Evaluation of standard versus nonstandard vital signs monitors in the prehospital and emergency departments: Results and lessons learned from a trauma patient care protocol

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BACKGROUND: This study aimed to determine the effectiveness of using a wireless, portable vital signs monitor (WVSM) for predicting the need for lifesaving interventions (LSIs) in the emergency department (ED) and use a multivariate logistic regression model to determine whether the WVSM was an improved predictor of LSIs in the ED over the standard of care monitor currently being used.

METHODS: This study analyzed 305 consecutive patients transported from the scene via helicopter to a Level I trauma center. For 104 patients in the study, a WVSM was also attached to the patient's arm and used to record and display prehospital and hospital physiologic data in real time on a handheld computer and in the trauma bay. Multivariate logistic regression analyses were performed for accuracy in predicting needs for LSIs in control and WVSM subjects. In addition, receiver operating characteristic curves were obtained to examine the discriminating power of the models for the outcome of one or more LSIs in the ED.

RESULTS: Of the 305 patients, 73 underwent 109 LSIs in the ED. Of these, 21 patients wore the WVSM during transport in addition to the standard monitor. Logistic regression analysis revealed that heart rate, respiratory rate, and systolic blood pressure were significantly associated with an increased risk for LSIs in the ED ($p < 0.05$). Receiver operating characteristic curve analysis also demonstrated better prediction for LSIs performed in the ED in WVSM subjects than in control subjects (area under the curve, 0.86 vs. 0.81, respectively).

CONCLUSION: The WVSM system leads to improved LSI accuracy in the ED. In addition, many important lessons have been learned in preparation for this study. Adoption of nonstandard vital signs monitors into critical care/trauma medicine may require a new paradigm of personnel education, training, and practice. (*J Trauma Acute Care Surg*. 2014;77: S121 S126. Copyright © 2014 by Lippincott Williams & Wilkins)

LEVEL OF EVIDENCE: Therapeutic/care management, level IV.

KEY WORDS: Prehospital physiologic data; lifesaving interventions; vital signs; signal quality; automatic data processing.

Current vital signs monitors (i.e., standard or traditional vital signs monitors [SVSMs]) in the critical care environment suffer from many drawbacks.[1–4] A majority of them are heavy and cumbersome, occupy too much space, cannot communicate to other systems, and do not have access to real-time patient information, such as point-of-injury data or data recorded from the injury scene. Because they do not facilitate information flow, these systems can make triage and treatment of trauma patients problematic in both military and civilian trauma environments.[3–6]

In contrast, previous studies have shown that the use of new computer technologies that allow for the development of more intuitive monitoring devices and interfaces (i.e., "smart device" or non-SVSMs) capable of supplying the medic with constant physiologic observations and data may enhance the care provider's ability to assess and treat battlefield and civilian injuries.[3,4,7] Specifically, because initiation of early and effective prehospital lifesaving interventions (LSIs) is a critical aspect of trauma patient care,[8,9] real-time observable and actionable physiologic data of patient progression are critical for better management of the patient's injury and could help facilitate more accurate prediction of the need for LSIs.[3,4,9–11]

The wireless vital signs monitor (WVSM, Athena GTX, Inc., Des Moines, IA) was developed to address the logistical and data limitations inherent in SVSMs and, thereby, help make assessment of the critical care patient easier. Its capabilities and other specifications are listed in Table 1. As a remote patient monitor for adult patients, the WVSM includes a single- or multiple-parameter vital signs monitor for electrocardiogram (ECG), noninvasive blood pressure (NIBP), and blood oxygenation (Spo_2). The WVSM is small enough to attach to the patient with a standard blood pressure cuff and uses a wireless connection to transmit data to handheld devices or personal computers. Moreover, the WVSM can stream all data captured from the patient to a receiving station for use by providers and can record 4.5 hours of trends with a battery life of approximately 8 hours. Because of its transportability and versatility, the WVSM system may be used throughout the entire critical care spectrum.

