CLINICAL RESEARCH STUDY

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Continuous Monitoring in an Inpatient Medical-Surgical Unit: A Controlled Clinical Trial

Harvey Brown, MD,[a] Jamie Terrence, RN,[a] Patricia Vasquez, RN, BSN,[a] David W. Bates, MD, MSc,[b,c] Eyal Zimlichman, MD, MSc[b,c]

[a]California Hospital Medical Center, a member of Dignity Health, Los Angeles; [b]The Center for Patient Safety Research and Practice, Division of General Internal Medicine, Brigham and Women's Hospital, Boston, Mass; [c]Harvard Medical School, Boston, Mass.

ABSTRACT

BACKGROUND: For hospitalized patients with unexpected clinical deterioration, delayed or suboptimal intervention is associated with increased morbidity and mortality. Lack of continuous monitoring for average-risk patients has been suggested as a contributing factor for unexpected in-hospital mortality. Our objective was to assess the effects of continuous heart rate and respiration rate monitoring in a medical-surgical unit on unplanned transfers and length of stay in the intensive care unit and length of stay in the medical-surgical unit.

METHODS: In a controlled study, we have compared a 33-bed medical-surgical unit (intervention unit) to a "sister" control unit for a 9-month preimplementation and a 9-month postimplementation period. Following the intervention, all beds in the intervention unit were equipped with monitors that allowed for continuous assessment of heart and respiration rate.

RESULTS: We reviewed 7643 patient charts: 2314 that were continuously monitored in the intervention arm and 5329 in the control arms. Comparing the average length of stay of patients hospitalized in the intervention unit following the implementation of the monitors to that before the implementation and to that in the control unit, we observed a significant decrease (from 4.0 to 3.6 and 3.6 days, respectively; $P < .05$). Total intensive care unit days were significantly lower in the intervention unit postimplementation (63.5 vs 120.1 and 85.36 days/1000 patients, respectively; $P = .04$). The rate of transfer to the intensive care unit did not change, comparing before and after implementation and to the control unit ($P = .19$). Rate of code blue events decreased following the intervention from 6.3 to 0.9 and 2.1, respectively, per 1000 patients ($P = .02$).

CONCLUSIONS: Continuous monitoring on a medical-surgical unit was associated with a significant decrease in total length of stay in the hospital and in intensive care unit days for transferred patients, as well as lower code blue rates.

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Requests for reprints should be addressed to Eyal Zimlichman, MD, MSc, Center for Patient Safety Research and Practice, Division of General Medicine, Brigham & Women's Hospital, 1620 Tremont St, Boston, MA 02120.

E-mail address: ezimlichman@partners.org

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Adult patients hospitalized in acute care facilities who are critically ill requiring either ventilation or hemodynamic support or cardiac monitoring, are usually admitted to either an intensive care unit (ICU) or a telemetry unit. These patients benefit from frequent monitoring of vital signs and pulse oximetry, continuous electrocardiography monitoring, and higher nurse-to-patient ratios. Because non-ICU/telemetry beds usually constitute the majority of available beds in acute care hospitals and academic medical centers, most adult acute care patients are admitted to medical-surgical units where continuous monitoring is not available. Unfortunately, these patients can experience unexpected clinical deterioration that may go undetected if it occurs in the interval between routine vital sign measurements, commonly measured every 4 to 6 hours. McGloin et al[1] demonstrated that potentially avoidable deaths and ICU admissions were associated with physiological deteriorations that may be overlooked. Hravnak et al[2] showed that an integrated monitoring system using standard measurements of heart rate, blood pressure, respiratory rate, and pulse oximetry in a step-down unit was able to detect cardiorespiratory instability.

The implementation of rapid response systems in acute care hospitals has focused primarily on building the efferent limb of the system—the response team. The mixed results reported on the effectiveness of these systems in reducing major adverse outcomes have shifted the emphasis to strengthening the afferent limb of rapid response systems—the ability to detect patients at risk for these outcomes.[3]

Continuous monitoring of low- to average-risk patients outside of ICUs poses a challenge. Frequent vital signs performed by nursing are labor intensive, and can be distressing to patients, especially when they are trying to sleep. However, a new generation of technologies can enable continuous monitoring of vital signs and at the same time are minimally intrusive. We evaluated the efficacy of a continuous, noncontact heart rate and respiration rate monitoring system in a medical-surgical unit of a community hospital to assess its impact on transfers from the unit to the ICU, length of stay (LOS) in the ICU for transferred patients, and LOS at the medical-surgical unit.

