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14. ABSTRACT- The overall project goal of this project is to deliver to the US Special Operations Command (SOCOM) a miniature, portable wireless vital signs monitor (MWVSM, Minimedic, www.athenagtx.com) and/or new algorithms based on non-invasively measured vital signs or other physiological variables, that could aid in the triage and diagnosis of trauma patients with and without traumatic brain injury (TBI). The MWVSM consists of two components: a miniature sensor that is placed either on the forehead or the fingertip of a casualty; and monitor carried by an emergency first responder that receives a wireless signal transmitted up to 100 m by the sensor. The weight, size and wireless properties of the two MWVSM offers significant logistic advantages over standard vital signs monitor for combat casualty care. However, this device has not yet been field tested.
To accomplish the goal, data from the MWVSM is being compared to data from a standard vital signs monitor during prehospital transport of trauma patients, during assessment in the trauma resuscitation area, and in the intensive care unit. One of the most important findings from this study will be whether an injury acuity index, or similar algorithm, derived from the MWVSM is practical for trauma triage.
The data collection/analysis is ongoing/incomplete at this point, but show: 1) No safety issues or adverse events. 2) The study objectives will be achieved with fewer than 800 patients enrolled; 3) We will have first of kind trauma data from the point of injury through the entire hospital cource; 4) An injury acuity algorithm has the potential to identify prehospital trauma patients who need a life saving intervention, and is superior to conventional vital signs; 5) The MWVSM finger and forhead sensors have different performance characteristics; 6) A loss of peripheral signals seems to be an early sign of traumatic shock.

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A. INTRODUCTION

The approved statement of work (SOW) and main questions related to the SOW for this project requires clinical data collection and analysis, and neither is complete. Therefore the primary focus of this report is to provide information on :

1) administrative and technical issues that affect enrollment

2) number of patients enrolled to date, number of disqualified patients if any and for what reasons, number of dropouts if any and why, will study meet its target number (state what that is or approved for) for clinical significance and if not what are the proposed strategies to address this shortfall, will study meet its target earlier than anticipated because of the uniformity of the data and if so, how that will impact the work

3) adverse events

The overall project goal of this project is to deliver to the US Special Operations Command (SOCOM) a miniature, portable wireless vital signs monitor (MWVSM, Mini-medic^{TM}, www.athenagtx.com) and/or new algorithms based on non-invasively measured vital signs or other physiologic variables, that could aid in the triage and diagnosis of trauma patients with and without traumatic brain injury (TBI) within 3 yrs. The MWVSM consists of two components: a cell phone sized sensor that is placed either on the forehead or the fingertip; and a cell phone sized monitor that receives a wireless signal transmitted up to 100 m by the sensor. The monitor is designed to be carried by the medic; the sensor is to be worn by the casualty. The weight, size, and wireless properties of the MWVSM offers significant logistic advantages for combat casualty care, relative to a standard vital signs monitor. However, at present, no vital signs are monitored in the field, so another question is "is it better than nothing?".

The forehead or fingertip sensor detects: arterial saturation by pulse oximetry (SpO2), heart rate derived from R wave detection, pulse wave transit time (PWTT) and skin temperature. The medic or first responder carrying the receiver inputs at least Glasgow Coma Score (GCS), plus if available, mechanism of injury, drugs, fluids, non-invasive blood pressure (NIBP, Systolic and Diastolic), end tidal CO2, respiration rate, pulse Integrity/Quality (feel, and digitized). All measured and any input parameters are used to calculate an injury acuity algorithm (Murphy factor, MF), which is continuously updated, color coded, and displayed. The MF also emphasizes rate of change of measured and input variables, to identify injury acuity and progression. MF theoretically could be a valuable triage tool in far forward or austere field conditions.

To accomplish the goal, data from the MWVSM is being compared to data from a standard vital signs monitor during prehospital transport of trauma patients, during assessment in the trauma resuscitation area, and in the intensive care unit, and to multiple patient outcomes. One of the most important findings from this study will be whether the MF, or similar algorithm, is practical for trauma triage.

