Airway and Hypothermia Prevention and Treatment via STEAM

The System for Thermogenic Emergency Airway Management†

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ABSTRACT

Military medicine has made significant advancements in decreasing mortality by addressing the lethal triad – metabolic acidosis, coagulopathy, and hypothermia. However, casualties are still succumbing to injury. Recent conflict zones have led to the development of remarkable life-saving innovations, including the management of compressible hemorrhage and whole blood transfusions. Nevertheless, hypothermia prevention and treatment techniques remain relatively unchanged. Hypothermia prevention is anticipated to become more critical in future operations due to a predicted increase in evacuation times and reliance on Prolonged Casualty Care (PCC). This is likely secondary to increasingly distanced battlespaces and the mobility challenges of operating in semi-/non-permissive environments. Innovation is essential to combat this threat via active airway rewarming in the vulnerable patient. Thus, we propose the development, fabrication, and efficacy testing of a device in which we estimate being able to control temperature and humidity at physiologic levels in the PCC setting and beyond.

Keywords: *Advanced Trauma Life Support care; airway management; critical care; emergency medicine; intellectual property; military medicine; patent; prehospital emergency care; prolonged casualty care; prolonged field care; resuscitation; technological innovations; war-related trauma; wilderness medicine hypothermia*

Introduction

Background and Importance of Medical Innovation and Hypothermia Prevention and Treatment

Between 2001 and 2011, an estimated 87% of combat injuries resulted in death prior to reaching a medical facility, with 57% of these deaths being potentially survivable.[1] Over the past two decades, innovation within military medicine have allowed the delivery of life-saving care as close to the point of injury as possible. With the most prevalent potentially survivable cause of death being exsanguination, efforts have been made to attenuate the "lethal triad." Metabolic acidosis, coagulopathy, and hypothermia make up this triad, which includes the broad major physiologic components of concern following massive hemorrhage.[1–3] Hypothermia is understood to exacerbate coagulopathy in trauma patients, thereby contributing to an increasing odds of mortality by upward of 200%.[4,5] Currently, it is reported that 66% of trauma cases are hypothermic upon arrival to the emergency department.[4–7]

Other groundbreaking, life-saving, military medical innovations include tourniquet use and implementation of Tactical Combat Casualty Care (TCCC) innovations to control noncompressible hemorrhage, the use of tranexamic acid (TXA), and whole blood transfusion in the prehospital setting.[1,8–12] Additionally, decreased medical evacuation (MEDEVAC) times reduce the rate of mortality, allowing combat casualties to receive damage control resuscitation and intra-operative control of the lethal triad.[9,13] Additionally of note, recent literature suggests that trauma-induced hypocalcemia may further interact with and exacerbate the lethal triad. As such, it has been proposed that hypocalcemia be added to the lethal triad. This forms the "lethal diamond," and practice guidelines now include calcium repletion in those requiring blood products.[14–17] The proponent authors of the lethal diamond paradigm foster future prospective analysis as this is an exciting and ongoing area of research.[14,18] With great respect to the above advancements, little has historically been accomplished to improve care surrounding hypothermia management and prevention on the battlefield.

Trauma-induced hypothermia (TIH) is considered to be congruent terminology of use for combat casualties, which is the primary focus of this article. However, we recognize the implications as it may pertain to wilderness medicine. In brief, the body works to control core temperature to approximately 37°C (98.6°F) by means of central and peripheral nervous system mechanisms. These mechanisms ultimately induce shivering and increase metabolic activity, to include an increase in respirations, cardiac output, and mean arterial pressure. Together, these are intrinsic ways the body compensates for heat loss. When the body is unable to adequately counteract its heat transfer to the environment, hypothermia ensues. TIH is further categorized based on classic clinical manifestations of hypothermia in trauma victims at various stages as mild, moderate, or severe, 36–34°C (96.8–93.2°F), 34–32°C (93.2–89.6°F), and <32°C (<89.6°F), respectively. As these stages of TIH progress from mild to severe, it is estimated that coagulopathy and metabolic acidosis are worsened, further highlighting the importance of lethal triad management.[6,19–21]