CLINICAL SIGNIFICANCE

- Continuous vital signs monitoring in a medical-surgical unit was found to be associated with a reduction in intensive care unit utilization for patients who require transfer due to clinical deterioration.
- Continuous vital signs monitoring in a medical-surgical unit also was found to be associated with a reduction in total time spent in the hospital.
- Results may support the hypothesis that continuous monitoring leads to earlier recognition of patient deterioration.

METHODS

Study Site

We performed a study on a medical-surgical service in a 316-bed community hospital, using 2 control groups. The study included a 9-month prospective intervention period (November 2009-July 2010) and a 9-month retrospective baseline period (January 2009-September 2009). Monitoring was performed in a 33-bed medical-surgical unit (the "intervention" unit) whose population included general medical, trauma, and surgical patients. A similar "sister" 33-bed medical-surgical unit served as a contemporaneous control. Patients were admitted to one of the 2 units by the hospital's admissions office in an alternating manner. As the 2 units were similar in patient population, level of supervision (both units had a nurse-to-patient ratio of 1:5) and services provided, the decision on placement of patients to one of the 2 units was practically random. All patients admitted or transferred to the intervention unit were monitored following the implementation of the monitoring systems on October 2009. The hospital's institutional review board approved the study.

Monitoring Technology

The monitoring system evaluated was the EarlySense system (Earlysense Inc., Waltham, Mass). The system consisted of a piezoelectric motion-sensing device embedded in a flat sensor plate placed under the patient's mattress and connected to a bedside processing and display unit, as previously described.[4-6] Previous research has shown these monitors to be accurate in measurement of both heart rate (HR) and respiration rate (RR),[4] and has shown this system's potential in early recognition of clinical deterioration.[6] Each bed on the intervention unit was equipped with a bedside unit that continuously monitored HR, RR, and movement level. The alert thresholds for HR were usually 40 and 135/min, and for the RR, 8 and 32/min. These could have been modified by the nurses with the approval of a supervisor to accommodate patients who regularly exceed the limits, provided a bedside assessment has been done. Alert annunciations were provided at both a central display station and directly to nurses using text messages on SpectraLink telephones. The hospital had implemented and utilized a rapid response system beginning in 2005. Rapid response teams were staffed with an intensive care physician and nurse. The system performance was reviewed periodically through an institutional review committee.

Outcomes and Definitions

Primary outcomes for the study included unplanned ICU transfers, average ICU LOS for transferred patients, and medical-surgical unit LOS. Unplanned ICU transfers were defined as direct transfers from the study and control units to the hospital's ICU (general and cardiac) for patients that spent at least 12 hours in the general medical-surgical

units where the transfer was not planned in the course of the hospitalization. An example of planned ICU transfers would include patients undergoing certain procedures (eg, gastrointestinal endoscopy, cardioversion, bronchoscopy), where there was felt to be a risk because of comorbidities, and the transfer was made before the procedure for safety concerns. Research nurses determined whether transfers were considered planned versus unplanned through a review of physicians' daily progress notes. Total ICU days were defined as total ICU days per 1000 admissions to the medical-surgical units for all unplanned ICU transfers.

Secondary outcomes for the study included Acute Physiology and Chronic Health Evaluation II (APACHE II) scores for unplanned ICU admissions, number of code blue events, and unexpected deaths.[7] APACHE II scores were used to assess the severity of illness at admission to the ICU. Cardiac arrests were defined as activation of "code-blue" teams in the study and control units as reported by the hospital. Unexpected deaths were defined as deaths in patients on the units that did not have a do-not-resuscitate (DNR) order.

Data Collection and Statistical Analysis

Admissions, transfers, and deaths were identified from the hospital's admission/discharge/transfer database. Research nurses calculated APACHE II scores through retrospective chart reviews. Code blue occurrences were obtained from de-identified risk management records. For comorbidity, Charlson scores were calculated from diagnosis codes in the Health Information Management database. Number and types of alerts throughout the study period were collected from the monitoring devices.

