TITLE: Evaluation of SOCOM Wireless Monitor in Trauma Patients

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### 14. ABSTRACT
A Wireless Vital Signs Monitor (WVSM) has been developed by the Office of Naval Research (ONR) and the United States Army Institute of Surgical Research (USAISR) in partnership with a Defense Contractor (Athena, http://www.athenagtx.com). This monitor incorporates several sensors from different manufacturers that can be implemented far out to the point of injury and adds complete trend analysis over four hours. Multicenter trials have been completed and the instrument is FDA approved. This WVSM is too bulky for field operations by US Special Forces (SOCOM), but functional prototypes of an alternative miniature wireless monitoring device with improved trend analysis even further out to the point of injury have now been delivered (SOCOM-Mini-medic™). There have been no field tests to date. The primary objective of this project is to perform the first field tests of the SOCOM Mini-medic. The main focus is to validate the Mini-Medic for combat casualty care (including, but not limited to, brain injury) in prehospital and hospitalized patients. Lessons learned from our previous and ongoing trials in trauma patients with and without brain injury will be applied.

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16
A. GOAL

To evaluate for the US Special Operations Command (SOCOM) a miniature, portable wireless vital signs monitor (MWVSM, Mini-medic™, www.athenagtx.com) that could aid in the triage and diagnosis of trauma patients with and without traumatic brain injury (TBI). The MWVSM consists of two components, both of which are the approximate size and weight of a cell phone: one is a multi-parameter sensor that is placed either on the forehead or the fingertip of a casualty and the other is a monitor that receives a wireless signal transmitted up to 100 m carried by the medic.

B. HYPOTHESIS

This project has been totally driven by the technological needs of SOCOM, rather than by a classical hypothesis. Basically, the MWVSM was developed by www.athenagtx.com to capture whatever useful biological information is possible from small sensors placed on the forehead (or at a peripheral extremity site) of up to 5 casualties, then wirelessly transmit to miniature monitors carried by any first responder within range. The need was to triage, prioritize transport and to track changes in numerous casualties in an austere environment from a remote location. Within that context, to evaluate the MWVSM, we proposed the overall working hypothesis that: changes in multiple parameters or derived variables monitored from the forehead (or extremity) of a severely injured patient correlate favorably with conventional vital signs monitors either before or after definitive treatment at a level 1 trauma center.

C. EVALUATION OF MWVSM

1) PREHOSPITAL

The purpose is to test whether spot measurements from miniature wireless vital signs monitor (MWVSM) can identify civilian trauma patients during prehospital transport who will require a lifesaving intervention (LSI) upon hospital admission.

METHODS From December 2011 to June 2013, a prospective trial was conducted in collaboration with prehospital providers. The MWVSM detects skin temperature, pulse oximetry (SpO2), heart rate (HR), pulse wave transit time, and a derived Murphy Factor (MF) which is an overall status indicator. LSIs included: intubation, tube thoracostomy, central line insertion, blood product transfusion, and operative intervention.
Prehospital MWVSM data were compared with simultaneous vital signs (SaO2, systolic blood pressure (SBP), and HR) from a conventional vital signs monitor. Sensitivity, specificity, negative predictive value, positive predictive value, and area under the receiving operating characteristic curves were calculated.

RESULTS Ninety-six trauma patients experienced predominantly blunt trauma (n = 80, 84%), were mostly male (n = 79, 82%), and had a mean ± SD age of 48 ± 19 years and an Injury Severity Score (ISS) of 10 (17). Those who received an LSI (n = 48) had similar demographics but higher ISS (18 vs. 5) and mortality (23% vs. 0%) (all p < 0.05). The most common LSIs were intubation (n = 24, 25%), blood product transfusion (n = 19, 20%), and emergency surgery (n = 19, 20%). Compared with HR > 100 beats/min, SBP < 90 mm Hg, SaO2 < 95% alone or in combination, MF > 3 during the entire transport time had the largest area under the receiving operating characteristic curves (0.620, p = 0.081). MF greater than 3 had a specificity of 81%, sensitivity of 39%, positive predictive value of 68%, and negative predictive value of 57% for the need for LSI.

CONCLUSION A single numeric score has the potential to summarize overall patient status and identifyprehospital trauma patients who need an LSI. Prehospital monitoring combined with algorithms that include trends over time could improve prehospital care for both civilian and military trauma.