B. BODY OF REPORT

1. PROJECT HYPOTHESIS

This project is totally driven by the technological needs of SOCOM, rather than by a classical hypothesis. Basically, the MWVSM was developed to capture whatever useful biological information is possible from small sensors placed on the forehead or finger of up to 5 casualties, then wirelessly transmit to any first responder within range. The need is to triage, prioritize transport and to track changes in numerous casualties from a remote location with a small, lightweight instrument. It should be emphasized that only 2 of the variables monitored by the MWVSM are directly comparable to the variables on a conventional vital signs monitor, i.e. heart rate and SpO2. The other monitored variables (skin temperature and PWTT) along with the calculated MF were intended to give a simple quantitative assessment of a patient displaying classical signs of hemorrhagic shock to a medic or first responder with limited skills and resources in an austere environment. The MWVSM was not designed to replace a conventional vital signs monitor. Within that context, a working hypothesis can be stated as follows: ***changes in multiple parameters or derived variables monitored from the forehead or finger of a severely injured patient correlate favorably with conventional vital signs monitors either before or after definitive treatment at a level 1 trauma center.***

2. SUMMARY OF PROGRESS TOWARD GOAL

At the time the original application was written, we had no experience working with AirRescue or other prehospital providers and no experience collecting field data from injured patients. The SOW was approved to collect data from 820 patients (400 in the prehospital area, 400 in the resuscitation area, and 20 in the ICU). It is now clear that we greatly overestimated the actual number of patients that will be required to address all the main questions and we will not meet those enrollment targets. Nevertheless, we will achieve the overall project goal, and answer all the questions, within the 3 yr award period.

The original enrollment targets were estimates based on power analysis and those power analyses were based on assumptions about several unknowns, especially on data variability, patient characteristics, and policies and protocols of prehospital providers. It turns out that some of the assumptions in the original proposal were wrong. For example, with a smaller sample size we have proof of concept that the MF outperforms standard vital signs as a triage tool (data submitted for presentation to 2013 American Association for Surgery of Trauma (AAST)), and that may be one of the most important findings from this project.

The administrative and technical issues that have prevented us from achieving the originally projected patient enrollment targets are as follows:

1) After the letters of agreement and other documents had already been signed, two senior chiefs of Miami Dade Fire rescue were replaced by the incoming mayor, and the chief of Monroe County Air Rescue retired; eventually, everything got back on track but this temporarily suspended protocols that were already ongoing.

2) the finger sensor consumes more power than the forehead sensor, and some data has been lost because of the short battery life. This has been solved by Athena engineers adjusting the power consumption and by using lithium batteries.

3) A new trauma center opened in Miami-Dade County in Nov 2011; this reduced the census at Ryder Trauma Center. The AirRescue flights in Miami-Dade are reduced (because some patients were close enough to be transported by ground rescue to the hospital) and some eligible patients were diverted to the new center away from Ryder Trauma (because state law requires that trauma patients must be transported to the nearest center). The legality of this new center is being challenged in court, but there is no way for us to solve this political issue.

4) for the past 3 yrs, state wide and national trauma and TBI patient census have been below historic averages; thus, fewer eligible patients have been transported to this and every other trauma center. There is no way to solve this problem.

5) non-trauma patients transported by AirRescue; consumed time and resources

6) all trauma patients transported by AirRescue are strapped to a backboard and the strap is located exactly where the forehead sensor is supposed to be placed; some EMTs have been unwilling to use the forehead sensor and will only use the finger sensor, so at this time, we have a disproportionate number of cases with the finger sensor. It has taken some time to convince our prehospital partners that the forehead sensor can be placed adjacent to the backboard strap, or even under the strap.

7) occasional equipment malfunction or operator error; this has led to data loss

8) pre-hospital run report lost or otherwise unavailable; this has led to data loss

Only the last three factors that account for reduced patient enrollment are even remotely under our control. Nevertheless, a practical strategy has been developed to address this shortfall; a higher percentage of trauma and TBI patients are now being instrumented in the trauma resuscitation area or ICU, where similar data can be collected, but all of the factors can be controlled, which reduces data loss. In addition, a higher percentage of pre-hospital patients have required a life-saving intervention than assumed in the power analysis for predicting sample size. We anticipated about 10% would require a life saving intervention (LSI) but almost 50% have actually received a LSI, this has had the effect of reducing the required sample size to achieve the milestones.