We used one-way analysis of variance to compare normal distributions of continuous variables (age, acuity level, and Charlson score), and used one-tailed unpaired *t* tests to compare the distributions of these variables between pairs of study groups. Likelihood ratio chi-squared statistics were used to compare sex prevalence and number of ICU transfers between the study and control arms. To determine significant differences between study groups, we have defined the comparison between the outcome for the intervention unit postimplementation patients to the preimplementation in the same unit and to the control unit in the postimplementation phase (sample size needed for the study in the planning phase also was calculated using this *P*-value). A *P*-value of $<.05$ was considered significant.

To account for potential confounders that might have contributed to some of the changes between study arms, we have performed a Box-Cox multivariable regression model for the LOS parameters where age, sex, comorbidities, and primary diagnosis served as the independent variables and the LOS served as the dependent variables. Statistical analysis was performed using the JMP software (SAS, Cary, NC).

Literature Review for Alerts Frequency

For a comparison of alert frequency for traditional monitoring systems used within ICUs and general floors, we have conducted a structured literature search. For this we have used the Medline engine using the following MESH terms: Monitoring, Physiologic/instrumentations, Intensive care units, Equipment failure. We have limited our search results to studies published in English and only within the last 20 years.

RESULTS

The study population included 7643 patients, of which 2314 patients in the intervention unit were placed under continuous monitoring in the postimplementation phase. Patient demographics, acuity level on admission, and comorbidity score (Charlson) are presented in **Table 1**. Acuity level and age were similar across the groups, as were the Charlson scores. Overall, for the intervention unit we have recorded 585 HR alerts and 2904 RR alerts from the Earlysense monitor, or a rate of 0.06 alerts/day/bed for HR and 0.3 alerts/day/bed for RR. A list of primary diagnoses grouped by International Classification of Diseases, version 9 codes and compared between study groups is presented in **Table 2**.

After adjusting for confounders, we did not find a significant change in number of transfers from the intervention unit or the control unit to the ICU comparing the postimplementation period with the preimplementation period (**Table 3**). However, total ICU days of patients transferred from the intervention unit decreased postimplementation

Table 1 Demographics and Clinical Baseline Information for the Control and Study Units

	Control Unit			Study Unit			All Units
	Baseline (Pre)	Control (Post)	*P*-Value	Baseline (Pre)	Intervention (Post)	*P*-Value	*P*-Value
Patients, n	1535	2361		1433	2314		
Age, mean (SD)	49.8 (19.6)	49.6 (20.3)	.76	49.5 (19.6)	49.3 (19.9)	.73	.81
Males %	46.2	45.0	.57	44.5	48.9	.04	.19
Acuity level*, mean (SD)	2.9 (0.4)	2.9 (0.4)	.36	2.8 (0.4)	2.8 (0.4)	.70	.11
Charlson score, mean (SD)	1.8 (2.4)	1.9 (2.4)	.62	1.8 (2.3)	1.8 (2.4)	.61	.90

*Acuity level based on internal acuity scale of 1 to 4 (4 being highest acuity).

Table 2 Primary Diagnosis for Hospitalization by International Statistical Classification of Diseases, Version 9 (ICD-9) Codes For All Patients

ICD-9		CU-Pre	CU-Post	SU-Pre	SU-Post	*P*-Value
001-139	Infectious And Parasitic Diseases	604	949	587	923	.84
240-279	Endocrine, Nutritional And Metabolic Diseases, And Immunity Disorders	51	61	38	64	.57
280-289	Diseases Of The Blood And Blood-Forming Organs	17	16	12	21	.56
290-319	Mental Disorders	16	16	13	12	.26
320-389	Diseases Of The Nervous System And Sense Organs	17	11	10	10	.06
390-459	Diseases Of The Circulatory System	33	35	27	24	.03
460-519	Diseases Of The Respiratory System	49	38	38	47	.01
520-579	Diseases Of The Digestive System	46	72	38	67	.91
580-629	Diseases Of The Genitourinary System	21	22	20	23	.41
630-679	Complications Of Pregnancy, Childbirth, And The Puerperium	31	42	24	45	.88
680-709	Diseases Of The Skin And Subcutaneous Tissue	10	23	9	17	.59
710-739	Diseases Of The Musculoskeletal System And Connective Tissue	26	66	28	57	.10
780-799	Symptoms, Signs, And Ill-Defined Conditions	359	562	356	534	.65
800-999	Injury And Poisoning	146	266	117	298	<.01
E000-E999	Supplementary Classification Of External Causes Of Injury And Poisoning	15	35	19	25	.46
	Others (Neoplasms, Congenital Anomalies, Certain Conditions Originating In The Perinatal Period, and Supplementary Classification Of Factors Influencing Health Status And Contact With Health Services)	94	147	97	147	.89
	Sum	1535	2361	1433	2314	