2) INHOSPITAL The previous study demonstrated basic proof of principle of a numeric score derived from MWVSM vital signs for battlefield triage. However, there were unanswered questions related to sensor reliability and uncontrolled conditions in the prehospital environment. For example, there was variation in sensor placement between the forehead and thenar, the time of monitoring ranged from a few minutes to almost an hour, patient acuity varied from essentially no injury to near death, and conventional monitoring was intermittent for comparison. This study was conducted in a “more controlled” ICU environment to determine whether MWVSM sensors accurately track vital signs and allow for appropriate triage compared to a gold standard bedside monitor in trauma patients.

METHODS A prospective study was conducted in 59 trauma intensive care unit patients. Systolic blood pressure (SBP), temperature, heart rate (HR), skin temperature, and pulse oximetry (SpO2) were displayed on a bedside monitor for 60 min. Shock index (SI) was calculated. A separate MWVSM monitor was attached to the forehead and finger of each patient. Data from each included pulse wave transit time (PWTT), temperature, HR, SpO2, and a summary status termed "Murphy Factor" (MF), which ranges from 0-5. Patients are classified as "routine" if MF = 0-1 or SI = 0-0.7, "priority" if MF = 2-3 or SI = 0.7-0.9, and "critical" if MF = 4-5 or SI ≥ 0.9.

RESULTS Forehead and finger MWVSM HRs both differed from the monitor (both p < 0.001), but the differences were no more than a few beats per min and were clinically insignificant. Differences in MWVSM SpO2 (1-7%) and temperature (6-13°F) from the monitor were site specific (all p < 0.001). Forehead PWTT (271 ± 50 msec) was less (p < 0.001) than finger PWTT (315 ± 42 msec); both were dissociated from SBP (r² < 0.05). The SI distributed patients about equally as "routine," "priority," and "critical," whereas MF overtriaged to "routine" and undertriaged to "critical" for both sensors (all p < 0.001).

CONCLUSION MF does not accurately triage critically ill trauma patients, likely because erroneous PWTT values confound MF calculations. MF and the MWVSM are promising, but require fine-tuning prior to deployment.

D. ALTERNATIVE METHODS FOR TRIAGING TRAUMA PATIENTS

1) Heart rate variability In 216 hemodynamically stable adults undergoing computed axial tomography (CT) scan to rule out traumatic brain injury (TBI), we showed that heart rate variability predicted survival, severity of TBI, intensive care unit LOS, and hospital LOS. Beta-blockers or diabetes had no effect, whereas age, sedation, mechanical ventilation, spinal cord injury, and intoxication influenced one or more of the variables with age being the most powerful confounder. Except for the Glasgow Coma Scale, no other routine trauma or hemodynamic criteria correlated with any of these outcomes.
2) **Hematocrit** In a series of 4 studies in >2000 adult and pediatric patients during ongoing fluid resuscitation, we showed that change in hematocrit was a more powerful predictor of bleeding than blood pressure, heart rate, or base deficit alone or in combination.

3) **Near Infrared (NIRS) monitoring of tissue oxygen saturation (StO2)**. This prospective study consisted of 30 subjects: 20 trauma patients with extremity injury and 10 healthy volunteers. StO2 reliably identified any vascular injury (P < 0.001), whereas pulse examination alone or in combination with Doppler exam could detect only arterial injury. A change in StO2 of 6 had the greatest sensitivity and specificity (P < 0.001). These data show that continuous monitoring of bilateral limbs with NIRS detects changes in perfusion resulting from arterial or venous injury and may offer advantages over serial manual measurements of pulses or Doppler signals. This technique may be most relevant in military and disaster scenarios or during transport, in which the ability to monitor limb perfusion is difficult or experienced clinical judgment is unavailable.

4) **Pre hospital interventions based on routine vital sign monitoring reduce mortality**. This study established the rationale for developing a MWVSM for use in pre hospital trauma triage. In two studies in >4000 pediatric and adult trauma patients, we show that pre-hospital interventions with any signs of life increased survival to the hospital.

5) **Bispectral Index (BIS)** in 94 mechanically ventilated trauma patients, we compared BIS, Richmond Agitation Sedation Scale (RASS), electromyography, and heart rate variability, as a test of autonomic function, were measured for 45 minutes during daily spontaneous awakening trials in the ICUs. In the first trial in trauma patients and largest trial in any surgical population, the BIS was reliable and has advantages over RASS of being continuous and objective, but interpretation remains somewhat subjective in patients receiving paralytic agents or with traumatic brain injury.