This study was designed to (1) analyze the efficacy of using the Athena WVSM system at predicting the need for LSIs in the emergency department (ED) and (2) use a multivariate logistic

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This study was conducted under a protocol reviewed and approved by the University of Texas Health Science Center at Houston and in accordance with the approved protocol.

The opinions or assertions contained herein are the private views of the authors and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

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TABLE 1. Comparison Between SVSM and the WVSM

SVSM	WVSM
• Weighs 14.8 lb (without cables)	• Weighs 1 lb
• Height, 31.7 cm (12.5 in); width, 39.6 cm (15.6 in); depth, 23.1 cm (9.1 in)	• Height, 6.6 cm (2.6 in); width, 10.2 cm (4.0 in); depth, 13.7 cm (5.4 in)
• Battery life (monitoring) of 110 180 min	• Battery life of approximately 8 h
• Basic system can monitor 1 patient individually	• Entire system can monitor up to 20 patients simultaneously
• Wi-Fi, 802.11g, Bluetooth	• Wi-Fi, 802.11g
• Automatically monitors NIBP, Spo_2, HR, and ECG	• Automatically monitors NIBP, Spo_2, HR, and ECG
• Captures 2 full-capacity patient records and 45-min ECG	• Captures 4.5 h of patient data and trending
• Manual mode for defibrillation	• Manual inputs include GCS score, temperature, and RR
• NIBP systolic, 30 245 mm Hg/ diastolic, 21 210 mm Hg	• NIBP systolic, 40 260 mm Hg/ diastolic, 20 200 mm Hg
• Spo_2 ranges 1 100% saturation	• Spo_2 ranges 0 100% saturation
• 12-lead ECG	• 3-lead (Lead II) ECG

Wi-Fi, wireless fidelity.

regression model to determine whether the WVSM was a better predictor of LSIs in the ED compared with SVSMs currently used for patient care. The major hypothesis was that the unique aspects of the WVSM would allow physicians to improve the prediction of the need for LSIs in the ED compared with standard monitors.

PATIENTS AND METHODS

Subjects and Protocol

This study was approved by the institutional review board at the University of Texas Health Science Center at Houston. From June 27, 2011, to January 6, 2012, 305 consecutive patients transported via the Life Flight helicopter service to the Memorial Hermann Hospital, a Level I trauma center in Houston, Texas, were enrolled in the study based on the following criteria: (1) patient was older than 18 years, (2) Code 2/3 trauma patient with blunt or penetrating trauma, and (3) direct transport of the patient from the injury scene to the hospital via helicopter service. Code 2 denotes a nonemergency but highly important response, whereas Code 3 denotes a life-threatening response requiring emergency traffic or simultaneous use of lights and sirens. Subjects were randomized onsite to include an SVSM (LIFEPAK 12, Physio-Control, Inc., Redmond, WA) for monitoring (control) or both an SVSM and WVSM (study) based solely on the Life Flight team's ad hoc decision. Patients who did not wear the device because of technical issues, shortage of time, arm injuries precluding use of the device, unavailability of device in helicopter, and/or provider's decision to not use the device were assigned to the control group.

For WVSM subjects, data were also collected using a computerized server system that stored and transmitted all data from the WVSM device through a wireless connection once a patient arrived in the ED. Numeric data from the WVSM device were stored at a rate of 1 Hz. In addition, ECG waveform data from a single lead and pleth waveform data from a thumb-mounted pulse oximeter to the WVSM were recorded at rates of 230 Hz and 75 Hz, respectively. For trauma patients with concomitant lung injuries, respiration waveform data were also recorded at a rate of 10 Hz. Data collection was stopped when the subject was moved from the ED trauma bay.