We performed contingency analysis of primary diagnosis by the different arms using chi-squared test.

of monitors compared with the period before implementation and compared with the control unit (63.44 days/1000 patients postimplementation compared with 120.11/1000 patients pre- and to 85.36/1000 patients for the control concurrent post; $P = .04$). The **Figure** illustrates the significant difference in LOS at the ICU between the intervention group and the 2 control groups—both preimplementation and the corresponding time in the control unit.

Following the intervention, the length of stay was significantly lower in the study unit in the period following the implementation of the monitoring systems compared with the period before the implementation and with the control unit in the postimplementation phase (3.63 compared with 4.00 days in the intervention unit and 3.61 compared with 3.8 days in the control unit, respectively; $P < .01$). When comparing APACHE II scores between the study groups, no statistically significant changes were noted.

The incidence of code blue events in the intervention unit decreased significantly following the implementation of the monitors when comparing postintervention with the preintervention in the study unit and with the concurrent post period in the control unit (0.9/1000 patients compared with 6.3/1000 patients and 2.1/1000 patients, respectively; $P = .01$), while no significant change was observed for the control unit (3.9 to 2.1/1000 patients; $P = .45$) (**Table 3**). Overall mortality was low, with 2 non-DNR deaths during the control period (one each in the study and control units), and one non-DNR death during the intervention period on the control unit. **Table 4** presents the studies we found in our structured literature search and the alert frequency found at each study adjusted for alerts per 100 monitoring hours.[8-12]

DISCUSSION

We evaluated a contact-less monitoring system and found the implementation of the system on a medical-surgical floor setting was associated with a lower number of ICU days for transfers, shorter overall hospital LOS in the intervention group, and a lower frequency of code blue events, although the rate of transfers to the ICU did not change significantly.

Several solutions for the need for continuous monitoring on the floors have emerged in recent years. Electrocardiographic monitoring (telemetry) has been invaluable for higher-risk cardiac patients, yet in recent years we are witnessing significant overuse of this application,[13] with most monitored patients gaining little cardiac arrest survival benefit.[14] Pulse oximetry is regarded as one of the most important technological advancements in monitoring patients, especially under anesthesia. Although designed to provide point-measurement assessment, it also has been used for continuous monitoring, specifically in the ICU setting and perioperatively.[15] In a recent study, researchers have found that for postoperative patients, continuous patient surveillance of pulse oximetry resulted in a reduced need for rescue events and ICU transfers.[16] However, this modality carries important limitations that might prevent

Table 3 Study Outcomes Comparing the Control and Study Units Before and After Implementation of the Monitors

	Control Unit (CU)			Intervention Unit (IU)			*P*-Value		
	Baseline (Pre)	Control (Post)	*P*-Value	Baseline (Pre)	Intervention (Post)	*P*-Value	(CU-IU Pre)	(CU-IU Post)	3 Arms*
LOS in med/surg unit,† mean (25%-75% IQR)	3.80 (1.26-4.25)	3.61 (1.19-4.12)	.07	4.00 (1.26-4.66)	3.63 (1.19-4.22)	.02	.19	.37	<.01
ICU transfers									
Transfers/1000 pt	18.89	19.06	1.00	26.52	25.93	.92	.17	.12	.19
Days/1000 pt	32.69	85.36	.01	120.11	63.44	.10	.06	.02	.04
ICU LOS,† mean (25%-75% IQR)	1.73 (1.06-2.28)	4.48 (0.94-4.09)		4.53 (0.91-4.39)	2.45 (0.86-2.82)				
APACHE II score, mean (25-75% IQR)	13.08 (7.75-18.00)	14.0 (6.00-19.00)	.59	15.19 (10.00-18.00)	13.38 (7.00-18.25)	.25	.29	.61	.53
LOS in unit before transfer to ICU,† mean (25%-75% IQR)	13.07 (7.26-19.46)	17.03 (6.97-19.9)	.29	16.82 (5.97-19.95)	11.94 (5.77-14.40)	.07	.19	.13	.14
Code blue events/1000 pt	3.9	2.1	.36	6.3	0.9	<.01	.44	.45	.01

