients judged to have minimally fulfilled medical emergency team (MET) activation criteria (MET_{min}) (A) or who fulfilled MET activation criteria, which should have resulted in MET activation (MET_{full}) (B and C). A, Patient has baseline hypertension but heart rate (HR), respiratory rate (RR), and peripheral oxygen saturation by pulse oximetry (SpO_2) are in the normal range. The blood pressure (BP) was further elevated at 4:00 AM, with BioSign Index (BSI) alert threshold (dotted line), but then reverted to baseline. B, Note progressive and interactive increase in both HR and RR, and, finally, hypertension, resulting in recurrent BSI alerts. C, Progressive and interactive increase in both HR and RR and dips in SpO_2 result in persistent BSI elevation that intermittently crosses the alert threshold.

Table 2. Demographic Data for the 326 Patients Composing the Study Population

Variable	No. (%)
Age, y	
≤20	6 (1.8)
21-30	35 (10.7)
31-40	20 (6.1)
41-50	50 (15.3)
51-60	62 (19.0)
61-70	57 (17.5)
71-80	47 (14.4)
81-90	38 (11.7)
≥91	11 (3.4)
Sex	
Male	191 (58.6)
Female	135 (41.4)
Race/ethnicity	
White	240 (73.6)
Black	42 (12.9)
Other	6 (1.8)
Unknown	38 (11.7)
Admitting service	
General surgery	141 (43.3)
Vascular surgery	52 (15.9)
Critical care medicine	40 (12.3)
Other	93 (28.5)
Intake disposition	
Higher intensity monitoring unit	87 (26.7)
Direct, same, or lower intensity monitoring unit	239 (73.3)
Medical history	
Myocardial infarction	41 (12.5)
Congestive heart failure	43 (13.1)
Chronic obstructive pulmonary disease	64 (19.6)
Diabetes mellitus	78 (23.9)
Chronic renal disease	5 (1.5)
Charlson-Deyo Comorbidity Index	
0	147 (45.1)
1	74 (22.7)
2	52 (15.9)
3	24 (7.4)
4	13 (4.0)
5-9	17 (4.9)
Admission diagnosis by ICD-9 code	
959 Injury	126 (38.6)
780 General symptoms	19 (5.8)
786 Respiratory system/other chest	17 (5.2)
789 Other abdominal/gastrointestinal	11 (3.4)
444 Arterial embolism	12 (3.7)
560 Intestinal obstruction	9 (2.8)
Discharge disposition	
Home	212 (65.0)
Subacute care facility	106 (32.6)
Death	6 (1.8)
Other	2 (0.6)

Abbreviation: ICD-9, *International Classification of Diseases, Ninth Revision*.

greater was reached was 6.3 hours before the activation occurred. Although these data imply that having IMS triggers available to nursing services may improve earlier recognition of cardiorespiratory instability of the patient, the present study did not address this point directly, only that the potential for earlier recognition exists. These points are addressed further later in this section.

An unexpected finding was that SpO₂ monitoring occurred much less frequently in this SDU than antici-

Table 3. Evaluation of Events in Which Noninvasive Vital Sign Variable Information Fulfilled the Trigger Criteria for Medical Emergency Team (MET) Activation

Event	No. (%)
All events	
Patients	118
Events in which MET activation criteria were reached	401
Criteria	
HR	
High	21 (5.2)
Low	3 (0.7)
RR	
High	52 (13.0)
Low	42 (10.5)
SpO ₂ low	136 (33.9)
BP	
Systolic high	16 (4.0)
Systolic low	50 (12.5)
Diastolic high	81 (20.2)
Duration of event, mean (range), min	32 (0-420)
MET _{min} events	
Patients	83
Events in which MET criteria were reached	238
Criteria	
HR	
High	20 (8.4)
Low	3 (1.3)
RR	
High	52 (21.9)
Low	36 (15.1)
SpO ₂ low	43 (18.1)
BP	
Systolic high	13 (5.5)
Systolic low	38 (16.0)
Diastolic BP high	33 (13.9)
Duration of event, mean (range), min	39 (0-417)
MET _{full} events	
Patients	59
Events in which MET criteria were reached	111
Criteria	
HR	
High	15 (13.5)
Low	2 (1.8)
RR	
High	23 (20.7)
Low	6 (5.4)
SpO ₂ low	38 (34.2)
BP	
Systolic high	4 (3.6)
Systolic low	16 (14.4)
Diastolic high	7 (6.3)
Duration of event, mean (range), min	34 (0-222)

