A Prehospital Feasibility Assessment of a Lightweight, Durable, Wearable Biosensing Platform to Improve Combat Medic Management and Triage of a Massive Casualty (MASCAL) Incident in the Future Battlefield: A Pilot Study

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PILOT STUDY TO ASSESS FEASIBILITY OF THE BIOINTELLISENCE BIOSTICKER TO IMPROVE COMBAT MEDIC MANAGEMENT BY COMPARING TIME TO TRIAGE A MASCAL WITH AND WITHOUT THE DEVICE

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14. ABSTRACT-

Advanced monitoring is a top priority for both Tactical Combat Casualty Care (TCCC), En Route Care, and Prolonged Field Care (PFC). Current methods for monitoring do not permit the combat medic to rapidly assess and triage multiple casualties. Rendering care in the mass casualty scenario is challenging and made more so without adequate preparation and mitigation strategies for managing a large number of patients at one time. The FDA approved, wearable BioIntelliSense BioSticker™ is capable of capturing data such as heart rate, respiratory rate, body position and skin temperature. One portable hub collects data from numerous patients and delivers that data to the provider's handheld electronic device and/or relay to advanced medical control allowing the provider to monitor multiple patients. The purpose of this study was to assess the potential application of the BioSticker in a simulated MASCAL scenario. We hypothesize that use of the BioSticker can identify subjects with abnormal vital signs in a simulated MASCAL scenario. Twelve volunteers and one medical provider were recruited to simulate each MASCAL situation. Some Volunteers had their regular vitals monitored, and the remaining casualties were asked to hold their breath to simulate apnea. The medical provider was assigned to triage the simulated casualties and identify those that were apneic. The provider performed their duties once without and once with the BioSticker. Using the BioSticker to triage multiple patients in a MASCAL simulation was not significantly faster or more accurate than standard triage protocols.

15. SUBJECT TERMS- Biosensors, Triage, Remote Monitoring, MASCAL

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1.0 EXECUTIVE SUMMARY

The BioIntelliSense BioSticker™ is a portable device that can serve as a force multiplier to extend the monitoring capabilities of the limited number of providers who are typically available in combat theater. Moreover, the BioIntelliSense BioSticker™ can be used both in the battlefield settings and at Military Treatment Facilities (MTFs) that may encounter a mass casualty situation. This pilot study was designed to assess the feasibility of using the BioIntelliSense BioSticker™ in a mass casualty (MASCAL) scenario by comparing the time to triage 12 simulated casualties between two groups: one group performing standard triage methods and one group triaging while utilizing data from the BioSticker. With minimal training and no previous exposure, medical providers were able to utilize the BioIntelliSense BioSticker™ to triage multiple casualties as fast and as accurately as with standard triage methods.

2.0 INTRODUCTION

The US military is rapidly expanding the global battlespace into a footprint not seen during previous conflicts.[1] Advanced monitoring is a top priority for both Tactical Combat Casualty Care (TCCC) and Prolonged Casualty Care (PCC) research. [1,2] Current methods for monitoring do
not permit the combat medic to rapidly assess and triage multiple casualties. [1-3] The prehospital combat environments pose challenges in a dynamic tactical situation. [1-6] In the hospital, monitoring systems are limited in number and portability.

Recent advances in flexible/stretchable electronics have led to an entirely new class of 'epidermal' wearable biosensing systems that monitor motion, breath sounds, location, voice patterns, heart sounds, heart rate, respiratory rate, ECG, and temperature. The Food and Drug Administration (FDA) cleared the BioIntellisense BioSticker™ medical device in 2019 (510K191614) as a robust method to monitor patients. The device was approved for use in general care of patients to provide physiological information to health care professionals. The BioSticker is capable of capturing data such as heart rate, respiratory rate, body position and skin temperature. One compact, portable hub can collect data from over 100 patients simultaneously and deliver data to the provider's handheld electronic device or any approved ruggedized tablet and/or relayed to advanced medical control. Computer algorithms could rapidly assess this information and identify critically injured patients who require immediate life-saving interventions, less critically ill patients who are amenable to delayed care, and expectant patients on whom medics should avoid using limited resources. This will reduce cognitive burden for the medic and enable them to focus their effort on performing life-saving interventions (LSI). Furthermore, it will assist in more rapid casualty triage and evacuation, enabling the operation unit to remain combat effective and complete the assigned mission.

Therefore, this device can be applied to the far forward setting and be applicable to MASCAL situations to allow for more timely, effective care, and potentially decrease the risk of nosocomial infection and improve resource utilization, which can lead to improved patient care and decrease costs.

3.0 METHODS, ASSUMPTIONS AND PROCEDURES

The study was approved by the Institutional Research Board at the participating site before any study procedures or data collection was performed.

We conducted a pilot, prospective, simulation-based model of a MASCAL situation to compare the accuracy and efficiency of the monitoring capabilities of the BioIntelliSense BioSticker™ with current protocols of triage and mass casualty scenarios. We assessed the time to recognize casualties with abnormal vital signs using current protocols of management/triage compared to protocols using the BioSticker.