E. PEER REVIEWED PUBLICATIONS DIRECTLY RELATED TO APPROVED SOW DURING REPORT PERIOD


F. ABSTRACTS/PRESENTATIONS DIRECTLY RELATED TO APPROVED SOW DURING REPORT PERIOD


   a. Presented at 74th Annual Meeting of the American Association for the Surgery of Trauma & Clinical Congress of Acute Care Surgery Las Vegas, NV Sept 2015
   b. Presented at 2015 American College of Surgeons Florida Committee on Trauma Paper Competition Delray Beach, FL Oct 2015

   a. Presented at 101st Annual American College of Surgeons, Clinical Congress Chicago, IL Oct 2015
   b. Presented at 2015 American College of Surgeons Florida Committee on Trauma Paper Competition Delray Beach, FL Oct 2015 (* 1st place Research Award)
   c. Presented at 2015 American College of Surgeons Regions 4 Committee on Trauma Paper Competition Atlanta, GA (* 1st place Research Award)


   a. Presented at 2014 American College of Surgeons Committee on Trauma Region 4 Competition Orlando, FL Nov 2014
   b. Presented at 2014 American College of Surgeons Florida Committee on Trauma Paper Competition Jacksonville, FL Oct 2014 (* 1st place Research Award)
   c. Presented at 6th Annual Postdoctoral Fellows Research Day, University of Miami Miller School of Medicine, Miami, FL Sep 2014


   b. Presented at 6th Annual Postdoctoral Fellows Research Day, University of Miami Miller School of Medicine, Miami, FL Sep 2014
   c. Presented at 6th Annual Southwest Trauma and Acute Care Symposium, Scottsdale, AZ Nov 2014


14) 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


   a. Presented at 2011 American College of Surgeons Florida Committee on Trauma Resident Paper Competition, Miami, FL, Nov 2011
   b. Presented at 5th Annual Copeland Resident Paper Competition Florida Chapter American College of Surgeons, Sarasota, FL May 2012 (*1st place research Award)


19) Thorson CM, Ryan ML, Otero CA, Vu T, Manning RJ, Schulman CI, Livingstone AS, Proctor KG. Early drop in hematocrit during initial trauma resuscitation is not just dilutional.
G. OTHER PEER REVIEWED PUBLICATIONS ON MILITARY MEDICINE RELEVANT TOPICS DURING REPORT PERIOD


7) Ogilvie MP, Ryan ML, Proctor KG: Hetastarch during initial resuscitation from trauma. *J Trauma* 2011 May;70(5):S19-21


hemoperitoneum cause peritonitis? A review of 400 trauma laparotomies. *Amer Surgeon* in press


H. OTHER ABSTRACTS/PRESENTATIONS ON MILITARY MEDICINE RELEVANT TOPICS DURING REPORT PERIOD

1) Karcutskie CA, Meizoso JP, Ray JJ, Horkan D, Ruiz XD, Schulman CI, Namias N, Proctor KG: Validation of greenfield risk assessment profile score in both blunt and penetrating trauma. Submitted Dec 4, 2015 to Annual Meeting of Association of VA Surgeons, Committee on Trauma, Virginia Beach, VA Apr 2016


4) Karcutskie CA, Ray JJ, Meizoso JP, Bullock MR, Namias N, Schulman CI, Proctor KG Initial presentation severity and mortality of traumatic brain injury in elderly patients Presented at 2015 American College of Surgeons Florida Committee on Trauma Paper Competition Delray Beach, FL Oct 2015


11) Presented at 26th Annual Fellow, Resident Medical Student Surgical Research Forum Miami Beach, FL Apr 2015


   a. Presented at 47th Annual Meeting of American Burn Assoc, Chicago, IL Apr 2015
   b. Presented at 26th Annual Fellow, Resident Medical Student Surgical Research Forum Miami Beach, FL Apr 2015


20) Presented at 26th Annual Fellow, Resident Medical Student Surgical Research Forum Miami Beach, FL Apr 2015

21) Presented at 41st annual Eastern Atlantic Student Research Forum Miami, FL Feb 2015

22) Presented at 12th Annual AMA Research Symposium Dallas, TX Nov 2014


   a. Presented at 10th Annual Academic Surgical Congress, Las Vegas, NV Feb 2015
   b. Presented at 27th Annual Southern Region Burn Conference Southern Medical Assoc Houston, TX Nov 2014


28) Allen CJ, Meizoso JP, Ray JJ, Ruiz XD, Hanna MM, Schulman CI, Namias N, Livingstone AS, Proctor KG: Coagulation Profile Changes Due To Thromboprophylaxis And Platelets In Trauma Patients At High-Risk For Venous Thromboembolism.
   a. Presented at 8th Annual Copeland resident/medical student Paper Competition Florida Chapter of the American College of Surgeons, Gainesville, FL May, 2015
   b. Presented at the 26th Annual Fellow, Resident & Medical Student Surgical Research Forum South Florida Chapter, American College of Surgeons, Miami, FL, Apr 2015 (* 2nd place Research Award)

29) Presented at 2015 Annual Scientific Meeting Southeastern Surgical Congress, Chattanooga, TN, Feb 2015

30) Presented at the 7th Annual Southwest Trauma & Acute Care Symposium, Scottsdale, AZ, Nov, 2014.