APACHE II = Acute Physiology and Chronic Health Evaluation II; ICU = Intensive Care Unit; IQR = interquartile range; LOS = length of stay; med/surg = Medical-Surgical Units.
* *P*-value comparing 3 arms: intervention unit post, intervention unit pre, and control unit post.
†Results are adjusted for sex, age, comorbidities, and primary diagnosis through a multivariable regression model (Box-Cox).

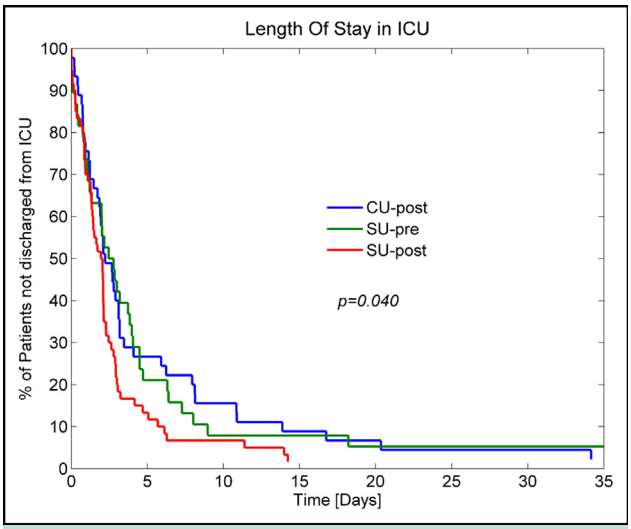

Figure Stay in the intensive care unit (ICU) for patients transferred from the study unit (SU) and control unit (CU) before implementation (pre) and after implementation (post) of the monitors over time.

early detection of respiratory failure.[17,18] A third emerging modality is continuous end-tidal CO_2 monitoring (capnography). The use of capnography, which up until recently has been used nearly exclusively for monitoring patients' ventilatory status during general anesthesia, is now expanding to include procedural sedation and analgesia,[19] and has been suggested as a tool for continuous monitoring in the postoperative period.[20] All 3 above-mentioned modalities, however, require continuous contact of leads/sensors to the patient, a disadvantage when regarding monitoring for low-/average-risk patients on non-ICU hospital floors.

Previous studies[21-24] have shown that deterioration in simple vital signs, such as HR and RR, often precede adverse events by hours, providing a window of opportunity for earlier intervention that can help stabilize patients before more serious complications occur. The result is a less acutely ill ICU transfer patient, a shorter recovery, and a reduced LOS in the ICU. Hillman et al[24] found that patients transferred to the ICU from the general wards had a larger number of serious antecedents (72%) than those from the operating room (64%) or emergency department (62%), with a majority showing potentially life-threatening abnormalities during the 8 hours before transfer. Using APACHE II scores, Goldhill et al[25] found that significant deterioration in respiratory function occurred in the 24 hours preceding ICU admission from the ward, with only respiratory rate showing a significant increase in APACHE II points over time. Jacques et al,[26] in a study of 3046 adult admissions, looked at early and late signs of critical conditions and serious adverse events, and found that abnormal pulse rates and respiratory rates, either as early or late signs, raised the odds ratio of transfer to the ICU. Kause et al[27] demonstrated clinical antecedents, including abnormal heart and respiratory rates, in 54.5% of unanticipated ICU admissions.