Provider: Military medical personnel from Brooke Army Medical Center and Fort Sam Houston were approached for potential participation in the study. The study team focused primarily on recruiting military medics. We did so by approaching their command to determine when the best time for recruitment might be and information on who may be available to participate. The provider was given an Informational Informed Consent Memo which included relevant information regarding study participation. No personal identifying information (PII) was obtained from the providers. Providers were given ample time to ask questions and decide whether or not to participate. Participants were allowed to withdraw or end their study participation at any time. If the provider had chosen to continue with the study, they were provided with a study ID number (01, 02, 03, and so on if necessary). Three providers underwent a brief (< 2 hour) training session on the use of the BioIntelliSense BioSticker™ device. Following the training, the medical provider was assigned to perform his/her standard duties during a simulated MASCAL incident involving 12 simulated casualties.

Volunteer: A minimum of 12 volunteers were recruited to simulate each MASCAL situation (i.e., MASCAL with and without the use of the BioSticker). Volunteers consisted of available Active-Duty personnel not currently participating in the scenario. Volunteers were provided with an Informational Informed Consent Memo document. A member of the study team reviewed the consent document with the potential volunteer(s) and they were given ample time to decide whether to participate in the simulation. Volunteers were allowed to withdraw or end their study participation at any time. From the pool of consented volunteers, half of the casualties had their regular vitals determined, and the remaining casualties were asked to simulate apnea by periodically holding their breath. The casualties that were designated to hold their breath were randomly chosen immediately before the start of the simulation.

The medical provider was assigned to perform his/her standard duties during the simulated MASCAL scenario using the BioSticker on each patient, with transmission of the data to a single hub. The time necessary to complete evaluation, triage, and recognition of the casualties that were designated to hold their breaths by the medic/provider was recorded. The scenario was executed 3 times with three different providers to account for individual variability in the study subjects. A simple randomization method was used to determine if the medic performs the triage scenario with the BioSticker first or second. There was at least a 20-minute break between scenarios. Following the scenario, providers and volunteers were asked to report any injuries or harm sustained during the scenario.

Data Collection: Data such as heart rate and respiratory rate trends for each participating volunteer from each BioSticker was collected and summarized. The data points collected by the

biosensor do not personally identify the volunteer and were not shared with the volunteer during or after their participation in the study. The primary end point was the time required to complete evaluation, triage and identification of those potentially needing life-saving interventions. The study team collected overall time of the scenario as well as the number of apneic patients who were correctly identified.

Statistical Analysis: We summarized provider characteristics, volunteer characteristics, simulation characteristics, and vital signs using means and standard deviations (for normally distributed continuous variables), medians and interquartile ranges (for non-normal continuous or ordinal variables), or counts and percentages (for nominal variables). To compare the time to completion of evaluation, triage, and identification of patients potentially needing life-saving interventions between the two groups (BioSticker vs. current triage protocols), we used Cox proportional hazards models for time-to-event data. We used conditional logistic regression models stratified by provider to compare the two groups' ability to accurately identify the patients with abnormal vital signs. Results are considered statistically significant at $p<0.05$ and if the corresponding hazard ratio or odds ratio does not include 1. Analyses was completed in SAS version 9.4 (SAS Institute, Cary, NC).

4.0 MAJOR EVENTS/MILESTONES/SUCCESS

We successfully met the following milestones:

- Recruited 12 volunteers and a medical provider for each MASCAL simulation
- 3 MASCAL simulations completed
- Time to completion (standard triage vs. data from BioSticker) collected in all simulations
- Data compiled and analyzed
- Study findings presented at MHSRS 2022 (poster)
- Study findings presented at AMTI/MITRE lunch and learn session in November 2022
- Abstract submission to SOMA 2023 in progress
- Manuscript generation is in progress

5.0 RISK ASSESSMENT

5.1 Risk Analysis

There is little to no risk to the medical provider during the course of study participation. There is a potential for performance anxiety or uncomfortable feelings as participation in the simulation may trigger memories of difficult patient care settings.

The risk to the MASCAL volunteers is minimal. As result of wearing the BioIntelliSense BioSticker™, the volunteer could experience an allergic reaction or skin irritation due to the adhesive on the BioSticker.

As a result of being randomized into the volunteer groups, volunteers could be asked to "hold" their breath by taking a deep breath and holding it for 30 seconds before releasing 3-5 times to simulate apnea. Consequently, they could experience discomfort or lightheadedness.

This study involves a simulation of a situation in which multiple people were injured, or a mass casualty event. Due to the nature of the scenario, volunteers could experience

emotional discomfort. This may be more prevalent for healthcare providers and current or former military members who have been in similar, difficult patient situations.

A major risk and challenge encountered was recruitment of subjects. Given tight schedules of the participants, it was initially difficult to enroll subjects and conduct the experiments. After creative efforts by the study team members, we were able to enroll the target number of subjects to complete the study.