31) Valle EJ, Allen CJ, Van Haren RM, Jouria JM, Li H, Livingstone AS, Proctor KG: Tranexamic acid may have undesirable actions in some trauma patients. Presented at 2014 MHSRS (Military Health Science Research Symposium), Fort Lauderdale, FL, Aug 2014


34) Allen CJ, Hsu A, Valle EJ, Namias N, Livingstone AS, Lineen E, Proctor KG. Repair vs ligation of major venous injury after penetrating trauma: is there a difference in the development of pulmonary embolism? Presented at 73rd Annual Meeting of the American Association for the Surgery of Trauma and Clinical Congress of Acute Care Surgery Philadelphia, PA

35) Allen CJ, Valle EJ, Jouria JM, Schulman CI, Namias N, Proctor KG: Does isolated hemoperitoneum cause peritonitis? A review of 400 trauma laparotomies Presented at South Florida Chapter of the American...
College of Surgeon’s 25th Annual Fellow, Resident & Medical Student Surgical Research Forum Paper Presentations Miami Beach, FL May 2014 (*3rd place Research Award)


38) Allen CJ, Valle EJ, Jouria JM, Namias N, Livingstone AS, Schulman CI, Proctor KG: Differences in acute kidney injury and death between blunt and penetrating trauma after resuscitation with hydroxyethyl starch
   a. Presented at 44th Annual Meeting, Western Trauma Association, Steamboat Springs, CO Mar 2014
   b. Presented at South Florida Chapter of the American College of Surgeon’s 25th Annual Fellow, Resident & Medical Student Surgical Research Forum Paper Presentations Miami Beach, FL May 2014 (*1st place Research Award).


   a. Presented at 2012 Annual Meeting, American College of Surgeons, Florida Committee on Trauma Resident Paper Competition, Gainesville, FL Oct 2012 (*1st place Research Award)
   b. Presented at 2012 Region IV American College of Surgeons Committee on Trauma Resident Paper Competition, Memphis TN, Nov 2012 (*2nd place Research Award)
   c. Presented at 42nd Critical Care Congress, Society of Critical Care Medicine, San Juan, Puerto Rico, Jan, 2013.


   a. Presented at 5th Annual Copeland Resident Paper Competition Florida Chapter American College of Surgeons, Sarasota, FL May 2012 (*1st place research Award)
   b. Presented at Sylvester Cancer Center Research Poster Session, Univ of Miami Miller School of Medicine, Miami, FL May 2012


   a. Presented at 71st Annual Meeting of the American Association for the Surgery of Trauma and
Clinical Congress of Acute Care Surgery Kauai, Hawaii Sep 2012 (*Resident Travel Scholarship)
http://www.aast.org
b. Presented at 2011 American College of Surgeons Florida Committee on Trauma Resident Paper Competition, Miami, FL, Nov 2011 (*1st place Research Award)
c. Presented at American College of Surgeons Region IV Committee on Trauma Resident Paper Competition, Kiawah Island SC, Nov 2011

   a. Presented at 5th Annual Copeland Resident Paper Competition Florida Chapter of American College of Surgeons, Sarasota, FL May 2012 (*2nd place research Award)
   b. Presented at 23rd Annual Fellow, Resident, and Medical Student Surgical Research Forum, South Florida Chapter of the American College of Surgeons, Miami, FL Apr 2012 (*2nd place Research Award)

   a. Presented at 23rd Annual Fellow, Resident, and Medical Student Surgical Research Forum, South Florida Chapter of the American College of Surgeons, Miami, FL Apr 2012 (*3rd place Research Award)
   b. Presented at 41st Critical Care Congress, Society of Critical Care Medicine, Houston, TX, Feb 2012 Crit Care Med 2011 Dec 39:12 (Suppl) A106 (*Burns/Trauma Specialty Award)


I. SUMMARY

The MWVSM monitor manufactured by www.athenagtx.com according to SOCOM specifications cannot reliably triage trauma patients and therefore should not be deployed. Alternative methods for triaging trauma patients include, 1) heart rate variability which can reliably triage severity of brain injury in hemodynamically stable patients, 2) hematocrit which is more accurate than conventional vital signs for detecting bleeding, and 3) near infrared spectroscopy which can distinguish limb threatening vascular injury as well as, or better, than conventional physical or Doppler exams, especially in field situations.