Standard vital signs used during trauma care for patient assessment included heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure, mean arterial pressure, respiratory rate (RR), and blood oxygenation (Spo_2). Combinations of these vital signs were also used to derive other measurements including shock index (shock index = HR / SBP) and pulse pressure (pulse pressure = SBP − diastolic blood pressure). All nonelectronic data were manually recorded on an electronic run sheet (Tablet PCR, Zoll Medical, Chelmsford, MA) by emergency medical services medics, then collected on a standardized form, and entered into the study research database (https://openclinica.com, OpenClinica, LLC, Waltham, MA). Data included demographic information, physical examination results, Glasgow Coma Scale (GCS) scores (motor, verbal, eye), and interventions performed on the patients in the field. ED LSIs consisted of endotracheal intubations, blood product transfusions, tube thoracostomies, cardiopulmonary resuscitations, needle decompressions, angioembolizations, cricothyrotomies, thoracotomies, and cardioversions.

Statistical Analysis

Multivariate logistic regression analyses were performed for control subjects alone with independent variables of age, height, race, and weight and with dependent variables of in-hospital initial vital sign measurements and GCS scores. Factors that were not significant were removed from the model via backward elimination. The same analyses were also performed for WVSM subjects. Receiver operating characteristic curves were also obtained to examine the discriminating power of the models for the outcome of at least one LSI in the ED.

The accuracy of the statistical models were assessed by calculating the number of outcomes correctly or incorrectly classified. The power of demographics and vital sign measurements to predict whether LSIs were performed was estimated using multivariate logistic regression. JMP version 9.0.0 (SAS Institute, Cary, NC) and the R Language (http://www.r-project.org/), a well-known open-source statistical software package, were used for statistical analysis.

RESULTS

Physiologic data were collected on 305 consecutive patients during an 8-month period. Of these, 34% (104 of 305) wore the WVSM during transport. The other 66% (201 of 305) were classified as control subjects. Demographics for all patients are shown in Table 2. The mean (SD) flight time was 24.5 (35.4) minutes, median flight time was 17.5 minutes, maximum flight time was 371 minutes, and minimum flight time was 8 minutes.

Interventions performed in this study and classified as lifesaving by a multidisciplinary team of trauma experts are shown in Table 3. Age and race were not different between those patients who received at least one LSI and those who received none. Increasing patient age did not increase the frequency of an LSI in this sample/study. Likewise, there were no statistical differences in demographic information (age, race, etc.) between WVSM and

TABLE 2. Demographics

	All Patients		Patients With LSIs		Prehospital LSIs		ED LSIs	
	#	%	#	%	#	%	#	%
Variable	**N**	**N/305**	**n**	**n/N**	**i**	**i/90**	**j**	**j/109**
All patients	305	100	115	38	90	100	109	100
SVSM	201	66	86	43	62	69	70	64
WVSM	104	34	29	28	28	31	39	36
Sex								
Female	104	34	32	31	31	34	44	40
Male	201	66	83	41	59	66	65	60
Race								
White	191	63	71	37	58	64	62	57
Black	30	10	12	40	10	11	13	12
Hispanic	64	21	28	44	19	21	27	25
Asian/Pacific	3	1	2	67	1	1	5	5
Not recorded	17	5	2	12	2	3	2	1
Age								
Mean (SD), 39 (16)								
Quartiles								
18 26	76	25	30	40	30	33	37	34
27 36	76	25	28	37	22	25	19	17
37 50	76	25	26	34	17	19	27	25
51 85	77	25	31	40	21	23	26	24
HR,* beats/min								
Mean (SD), 95 (19)								
Quartiles								
53 80	76	25	21	28	16	18	18	17
81 92	68	22	22	32	13	14	13	11
93 105	72	24	20	28	17	19	19	17
106 170	74	24	45	61	40	44	54	50
Unknown	15	5	7	47	4	5	5	5
SBP,* mm Hg								
Mean (SD), 133 (26)								
Quartiles								
61 118	74	24	45	61	31	34	50	46
120 133	73	24	24	33	19	21	11	10
134 105	72	24	16	22	13	14	17	16
106 170	74	24	25	34	22	25	27	25
Unknown	12	4	5	42	5	6	4	3
All patients	305	100	115	38	90	100	109	100
SVSM	201	66	86	43	62	69	70	64
WVSM	104	34	29	28	28	31	39	36
RR,* breaths/min								
Mean (SD), 18 (4)								
Quartiles								
3 15	45	15	16	36	14	16	10	9
16 17	60	20	17	28	7	8	25	23
18 19	57	19	8	14	3	3	10	9
20 32	83	27	25	30	11	12	27	25
Unknown**	60	19	49	82	55	61	37	34