Abbreviations: All events, those events fulfilling minimal trigger criteria for MET activation (real and artifact); BP, blood pressure; HR, heart rate; MET, medical emergency team; MET_{full}, subset of all MET_{min} events fulfilling trigger criteria and that should have caused MET activation; MET_{min}, all real events fulfilling minimal trigger criteria for MET activation; RR, respiratory rate; SpO₂, peripheral oxygen saturation by pulse oximetry.

pated, despite continuous monitoring being the standard of care. As a consequence, we conducted another quality improvement subproject to explore and rectify the problem of low SpO₂ monitoring compliance. Reasons for noncompliance included patients disliking probes, patients or staff unaware of the standard, and equipment unavailability. Educational effort and improved

equipment availability resulted in a subsequent 85% compliance for the remainder of the study.

That 75% of patients in our SDU remained stable has important implications for SDU use and staffing. In our SDU population, cardiorespiratory instability was not common either in the patients as a whole or over time for those who developed instability. Thus, continuous vigilance by nursing staff of cardiorespiratory variables at a central station or periodically at the bedside by direct inspection reflects a highly inefficient use of human resources. Furthermore, instability, when noted, was generally not owing to abnormalities of a specific variable across all patients but to variable combinations. Thus, targeting single-variable abnormalities to identify global cardiorespiratory instability is not only inefficient but insensitive. This finding of early signs of compromise reflecting a combination of variable and parameter changes, rather than single changes, agrees with those of a recent study by Harrison et al.⁸ Single-channel monitoring is also subject to a high false alarm rate, approaching 86% in some studies.⁹ Thus, attention to single-monitored parameter alarms also reflects inefficient use of monitoring technology and nurse time. Automated systems that track multimodality cardiorespiratory status can potentially alert the nursing staff earlier than can the currently used visual inspection and can amalgamate trends and changes across different variables even if not individually outside normal threshold values. Aiken et al,¹⁰ using 4 patients in a nurse's caseload as a baseline, identified that the odds of patient death increased by 7% for each patient added to the caseload. Thus, identifying means to improve the ability of nurses to monitor patients for deterioration in SDU settings using systems that are both effective and efficient is vital. Using noninvasive IMS is one solution.

We found that cardiorespiratory instability occurred in different patterns. We observed progressive deterioration with occasional intervals of normalcy in most patients with MET_{full} status and in half of those with MET_{actual} status (Figure 3). Periodic bedside examination of patient status is an insensitive method to identify early cardiorespiratory deterioration. Although the mean lead time for the 7 patients with MET_{actual} status to reach a BSI of 3 or greater (MET_{full}) was 6.3 hours, the temporal distribution to times from MET_{full} to MET_{actual} exhibited a bimodal pattern, with 3 patients demonstrating deterioration in less than 1 hour and 4 in whom deterioration progressed during more than 6 hours. Of the 3 patients with BSI greater than 3 within an hour, 2 also had elevated BSIs hours earlier. Thus, deterioration was evident before MET_{actual} in all patients, and in more than half of the patients in whom instability progressed to MET activation, the nursing staff could potentially have activated the MET hours earlier if an IMS was being used. Furthermore, we reviewed the nursing records of all 7 patients in whom MET_{actual} occurred to determine whether those patients were documented as at risk. Of the 7 patients with MET_{actual}, 1 patient with acute bleeding was not (and could not have been) identified as being at risk before the call. However, in the other 6 patients, there was some notation of risk that was not acted on or was acted on without close follow-up to response and reso-

