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TITLE: Evaluation of SOCOM Wireless Monitor in Trauma Patients

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Evaluation of SOCOM Wireless Monitor in Trauma Patients

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). 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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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 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 small cell-phone sized 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
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 value has the potential to summarize overall patient status and identify prehospital 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 purpose was to compare continuous data from a bedside hemodynamic monitor with a MWVSM. The previous study demonstrated basic proof of concept. This study was conducted in more controlled setting of a trauma intensive care unit (TICU).

METHODS: A prospective trial was conducted in 59 TICU patients. Systolic blood pressure [SBP], temperature, heart rate [HR], and O2 saturation [SpO2] were continuously displayed on a bedside monitor for 60 min. Shock index (SI) was calculated off line. MWVSM sensors were attached to the forehead and finger of each patient. Data included pulse wave transit time (PWTT), temperature, HR, SpO2, and a summary value termed “Murphy factor” (MF), which ranges from 0-5. The patient is 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: Both forehead and finger MWVSM HRs differed from the monitor (both \( p<0.001 \)) but only by 2-3 bpm. 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) and both were dissociated from SBP (both \( r^2<0.05 \)). SI distributed patients about equally as “routine,” “priority,” and “critical”, whereas MF overtriaged to “routine” and undertriaged to “critical” for both sensors (all \( p<0.001 \)).

CONCLUSIONS: MF does not accurately predict the most critical patients likely because erroneous PWTT values confound MF. The concept of MF and the MWVSM is promising, but requires further fine-tuning prior to deployment.

D. PUBLICATIONS/PRESENTATIONS DIRECTLY RELATED TO EVALUATION

Other works, presentations and abstracts
   a. submitted 1/19/2015 to 26th Annual Fellow, resident, and medical student surgical research forum, South Florida Chapter of the American College of Surgeons, Miami, FL Apr 2015
b. Presented at 2014 Amer College of Surgeons Committee on Trauma Region 4 Competition Orlando, FL Nov 2014
c. Presented at 2014 Amer College of Surgeons Florida Committee on Trauma Paper Competition Jacksonville, FL Oct 2014 (* 1rst place Research Award)
d. Presented at 6th Annual Postdoctoral Fellows Research Day, University of Miami Miller School of Medicine, Miami, FL Sep 2014

3) Allen CJ, Meizoso JP, Tashiro J, Nissan JJ, Schulman Cl, Neville HL, Sola JE, Proctor KG: Pre-Hospital Care And Transportation Times Of Pediatric Trauma Patients. Accepted for presentation 10th Annual Academic Surgical Congress, Las Vegas, NV Feb 2015


9) 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

F. OTHER PUBLICATIONS RELATED TO APPROVED SOW DURING AWARD PERIOD

Monographs, editorials, and invited reviews


Juried or refereed journal articles:

1) Allen CJ, Straker RJ, Murray CR, Hannay WH, Hanna MM, Meizoso JP, Manning RJ, Schulman CI, Seery JM, Proctor KG: Recent advances in forward surgical team training at the United States Army Trauma Training Department. Submitted 2/12/2015 to Military Med


Other works, presentations and abstracts


   a. accepted for presentation 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


10) Allen CJ, Meizoso JP, Nissan JJ, Ruiz XD, Hanna MM, Schulman CI, Namias N, Proctor KG: Coagulation Profile Changes Due To Thromboprophylaxis And Platelets In Trauma Patients At High-Risk For Venous Thromboembolism. Accepted for presentation 2015 Annual Scientific Meeting Southeastern Surgical Congress, Chattanooga, TN, Feb 2015


14) 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 Sep, 2014


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


19) 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).


and Efficacy of Tranexamic Acid in Trauma Patients at High Risk for Venous Thromboembolism.

b) Presented at the 6th Annual Copeland Resident Paper Competition at the 60th Annual meeting of the Florida Chapter of American College of Surgeons. Orlando, FL May 2013 (*1rst place Research Award).


a) Presented at 2012 Annual Meeting, American College of Surgeons, Florida Committee on Trauma Resident Paper Competition, Gainesville, FL Oct 2012 (*1rst 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.


b) Presented at Academic Surgical Congress New Orleans, LA Feb 2013


a) Presented at 71rst 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 (*1rst place Research Award)

c) Presented at American College of Surgeons Region IV Committee on Trauma Resident
   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 41rst 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)


   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 (**1rst place research Award)

F. SUMMARY
The MWVSM monitor cannot reliably triage trauma patients and therefore should not be deployed.