3. MAIN QUESTIONS PROPOSED IN THE ORIGINAL APPLICATION

1) Does R wave and SpO2 detection from the MWVSM generate values that favorably compare to ECG and/or SpO2 monitored conventionally? If not, do the MWVSM values provide any useful information regarding casualty status? Is there another variable that would be more useful to measure from the forehead (e.g. near infrared spectroscopy (NIRS) or bispectral EEG)?
2) Does PWTT reflect changes in NIBP? If not, is there an alternative?
3) Can modified shock index (i.e MF) from the MWVSM summarize trauma patient condition or change in condition, or predict the need for LSI, as reliably as a conventional monitor with standard ECG and NIBP capability? If not, can new or better algorithms based on other vital signs or physiologic variables be developed?
4) Can the calculated HRV-related values (Cardiac complexity and approximate entropy) from the MWVSM summarize trauma patient condition or change in condition, or predict the need for LSI as reliably as standard monitors with standard ECG capability with or without HRV? If not, can new or better algorithms based on other non-invasively measured vital signs (e.g., BIS EEG or NIRS) be developed?

4. KEY RESEARCH ACCOMPLISHMENTS RELATIVE TO MAIN QUESTIONS

a. PREHOSPITAL This study population to date is comprised of 86 trauma patients and 17 stroke and ST segment elevated myocardial infarction (STEMI) patients. An additional 23 prehospital patients were excluded because of missing or incomplete data (i.e., loss of peripheral signals for patients in extremis, lost or inaccessible prehospital run reports). The majority of prehospital transports are trauma patients, and have finger sensors. This study is ongoing and data collection continues. The interim data collection period was from 12/11 until 1/13. We enroll 2-3 patients per week and expect to add an additional 50-100 patients by the end of the funding period.

Table 1: Characteristics of prehospital patient population

median(interquartile range)	trauma, n=86	non-trauma, n=17
monitoring time, min	18.0(19.8)	39.0(11.0)
transport time, min	15.5(27.3)	37.0(11.0)
blunt/penetrating	72/14	na
age, yrs	47(28.5)	67(24)
wt, lbs	180(42)	155(60)
gender,% male	84	71
SBP mm Hg	136(48)	150(22)
HR ,beats/min	88(29)	82(21)
Total LSI	79	1
mortality	9.4%	0%

Obviously the characteristics are completely different in the two patient groups. Since the main emphasis of this project is on trauma patients, data are only compared to the non-trauma patients to understand performance characteristics of the sensors.

Table 2:
Comparison between MWVSM and conventional vital signs during prehospital transport

	trauma n=86		non-trauma n=17	
	heart rate	SpO2	heart rate	SpO2
paired difference	0.8±2.8	-4.3±3.4	11.7±5.1	-22.4±4.3
	t=0.29; p=NS	t=1.26; p=NS	t=2.29; p<0.05	t=5.21; p<0.001
correlation coefficient	0.588	0.358	-0.091	-0.233
	t=6.17; p<0.001	t=3.32; p<0.002	t=0.33; p=NS	t=0.86; p=NS

In addition, PWTT was negatively correlated with mean arterial pressure (MAP; r=-0.291; t=2.212; p<0.05), but the relationship was relatively weak (i.e. only 29% of the change in PWTT was attributable to changes in MAP.

It should be emphasized that continuous digital data from MWVSM are averaged over the entire transport time for each patient and compared to the average of intermittent spot checks from the standard monitor obtained from the prehospital run reports. These data suggest that the R wave detection and pulse oximeter in the MWVSM are accurate relative to a standard monitor and follow changes in trauma patients, but (for some unknown reason) not in non-trauma patients. This could be a function of the individual sensor performance, sensor location, duration of the monitoring period, or the fact that the MWVSM provides continuous data and it is compared to intermittent vital sign signals.

Table 3: Comparison between MWVSM forehead and finger sensor within trauma patients

	forehead n=23		finger n=63	
	heart rate	SpO2	heart rate	SpO2
paired difference	-0.1±9.5	-7.1±11.2	1.0±4.9	-4.4±5.2
	t=0.01; p=NS	t=0.64; p=NS	t=0.20; p=NS	t=0.86; p=NS
correlation coefficient	0.421	0.348	0.652	0.443
	t=1.14; p=NS	t=0.98; p=NS	t=4.12; p<0.001	t=2.47; p<0.02

These data cannot be attributed to differences in the monitoring period. The R wave detection and pulse oximeter in the MWVSM finger probe are more accurate and follow changes better than those in the forehead probe in trauma patients.