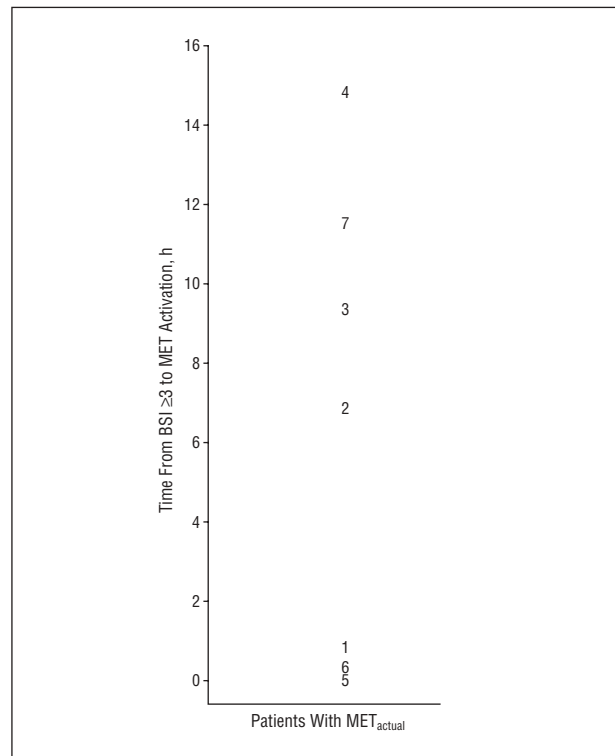


Figure 2. Time from initial deterioration as identified by a BioSign Index (BSI) of 3 or greater to medical emergency team (MET_{actual}) activation in 7 patients. Each of the patients' data point is represented by patient number.

lution before MET_{actual}. The reasons for these suboptimal responses cannot be determined by retrospective chart review. We might hypothesize that progression of deterioration or lack of response to therapeutic interventions (Figure 4) was not acted on because of the intermittent nature of conventional SDU patient evaluation and nurse workload. Inasmuch as MET activation using single-parameter intermittent-observation triggers in present algorithms has been shown to decrease the risk for adverse patient outcome by 58%,¹¹ our data suggest that multiparameter IMS could improve this activation further. MET services are cost-effective by reducing length of stay, averting ICU admissions, and reducing mortality.¹² Because currently described MET activation effectiveness is limited by the need for direct caregiver observation of the patient,¹³ our data suggest that having a robust and sensitive continuous IMS would have enabled more rapid identification of patients with cardiorespiratory instability in these previous studies.

Most current METs operate on criteria established for trigger changes in single parameters¹⁴; any single value beyond a defined threshold triggers system activation. Monitoring systems that integrate data from multiple physiologic sources may more efficiently identify patients at risk. There are data to support this. Subbe et al¹⁵ related experience with implementing an early warning score to provide more objective evaluation and synthesis of physiologic measures to identify patient deterioration. In a prospective study, they categorized data from 5 parameters intermittently observed by caregivers (BP, HR, RR, temperature, and level of consciousness) into graded scores for each parameter, and the individual parameter scores were