*Entry values taken from the run sheet.
**Of these 60 patients, 42 were SVSM subjects and 18 were WVSM subjects.

control subjects. Of the patients, 37% (115 of 305) underwent 199 LSIs. Of these patients, 25% (29 of 115) wore the WVSM. In the ED, 24% (73 of 305) of the patients underwent 109 LSIs, and only 29% (21 of 73) wore the WVSM.

Control Subjects Versus WVSM Subjects

After multivariate logistic regression, HR, RR, and SBP were associated with an increased risk for LSIs in the ED. Variables not significantly associated with ED LSIs were removed

TABLE 3. Lifesaving Interventions

	Control		WVSM		Total	
	#	%	#	%	#	%
LSIs	**m**	**m/199**	**n**	**n/199**	**N**	**N/199**
Prehospital	59	30	31	16	90	45
Blood	3	2	3	2	6	3
Cardiopulmonary resuscitation	2	1	4	2	6	3
Chest tube	0	0	0	0	0	0
Intubation	51	26	22	11	73	37
Needle decompression	1	0	0	0	1	0
Pericardiocentesis	0	0	0	0	0	0
Surgical cricothyrotomy	0	0	0	0	0	0
Thoracotomy	0	0	0	0	0	0
Tourniquet	2	1	2	1	4	2
ED	65	32	44	22	109	55
Angio nonembolized	0	0	0	0	0	0
Angio embolized	0	0	0	0	0	0
Blood	37	19	16	9	53	27
Cardiopulmonary resuscitation	3	2	3	2	6	4
Cardioversion	2	1	0	0	2	1
Chest tube 1	12	6	10	5	22	11
Chest tube 2	1	0	5	3	6	3
Intubation	8	4	4	2	12	6
Needle decompression	1	0	1	0	2	1
Pericardiocentesis	0	0	1	0	1	0
Surgical cricothyrotomy	1	0	1	0	2	1
Thoracotomy	0	0	1	0	1	0
Tourniquet	0	0	2	1	2	1
Total	124	62	75	38	199	100

from the final models via backward elimination. In the model for SVSM subjects (Table 4), odds ratios (ORs) were 1.02 (95% confidence interval [CI], 1.01–1.04; $p = 0.01$) for HR (per beat-per-minute increase), 1.02 (95% CI, 0.99–1.04; $p = 0.16$) for RR (per breath-per-minute increase), and 0.96 (95% CI, 0.94–0.97; $p < 0.0001$) for SBP (per millimeter-of-mercury increase). For the WVSM model, RR (OR, 1.10; 95% CI, 1.01–1.21; $p = 0.02$) and SBP (OR, 0.94; 95% CI, 0.91–0.97; $p = 0.0007$) remained significant after adjustment (Table 4).

Receiver operating characteristic curves (Fig. 1) demonstrated better prediction for ED LSIs in WVSM subjects (area under the curve [AUC], 0.86) than in SVSM subjects (AUC, 0.81). When using all LSIs (both prehospital and in-hospital LSIs) as outcomes for WVSM and SVSM subjects, AUCs increased to 0.94 and 0.87, respectively.

DISCUSSION

This study was the first to determine the effectiveness of using a wireless and portable vital signs monitor for predicting the need for LSIs in the ED. It was also the first to use a multivariate logistic regression model to determine whether the WVSM was a better predictor of LSIs in the ED compared with an SVSM. In the statistical analyses described earlier, HR and RR increased the odds of an LSI by approximately 2%. However, for SVSM subjects, RR measurements in LSI patients were not statistically different from the non-LSI patients, perhaps confirming the fact that RR measurements using an SVSM are often inaccurate and unreliable.[2] In contrast, because the WVSM could continuously acquire RR measurements in an intubated patient, results showed statistical differences between LSI and non-LSI patient groups.