The 86 patients suffered predominantly blunt trauma (n=72, 84%), were mostly male (n=72, 84%), age 47±19 yrs, with a median(interquartile range) injury severity score (ISS) 10(12). Those who received a LSI (n=40) had similar demographics, but higher ISS (15 vs 5) and mortality (21% vs 0%) (all p<0.05). LSI included intubation, tube thoracostomy, central line insertion, blood product transfusion, and operative intervention.

Table 4: Comparison between trauma patients who required LSI and those who did not

	None (n=46)	LSI (n=40)	p=
Age, yrs	47±18	48±20	0.946
Gender, % male	85%	83%	0.775
Mechanism, % blunt	85%	83%	0.775
ISS	5 (8)	15 (15)	<0.001
Mortality %	0%	21%	0.003

MF > 3 averaged over the entire transport time was superior to vital signs alone or in combination for identifying LSI. Prehospital data and MF from a MWVSM were compared to vital signs (SpO2, systolic blood pressure (SBP), and HR) from a conventional monitor. Sensitivity (Se), specificity (Sp), negative predictive value (NPV), positive predictive value (PPV), and area under the curve (AUC) were calculated.

Table 5: Diagnostic values of conventional vital signs and MWVSM for predicting need for LSI.

	Se	**Sp**	**NPV**	**PPV**	**AUC**	**p=**
SpO2 < 95	0.143	0.975	0.571	0.833	0.526	0.747
SBP <90	0.121	0.976	0.586	0.800	0.546	0.558
HR >100	0.314	0.786	0.740	0.550	0.549	0.536
HR,SBP,O2	0.486	0.762	0.640	0.630	0.616	0.142
MF > 3	0.414	0.875	0.622	0.750	0.665	0.038

REPORTABLE OUTCOMES FROM PREHOSPITAL AREA (DATA COLLECTION ONGOING)

1) there are major differences in the characteristics of trauma patients and non trauma patients during prehospital transport; in trauma patients the MWVSM heart rate and SpO2 estimates are comparable to the standard vital signs monitor, but in nontrauma patients the heart rate is significantly overestimated, and the SpO2 is significantly underestimated. In trauma patients, the MWVSM tracks changes in heart rate and SpO2, but in nontrauma patients, it does not.

2) an injury acuity algorithm calculated over an 18 min prehospital transport time has the potential to identify trauma patients who need a LSI, and is superior to conventional vital signs.

3) Both the finger sensor and the forehead sensor provide reliable estimates of heart rate and SpO2, but the finger sensor seems to be tracks changes more accurately than the forehead sensor.

4) Data from several hypotensive patients were excluded from the paired comparison and correlation analysis because of missing data for patients in extremis; specifically, the EMTs reported that the finger tip oximeter signal failed to register with the thready pulse characteristic of hemorrhagic shock. This observation suggests that using a forehead and finger sensor on the same patient and comparing the difference could be an accurate, specific, and precise indicator of shock state.

5) Neither changes in heart rate (derived from R wave detection) nor the SpO2 output from either the MWVSM finger or forehead sensor are highly correlated with the measured SpO2 or the heart rate (which is derived from EKG) on the conventional monitor. This might be attributed to the fact that the MWVSM provides continuous data and is compared to intermittent vital sign information.

b. TRAUMA RESUSCITATION AREA This study population is comprised of 48 trauma patients. An additional 7 patients were excluded because the chart was unavailable at the time this report was written. This study is ongoing and data collection continues. This interim data collection period was from 12/12 until 1/13. We enroll about 3-4 patients per week and expect to add an additional 50-100 patients by the end of the reporting period.