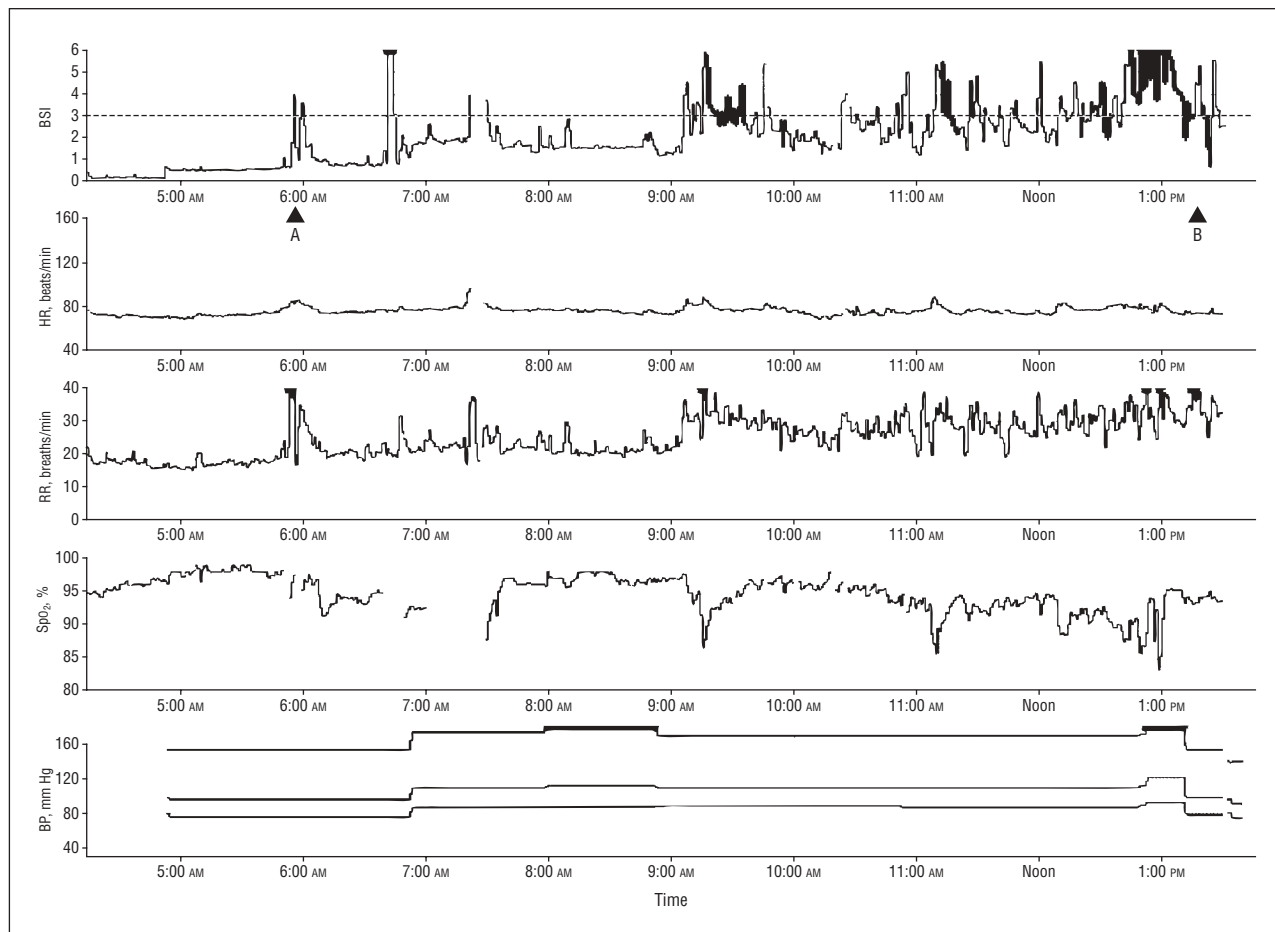


Figure 3. Single-day vital sign and BioSign Index chart for patient 1 over time leading to medical emergency team activation call. Cardiorespiratory status was stable until 6:00 AM (A), when the respiratory rate (RR) gradually increased. From 9:00 AM onward, the RR was high and peripheral oxygen saturation by pulse oximetry (SpO₂) gradually decreased, with occasional dips, and the systolic blood pressure (BP) remained high at about 180 mm Hg. BioSign alerts above the threshold value of 3 (dotted line) occurred from 12:30 PM until the medical emergency team activation was called at 1:29 PM (B). HR indicates heart rate.

then totaled to a single score. When they applied these criteria in 709 patients in acute medical units, cumulative scores of 5 or greater were associated with increased risk of death (odds ratio, 5.4; 95% confidence interval, 2.8-10.7), ICU admission (odds ratio, 10.9; 95% confidence interval, 2.2-55.6), and high-dependency unit admission (odds ratio, 3.3; 95% confidence interval, 1.2-9.2). A modified early warning score has also been shown to accurately identify patients at risk in the surgical population.¹⁵ Although the early warning score can identify unstable patients earlier,¹⁶ such nonautomated systems still require direct and intermittent data collection by clinicians, as well as intermittent calculation and reference to norms, thereby constraining effectiveness.