While HR measurements in SVSM subjects with LSIs were statistically different from those without LSIs, this was not the case for WVSM subjects owing to noise in the ECG and pleth waveforms acquired by the WVSM and the sensitivity of HR calculations to noise. HR was calculated from the ECG and when the ECG was unreliable, from the pleth waveform. The sensitivity of these waveforms to noise may have well affected HR calculations. Another possibility was human error introduced by

TABLE 4. Multivariate Logistic Regression for ED LSIs

Variable	OR for ED LSIs (95% CI)*	*p*
SVSM subjects		
HR	1.02 (1.01 1.04)	0.01
RR	1.02 (0.99 1.04)	0.16
SBP	0.96 (0.94 0.97)	<0.0001
WVSM subjects		
HR	1.02 (0.99 1.06)	0.21
RR	1.10 (1.01 1.21)	0.02
SBP	0.94 (0.91 0.97)	0.0007

*ORs for measurements reflect per-unit increase.

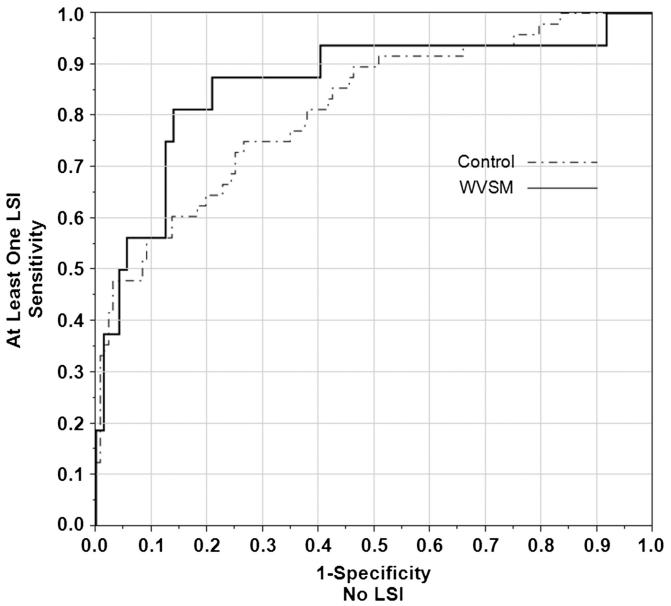

Figure 1. Receiver operating characteristic curves. Receiver operating characteristic curves were obtained to examine the discriminating power of multivariate logistic regression models for the outcome of at least one LSI and then for at least one ED LSI in control and WVSM subjects. The curves demonstrated better prediction for ED LSIs in WVSM subjects (AUC, 0.86) than in control subjects (AUC, 0.81). When using both prehospital and in-hospital LSIs as outcomes, AUCs increased to 0.94 and 0.87, respectively.

the provider's use of the WVSM while attaching the device to the patient's arm. It is important to point out here that the results of this study were preliminary, no collected data were excluded, and the number of LSI patients who wore the WVSM was relatively small. Because HR is critical for triage and decision making, new technologies must ensure robustness in HR calculations.

In this study, SBP differed most significantly between LSI and non-LSI patients for both control and study groups. These findings seemed to be similar to previous work, which reported that SBP was significantly associated with an LSI[12] and that hypotension could lead to more expeditious identification of battlefield casualties in need of LSIs such as the need for blood or surgical intervention.[13] Presence of hypotension was associated with an LSI. It is important to emphasize here that this is an association and not necessarily a cause-and-effect relationship. This study involved civilian patients who exhibited extremely high SBP values rather than low values. These values contributed to the overall performance of statistical models for predicting the need for LSIs.