Table 6: Characteristics of patients in resuscitation area

median(interquartile range)	trauma,n=48
monitoring time, min	70(108)
blunt/penetrating	42/6
age, yrs	51.0(28.0)
wt, lbs	180(42)
gender,% male	91
SBP mm Hg	141(32)
HR ,beats/min	89(21)
Total LSI	38

Table 7: Comparison between MWVSM and conventional monitor in the resuscitation area

all trauma patients, n=48			Finger sensor, n=45		Forehead sensor, n=3	
	heart rate	SpO2	heart rate	SpO2	heart rate	SpO2
paired difference	1.5±0.8	-2.4±0.7	1.7±0.8	-1.5±0.5	sample size too small for meaningful analysis	
t	1.875	3.429	2.125	3.000		
p	NS	<0.02	<0.05	<0.01		
correlation coefficient	0.961	0.013	0.961	0.185		
t	23.624	0.086	22.931	1.206		
p	<0.0001	ns	<0.0001	ns		

In addition, PWTT was inversely correlated to MAP ($r=-0.475$; $t=3.54$; $p<0.002$). The correlation coefficient for these variables in this resuscitation population was 60% higher than PWTT vs

MAP in the prehospital population (i.e. that r was -0.291). It is possible that the longer monitoring period was responsible (70 min vs 18 min) for the improved correlation. Alternatively, this population had almost no forehead sensors, so it is possible that R wave detection and PWTT is more reliable with the finger sensor.

REPORTABLE OUTCOMES FROM RESUSCITATION AREA (DATA COLLECTION ONGOING)

1) The MWVSM fingertip heart rate detector was reliable relative to a conventional vital signs monitor over a 70 min monitoring period for detecting both the absolute value and the change in heart rate and might explain the relatively high correlation with PWTT and MAP.

2) The MWVSM fingertip pulse oximeter consistently underestimates O2 saturation and does not reliably follow changes in O2 saturation.

c. TRAUMA ICU This study population is comprised of five patients in the ICU (n= 2 non TBI and n=3 TBI) instrumented with the MWVSM and a standard bedside hemodynamic monitor. This study is ongoing and data collection continues. The interim data collection period just started in 1/13. We enroll about 2 patients per week. We expect to add about 25-50 non TBI patients and 25-50 TBI patients by the end of the award.

EXPECTED OUTCOMES FROM ICU (DATA COLLECTION ONGOING)

At the time of this progress report, the sample size is not large enough for any meaningful comparison. This data set will be important to resolve several issues raised the other data sets. A major problem is that there is a continuous digital record from the MWVSM, but only intermittent spot checks manually entered into the nursing notes, patient chart, or paramedic run report from the standard vital signs monitor. Thus, we are basically comparing a continuous signal to an intermittent signal. Synchronized digital data from the MWVSM and the standard hemodynamic monitor in the ICU will allow a direct comparison of the phase and magnitude relationships between the heart rate and SPO2 signals and allow a more reliable test of whether PWTT tracks mean arterial pressure changes. Also help to determine whether the finger sensor actually outperforms the forehead sensor.

C. SUMMARY & CONCLUSIONS

1. There have been no safety issues or adverse events.
2. The study objectives will be achieved with fewer than 800 patients enrolled.
3. We are on track to have unique data from a significant number of trauma patients from the point of injury through the entire hospital course.
4. An injury acuity algorithm has the potential to identify prehospital trauma patients who need a LSI, and is superior to conventional vital signs.
5. The MWVSM finger and forehead sensors have different performance characteristics.

D. ABSTRACTS/PRESENTATIONS DIRECTLY RELATED TO APPROVED SOW

1. Van Haren RM, Thorson CM, Valle EJ, Busko AM, Guarch GA, Jouria JA, Blackbourne LH, Livingstone AS, Namias N, Proctor KG: Novel prehospital monitor with injury acuity algorithm to identify patients who require life saving intervention. Submitted 2/22/13

to 2013 Annual Meeting of the American Association for the Surgery of Trauma and Clinical Congress of Acute Care Surgery, San Francisco, CA Sep, 2013

2. Van Haren RM, Thorson CM, Ryan ML, Curia E, Barrera JM, Busko AM, Guarch GA, Namias N, Proctor KG: Non-invasive monitoring technologies from the frontline to the FST and beyond:
   a) Presented at Florida Medical Association Poster Symposium Boca Raton, FL Jul 2012
   b) Presented at Military Health System Research Symposium MHSRS/ATACCC 2012 , Fort Lauderdale, FL, Aug 2012
   c) Presented at University of Miami Annual Postdoctoral Fellows Research Day. Miami, FL, Sep 2012.