Table 4 Alert Frequency in the Intervention Unit with the EarlySense Monitor Compared with Other Studies

Study	Inpatient Setting	Type of Alerts	Alerts per 100 Recording Hours
Current study	Medical-surgical units	Heart rate (18%) and respiratory rate (82%)	2.2
Chambrin et al, 1999[8]	ICU*	Ventilators (38%), cardiovascular monitors (37%), pulse oximeters (15%) and capnography (14%)	161
Lawless, 1994[9]	Pediatric ICU	Pulse oximeter (44%), ventilators (31%), cardiovascular monitors (24%), capnography (1%)	230
Görges et al, 2009[10]	ICU	Ventilators (40%), cardiovascular monitors (21%), pulse oximeters (15%), infusion pumps (12%)	636
Siebig et al, 2010[11]	ICU	Cardiovascular monitors (66%), pulse oximeters (26%), respiration rate (3%)	604
Wiklund et al, 1994[12]	Postanesthesia care unit	Pulse oximeters	730

ICU = intensive care unit.
*Control Unit.

Young et al[28] found that patients transferred to the ICU more than 4 hours after physiologic deterioration were sicker according to APACHE II scores compared with those transferred in <4 hours, had a higher mortality (41% vs 11%), and had a reduced hospital LOS (14 days vs 9 days). For this group, earlier detection, intervention, and transfer conferred acuity, mortality, and LOS benefits.

Based on previous studies, one might hypothesize that the reduction in ICU LOS for transfers from the medical-surgical unit and also the reduced hospital LOS might be attributable to the continuous monitoring of heart and respiration rate, coupled with alerting to nurses of abnormal values. This probably reflects earlier detection and more effective intervention for clinical problems that can prolong the ICU or hospital stay. For those patients transferred to the ICU from the study and control units, the borderline significant trend towards shorter stays in the medical-surgical unit before transfer could support our hypothesis.

The lower rate of code blue events suggests that earlier recognition of deterioration and timelier intervention would prevent patients from reaching a crisis state. Previous studies have demonstrated that clear cardiac and respiratory warning signs are present 6-8 hours before cardiac arrest in a high percentage of cases,[21-24] including unstable vital signs and respiratory distress. Respiratory rate has been termed "the neglected vital sign" and is a predictor of potentially serious clinical events.[29] Acute respiratory insufficiency or compromise is a common reason for cardiac arrest,[30] exceeded only by arrhythmias, and abnormal respiratory rates have been found to be independent predictors of in-hospital mortality.[31]

The continuous monitoring used in this study was associated with a low alert frequency as compared with reports of alert burden in ICUs and postanesthesia care units (**Table 4**). A valid concern associated with continuous monitoring is alert burden on clinical staff. This refers to the multitude of monitors and alerting devices, especially in the ICU environment, many of which present very high false-positive rates, leading to both excessive work burden on staff and also desensitization in their response. While alert burden is particularly serious in ICUs, it also is important in general medical-surgical units. The fact that the monitoring technology used in our study was associated with low alert burden is important to consider as hospital administrators consider implementation.

Our study has several limitations. The study was done in a single setting, and the results might not be generalizable to other institutions or types of hospitals. Although we were able to show significant differences in our primary outcomes (somewhat due to an unexpected increase in census during the study period), our sample size was not big enough to demonstrate changes in other less common outcomes such as mortality. Second, we were unable to collect data about rapid response teams. This could have helped our understanding regarding the mechanism by which continuous monitoring might have helped in preventing adverse clinical outcomes. Calculating APACHE II scores retrospectively through chart reviews tends to result in underestimation of scores, yet we believe this bias was similar for all study groups, thus enabling a valid comparison. Lastly, although we used 2 control units, our study design prevents us from determining causality between the continuous monitoring and the effects we have found. Other unmeasured factors might have contributed to these differences, such as workload issues or other hospital initiatives.

In conclusion, we found that continuous monitoring on a medical-surgical unit was associated with lower ICU length of stay, lower hospital LOS, and lower code blue rates, with no effect on frequency of transfers to the ICU, and without contributing significantly to alert burden. We hypothesize that the mechanism for this is earlier detection of deterioration, more opportunity for intervention, and consequent reduction in acuity. We believe that the impact of continuous monitoring was to enable earlier recognition and treatment of clinical changes that can delay hospital discharge. Further research is needed to first reinforce our findings, assess effect on mortality, and provide a better understanding regarding the mechanisms for the effect.

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