This study had several limitations. It was conceived with the hypothesis that the WVSM, a nonstandard wearable vital signs monitor, could improve care in the ED compared with SVSMs and better predict the need for ED LSIs in trauma patients. LSI performance, rather than mortality, was chosen as an end point because of its usefulness for prehospital triage[8] and the fact that it could identify more patients requiring attention from medical personnel, treatment, and resources of a trauma center compared with mortality. Furthermore, ED LSIs were chosen to show that the seamless transfer of data via the WVSM from the prehospital to the ED may help better predict the need for LSIs in the ED compared with segregated data from SVSMs. (For this study, the WVSM was only useful in predicting the need for LSIs in the ED and not en route owing to the inconsistency of durations and quality of prehospital data among patients, which prevented full use of the data.)

To test the hypothesis that the WVSM system was superior, the study cohort would require monitoring exclusively with the WVSM device. This meant that the study design needed a control group using only the SVSM and a study group using only the WVSM for patient monitoring, so that the two monitors could be compared without bias and strengths of the WVSM system could be clearly identified. However, owing to the inability of the WVSM to interface directly with either the electronic health record or the electronic run sheet system, the SVSM had to be available to the care provider during all times. The WVSM was considered a new device that had not met the information technology department's requirements and was not able to transfer data to the electronic medical record.

Therefore, the WVSM was not supported by the information technology system, and its use was often considered an increase to the workload. The emergency medical services personnel could decide when they wanted to attach the WVSM to the patient and often left the device off when they were faced with a dire situation. Simultaneous availability of the SVSM and WVSM allowed paramedics, physicians, and other medical personnel to keep to traditional practices and continue with the use of the SVSM, thereby circumventing use of the WVSM. For this reason, neither care provider's preference nor the usability of the WVSM could be assessed.

A second drawback was that LSIs were recorded only when the nurse/paramedic manually pressed a button on the WVSM data-capture-and-display interface. Because of this limitation, the study suffered from scarcity of recorded times of LSIs needed to provide a validation set for algorithm development and validation.

As noted in the section earlier, a third limitation to this study was the discrepancy between numbers of patients in the study and control groups. Lastly, Injury Severity Scores (ISSs) and details regarding individual LSIs performed were missing from many patient records.

Nevertheless, statistical analyses and receiver operating characteristic curves have helped determine that the use of monitoring systems such as the WVSM leads to the identification of the need for an LSI in the ED (Fig. 1, Table 4). Repeated models for WVSM patients generally performed more accurately than those for SVSM patients.

There were a number of additional lessons learned from this effort. Any new medical devices/modalities to be used for a prehospital study will require incorporation into the local information technology infrastructure; otherwise, they are stand-alone and cannot be practically supported. Effective surveys will require training beforehand as well as careful onsite administration to ensure survey completion and accuracy of responses. In addition to an awareness of this study's shortcomings and how to correct them in future studies, a much better understanding of prehospital patient recruitment, a greater appreciation of how to define this population, and the value of designing and completing the trial to establish higher-quality evidence have been obtained through simulation runs of the protocol.

This study did not have recruitment issues. There were no serious adverse events to compromise the validity of completing the trial. Importantly, given new capabilities in monitoring technologies, such as miniaturization, wireless communications, and the ability to capture high-resolution vital signs, this study has demonstrated that it is now possible to conduct effective prehospital studies and develop high-fidelity databases for future research.

Adoption of non-SVSMs into critical care and trauma medicine may require a new paradigm of personnel education, training, and practice. This change needs to begin at the executive level. Otherwise, traditional vital signs monitors will continue to occupy precedence, and standards of care will remain the same technologically as before. A larger issue is the development of interoperability standards to facilitate device connectivity so that any monitor can be easily integrated into a medical setting.

A notable result of this study was the development of a prehospital data collection system that addressed the lack of high-resolution and continuous vital signs for effective analysis of trauma patients during the initial critical care phase. Future studies will use vital signs, trends, new biomarkers of patient stability, and machine learning to develop techniques and strategies for identifying trauma patients who received interventions.

AUTHORSHIP

N.T.L. contributed to the data analysis, data interpretation, writing, and critical revision. J.B.H., C.E.W., and M.I.D. contributed to the study design and critical revision. J.S. was the overall principal investigator and contributed to the study design, writing, and critical revision.

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DISCLOSURE

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