E. APPENDICES

1. Abstract submitted to 2013 AAST
2. Review article on heart rate variability, which is a non-invasively measured vital sign that could be easily incorporated into the new algorithms that could aid in the triage and diagnosis of trauma patients with and without TBI
3. Abstract of research article on near infrared spectroscopy. This is an alternative method for measuring tissue oxygenation, and was described in the original application as another potential triage tool for combat casualty care.

APPENDIX 1 ABSTRACT SUBMITTED TO 2013 AAST

Session [number]: [session title]
Paper [order]: [time]

NOVEL PREHOSPITAL MONITOR WITH INJURY ACUITY ALGORITHM TO IDENTIFY PATIENTS WHO REQUIRE LIFE SAVING INTERVENTION

Robert M. Van Haren MD, Chad M. Thorson MD, MsPH, Evan J. Valle MD, Alexander M. Busko BS, Gerardo A. Guarch MD, Jassin A. Jouria MD, Lorne H. Blackbourne* MD, Alan S. Livingstone MD, Nicholas Namias* MBA,MD, Kenneth G. Proctor* Ph.D., University of Miami

Invited Discussant: [discussant]

Introduction: The greatest opportunity for reducing military trauma mortality involves detection and treatment of life-threatening conditions in austere prehospital conditions. A miniature wireless vital signs monitor (MWVSM) has been designed according to the logistic requirements of the United States Special Operations Command. It incorporates a proprietary injury acuity algorithm termed the Murphy Factor (MF), which is a summary alarm based on vital signs and time trends. We test the hypothesis that the MF can identify trauma patients who require a life saving intervention (LSI).

Methods: From December 2011 to date, a prospective trial is being conducted in collaboration with prehospital providers. The MWVSM (mini-Medic, www.athenagtx.com) detects skin temperature, pulse oximetry (SpO_2), heart rate (HR), pulse wave transit time (PWTT), and MF. LSIs included: intubation, tube thoracostomy, central line insertion, blood product transfusion, and operative intervention. Prehospital data and MF from a MWVSM were compared to vital signs (SpO_2, systolic blood pressure (SBP), and HR) from a conventional monitor. Sensitivity (Se), specificity (Sp), negative predictive value (NPV), positive predictive value (PPV), and area under the curve (AUC) were calculated.

Results: 86 patients suffered predominantly blunt trauma (n=72, 84%), were mostly male (n=72, 84%), age 47±19 yrs, and ISS 10(12). Those who received a LSI (n=40) had similar demographics, but higher ISS (15 vs 5) and mortality (21% vs 0%) (all $p<0.05$). MF > 3 during transport was superior to vital signs alone or in combination for identifying need for LSI.

	Se	Sp	NPV	PPV	AUC	p=
HR>100	31	79	74	55	0.549	0.536
SBP<90	12	98	59	80	0.546	0.558
SpO_2<95	14	98	57	83	0.526	0.747
HR>100 or SBP<90 or SpO_2<95	49	76	64	63	0.616	0.142
MF>3	41	88	62	75	0.665	0.038

Conclusion: An injury acuity algorithm has the potential to identify prehospital trauma patients who need a LSI, and is superior to conventional vital signs. New technology combined with algorithms that include trends over time may have the ability to improve prehospital care for both civilian and military populations.

APPENDIX 2 PUBLISHED REVIEW ARTICLE

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Review Article

Clinical Applications of Heart Rate Variability in the Triage and Assessment of Traumatically Injured Patients

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Heart rate variability (HRV) is a method of physiologic assessment which uses fluctuations in the RR intervals to evaluate modulation of the heart rate by the autonomic nervous system (ANS). Decreased variability has been studied as a marker of increased pathology and a predictor of morbidity and mortality in multiple medical disciplines. HRV is potentially useful in trauma as a tool for prehospital triage, initial patient assessment, and continuous monitoring of critically injured patients. However, several technical limitations and a lack of standardized values have inhibited its clinical implementation in trauma. The purpose of this paper is to describe the three analytical methods (time domain, frequency domain, and entropy) and specific clinical populations that have been evaluated in trauma patients and to identify key issues regarding HRV that must be explored if it is to be widely adopted for the assessment of trauma patients.

1. Introduction

Heart rate variability (HRV) is defined by the fluctuating time between normal sinus beats (RR intervals) [1] and indicates modulation of the heart rate by the autonomic nervous system (ANS) [2]. Afferent inputs from sensory and baroreceptors within the heart and great vessels, respiratory changes, vasomotor regulation, the thermoregulatory system, and alterations in endocrine function determine ANS influence on the heart [1].