The IMS used in our study utilizes neural networking to adopt a probabilistic model of normality learned from a representative sample of adult patients at high risk. Recurrent neural networks interface with memory and can interrelate the current condition with previous states.^{17,18} Our data suggest that an IMS for continuously monitored variables has promise in functioning as an electronic early warning score system to trigger earlier MET activation.

Although cardiorespiratory instability was not common in our SDU population, when it did occur, it might

have been unnoticed 83% of the time. As noted, of our patients who achieved MET activation trigger criteria that should have resulted in a call (MET_{full}), a MET was actually called for (MET_{actual}) in only 17%. The reasons why the MET was not called, even in an institution such as ours in which a rapid response system is well established and accepted, are unclear. We did not monitor the bedside nurse activity associated with MET_{full} events in which the MET was not called.

METHODOLOGIC CONSIDERATIONS

This study was a blinded observational study, and the nursing staff had no additional reason to maintain complete and continuous noninvasive monitoring of patients. Thus, these data reflect as pure a census of SDU monitoring performance as can be collected without bias. Still, there are several limitations to data interpretation. First, 30% of patients did not have continuous SpO₂ monitoring. Lack of SpO₂ input degrades the accuracy but does not eliminate the calculation of the BSI value. Thus, our census reflects an incomplete picture of all SDU patients, and incidence frequencies of MET_{full} might be greater if all of the patients received their ordered continuous monitoring, but MET_{full} frequency