5.2 Technical Challenges

The data was captured in real-time, however the data output that showed on the provider's tablet only synched with the devices once every few minutes. This sometimes caused a delay in alarms when vital signs still registered in normal ranges. In addition, one device did not turn on and was replaced prior to the simulation. Technical difficulties were discussed and troubleshot with the manufacturer via a Zoom link and telecommunications. Volunteers were enrolled several days prior to the simulation. This allowed for a baseline reading. Occasionally, a small number of volunteers were not present on the day of the simulation due to schedule conflicts. These vacant volunteer spots were filled by other willing personnel.

6.0 TRANSITION PLAN

6.1 Military Relevance

The mass casualty scenario is a dangerous scenario, made more so without adequate preparation and mitigation strategies for managing a large number of patients at one time. Having adequate and proper resources to manage such scenarios can lead to improved patient care, better outcomes, more efficient personnel and resource utilization, cost savings, and lives saved. The BioSticker is a portable device that may serve as a force multiplier to extend the monitoring capabilities of the limited number of providers who are typically available in combat theater. Moreover, the BioSticker can be used both in the battlefield settings and at MTFs that may encounter a mass casualty situation.

6.2 Transition Strategy

This technology can contribute to improvements in operational Readiness, Prolonged Casualty Care and Delayed Evacuation by more efficiently identifying patients who may need more timely/significant interventions in a mass casualty scenario allowing for more efficient resource allocation which can contribute to improved patient outcomes and significant cost savings.

We have plans to debrief these data with the manufacturer. Together, we will formulate a plan to assess if adjustments to the software/device can be made with the experience and data obtained from this study. Furthermore, we are currently working on a plan to further assess the device in other operationally relevant scenarios such as during patient transport and on simulated military aircraft. These additional studies will help inform future decisions about development of this technology for applications that may be highly relevant to military operations. If so, we will work with the manufacturer to develop a plan to scale an operationally relevant device and work with the end users to assess if an acquisition plan would be appropriate moving forward.

7.0 RESULTS

The difference in time to complete the triage scenario between the two groups (standard triage vs. data from BioSticker) was not statistically significant. All the medical providers enrolled into the study were able to use the BioSticker with minimal preparatory training. There were no adverse effects of using the BioSticker.

Group not using the BioIntelliSense Biosticker™ (Standard triage):
(n = 3, mean = 111.3 seconds, SD = 7.1)
Miscategorized patients (apneic/non-apneic): 3

Group using the BioIntelliSense Biosticker™:
(n = 3, mean = 91.7 seconds, SD = 41.3; p = 0.9999).
Miscategorized patients (apneic/non-apneic): 2

8.0 CONCLUSION/DISCUSSION

Without a significant amount of preparatory training, medical providers were able to use the BioIntelliSense BioSticker™ in a simulated MASCAL scenario. There was no statistically significant difference in time to complete the triage in the MASCAL scenario between the two groups. Some limitations of the study included: small sample size, technical challenges with the technology, and no standardized method to train individuals to use the technology as it is relatively new.

For future studies, we are working with the manufacturer to assess the utility of recent developments of the technology since this study was conducted. Disseminating this data via manuscript and to end users to obtain feedback as well as assess operational applications will take place. Additionally, we are currently designing studies and seeking funding to further assess the device in different settings such as other parts of the en route care continuum and while in flight.

9.0 DELEVERABLES

9.1 Publications

Abstract Title: A prehospital feasibility assessment of a lightweight, durable, wearable biosensing platform to improve combat medic management and triage of a massive casualty (MASCAL): A pilot study
Conference: Military Health System Research Symposium (MHSRS); Kissimmee, FL; 12-15 September 2022; selected as poster presentation

Manuscript: In progress

9.2 Presentations

Poster Title: A Prehospital Feasibility Assessment of a Lightweight, Durable, Wearable Biosensing Platform to Improve Combat Medic Management and Triage of a Massive Casualty (MASCAL): a Pilot Study
Conference: Military Health System Research Symposium (MHSRS); Kissimmee, FL; 12-15 September 2022; selected as poster presentation

Presentation Title: A Prehospital Feasibility Assessment of a Lightweight, Durable, Wearable Biosensing Platform to Improve Combat Medic Management and Triage of a Massive Casualty (MASCAL): a Pilot Study
Venue: AMTI/MITRE Lunch and Learn, November 2022 Session, Virtual.

10.0 COST

The proposal was funded by the AMEDD Advanced Medical Technology Initiative (AMTI) in the amount of $180,000. All funds were expended.

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12.0 TABLES AND FIGURES

Group	Control – Time to Triage (secs)	BioSticker – Time to Triage (secs)	Control -Missed Categorization	BioSticker – Missed Categorization
Group A	**119**	**97**	**0**	**2**
Group B	**105**	**130**	**1**	**0**
Group C	**110**	**48**	**2**	**0**
Overall Mean	**111.3**	**91.7**	**1**	**0.7**
Overall SD	**7.1**	**41.3**	**1**	**1.2**

13.0 LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

Electrocardiogram - ECG
Food and Drug Administration – FDA
Life Saving Intervention – LSI
Massive Casualty – MASCAL
Military Treatment Facilities – MTFs
Prolonged Casualty Care – PCC
Tactical Combat Casualty Care – TCCC