In 1997, a consensus panel issued a set of guidelines regarding the measurement and interpretation of HRV [3]. Changes in HRV are now an accepted method of assessing autonomic dysfunction in patients in several pathologic states, with and without structural heart disease. In the 14 years since that report, there have been major technological advances and hundreds of publications in various patient populations, but there has been no comprehensive review specifically directed at trauma. This paper attempts to fill that gap.

It is now well established that absence of HRV is an early predictor of brain death [4, 5] and that low HRV correlates with increased mortality and morbidity after trauma [6–13]. Abnormal HRV is associated with increased intracranial pressure and decreased cerebral perfusion pressure [5, 9, 10, 14, 15]. Recently, it was suggested that HRV is a "new vital sign" and could be used as a trauma triage tool [7, 8, 11, 16, 17]. However, the mechanisms responsible for these associations are not clearly established, and no specific therapy is currently available to treat patients with abnormal HRV. Furthermore, there is no consensus on exactly how to measure HRV. Typically, it is quantified using at least one of three analysis domains: time, frequency, or entropy. Despite its enormous potential for assessment and triage, HRV has not been widely adopted in trauma patients. This paper will attempt to address the reasons for this and explore the major advances in various analytical techniques since the initial consensus report on HRV was issued in 1997.

2. Methods

2.1. Literature Search and Retrieval. The U.S. National Library of Medicine (Pubmed) Database was queried from January 1997 to August 2010 using the following keywords alone or in combination: "heart rate variability," "trauma,"

APPENDIX 3: Abstract of research article presented at the Academic Surgical Congress February 5-7, 2013. New Orleans, LA and submitted to Journal of Surgical Research.

Bilateral Near Infrared Spectroscopy: A Potential Tool for Detecting Traumatic Vascular Injury

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Introduction: Throughout history, extremity wounds have accounted for the majority of battlefield injuries. Physical examination may be unreliable for detecting vascular injury, especially for inexperienced medics. Continuous assessment may not be possible on the front line or during transport, and delay in diagnosis can result in ischemia, necrosis, or limb loss. Near-infrared spectroscopy (NIRS) is designed for continuous, non-invasive monitoring of tissue oxygen saturation (StO2). In practice, NIRS has not been widely adapted, because of large intra- and inter-patient variability. Bilateral sampling can potentially address this variability problem. We test the hypothesis that bilateral NIRS can reliably identify vascular injury after extremity trauma.

Methods: This prospective study consisted of 30 subjects: 10 trauma patients with vascular injury and 20 controls with no vascular injury (10 healthy volunteers and 10 trauma patients). Patients were prospectively monitored with bilateral Inspectra StO2tissue monitors (Hutchinson Technologies Inc, Hutchinson MN). Data are reported as median (IQR).

Results: Trauma patients were ages 31 (23), 85% male, with an injury severity score of 9 (5). There were 7 arterial and 3 venous injuries, most injuries involved the lower extremity (n=16, 80%), and resulted from penetrating mechanism (n=14, 70%). StO2 difference between limbs was 20.4 (10.4) vs. 2.4 (3.0) (p<0.001), for all patients with vascular injury and patients/volunteers with no vascular injury, respectively. Sensitivity (Se), specificity (Sp), negative predictive value (NPV), positive predictive value (PPV), and area under the curve (AUC) for various StO2 differences and physical exam (PE) ± Doppler are shown in the table.

	Se	**Sp**	**NPV**	**PPV**	**AUC**	**p=**
Δ StO2 > 6	90	90	94	82	.900	<0.001
Δ StO2 > 10	80	95	90	89	.875	.001
Δ StO2 > 15	70	100	87	100	.850	.002
PE	60	80	75	67	.700	.131
PE+Doppler	60	90	86	69	.750	.059

Conclusions: Continuous monitoring of bilateral limb NIRS detects changes in perfusion due to arterial or venous injury and may offer advantages over serial manual measurements of pulses or doppler signals. This technique may be particularly relevant to military and disaster scenarios in which the capability to monitor limb perfusion is difficult, and/or experienced clinical judgment is unavailable.