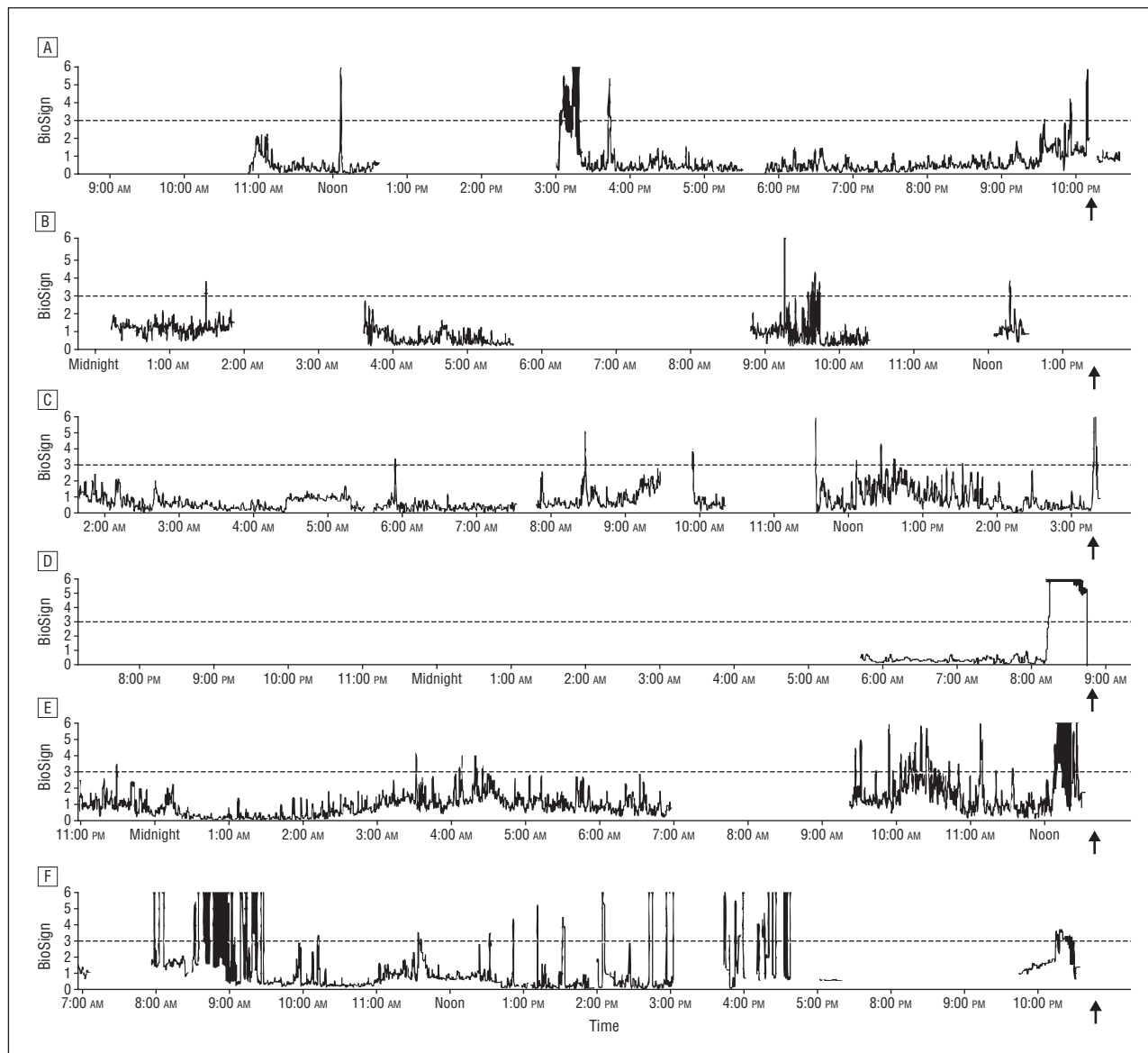


Figure 4. BioSign Index charts for 6 patients over time leading to medical emergency team (MET) activation call (arrows). A, Patient 2 had low blood pressure and acute onset of bleeding from the arterial sheath site. MET activation was called at 11:05 PM. B, Patient 3 had heart failure and unsteady gait. The patient was off the monitor shortly before 1:00 PM and fell in the bathroom. MET activation was called at 3:16 PM. C, Patient 4 status after lung transplantation. Respiratory distress developed at 11:30 AM. MET activation was called at 3:19 PM. D, Patient 5 status after sustaining trauma and multiple fractures. Low peripheral oxygen saturation and compensatory tachycardia developed at 8:15 AM. MET activation was called at 8:40 AM. E, Patient 6 status after a fall and hip fracture. Acute respiratory deterioration developed with compensatory tachycardia. MET activation was called at 12:28 PM. F, Patient 7 status after a traumatic fall and delirium. Tachypnea and hypoxemia developed at about 10:00 AM, and hypotension developed shortly after 8:00 PM. MET activation was called at 8:27 PM.

would not have been less. Second, our protocol did not call for examination of which interventions, if any, occurred for MET_{full} events not associated with MET_{actual} because such event monitoring would have introduced a measurement artifact possibly biasing nursing care and directly decreasing subsequent BSI values. Potentially, cardiorespiratory instability was recognized and treated with new or previously ordered interventions or routine practices. This issue can only be addressed in a subsequent study. However, we conducted nursing record reviews for 26 patients with MET_{full} criteria, and in only 20 of 46 events (43%) was patient instability or acute intervention documented. Third, the BSI value of 3.0 or greater for defining instability, as created by the

manufacturer from a training data set of ICU patients, was found to be highly discriminating in identifying instability in that cohort. Clearly, semiambulatory SDU patients will have different baseline physiologic characteristics and greater cardiorespiratory reserve than ICU patients. Thus, it is not clear that our use of a BSI of 3.0 or greater would remain an appropriate alert threshold in SDU patients. We reviewed our SDU patient data using multiple logistic regression with MET_{full} as our positive marker. Preliminary analysis suggests that for SDU patients, the BSI threshold should be increased to 3.2 or greater to maximize sensitivity and specificity. Whether this increased threshold value will demonstrate better discrimination will be the subject of another study.

CONCLUSION

Most patients in SDUs remain stable during their entire SDU stay, and those who exhibit deterioration do so infrequently but over hours, on average. The ability to identify and improve detection methods that decrease the time between fulfillment of MET trigger criteria and MET activation is important. Continuous noninvasive monitoring augmented with integrated information from multiple variables provides a more sensitive means to detect cardiorespiratory instability in SDU patients than does bedside nursing assessment. Future study will determine whether earlier detection improves patient outcomes.

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