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Capabilities Gap in Prehospital and Prolonged Casualty Care Hypothermia Management

The prevention of hypothermia will likely become more critical in future operations due to a predicted increase in medical evacuation times, arctic operations, and a reliance on prolonged casualty care (PCC), previously prolonged field care (PFC). These concerns are secondary to progressively distanced battlespaces and the mobility challenges of operating in semi-/non-permissive environments. PCC and TCCC guidelines are rapidly being created/updated to account for the new threats and needs.[22–25]

A recent publication identified serious difficulties when attempting to rewarm hypothermic casualties in the PCC setting, highlighting unique challenges of hypothermia management in this environment.[26] Another study demonstrated that current hypothermia guideline strategies may not be adequate alone in treating hypothermic combat casualties.[17] Furthermore, the current recommendations remain rudimentary, suggesting that medical teams plan to take extra supplies, such as hypothermia blanket kits, tarps, and shelters in anticipation of heat loss prevention and caring for hypothermic patients.[6,26–29]

Active airway warming is an underutilized hypothermia management strategy in the prehospital and PCC setting. Under normal physiologic circumstances, approximately 75% of inspiratory air warmth and humidity that is supplied to the lungs is controlled at the upper airway.[30] Body heat loss due to respiration of cool and/or dry air can account for approximately 25–30% of the resting metabolic rate. When the upper airway is bypassed via intubation, the airway lacks its primary mechanism to warm and humidify inspiratory air. Regardless of other contemporary hypothermia prevention strategies utilized, the lack of airway compensation for hypothermia can lead to increased physiologic stress. As such, clinical practice guidelines (CPGs) recommend the management of temperature and humidity of inspiratory air in intubated patients and can also be used as an adjunct for patient re-warming.[21,31] Given the current technology available, the Joint Trauma System (JTS) practice guidelines reflect the above mentioned in the CPG entitled *Management of COVID-19 in Austere Operational Environments*. This CPG specifically outlines the use of the Hamilton H900, or a heat-moisture-exchange device, in conjunction with Department of Defense (DoD) approved ventilators for in-line heat and humidification control of inspiratory air in intubated patients.[32] Of note, other current JTS CPGs regarding ventilator management have yet to include this recommendation.[33,34] Currently there is not an adequate portable device that can actively perform the above mentioned function outside of the hospital, or Role 2+ setting. Thus, we propose a novel device that has the capability to actively warm and humidify inspiratory air to physiologic levels.

Methods

Digital Design and Digital Prototype Manufacturing and Patenting

Three-dimensional (3D) computer-aided design (CAD) techniques were employed in the design and digital prototyping of STEAM. Proposed device capabilities and functionality were drafted and submitted with various CAD schematics of STEAM for patent protection with the United States Patent and Trademark Office.[35]

Medical Device Concept and Design

The System for Thermogenic Emergency Airway Management (STEAM)

STEAM is a novel, portable, handheld, battery powered, airway management system having the capability to regulate the temperature and humidity of inspiratory air when delivered to a patient by means of manual or automatic positive pressure ventilation (Figure 1). The STEAM device is intended to be used in the treatment and prevention of hypothermia, patients at risk of hypothermia, and in any given environment including the pre-hospital setting. This device is designed to be compatible with commonly used positive pressure sources such as a bag-valve-mask (BVM) or ventilator. STEAM utilizes internal temperature, humidity, and pressure sensors to heat and humidify ambient air to physiologic levels as required by the medical professional.

By utilizing an active electronic heating and humification element, STEAM can maintain an output air temperature and humidity as set by the end-user for the patient regardless of the variable conditions found around the world (e.g., jungle, mountain, desert, arctic). This is accomplished by controlling the amount of electrical power the temperature and humidification elements receive via an onboard microcontroller. Further, STEAM incorporates an air splitting mechanism to prevent exhaled carbon dioxide from reentering, which greatly reduces the amount of dead space and rebreathing.

A variety of safety features have been implemented in the design of STEAM to prevent thermal injury to the patient and the potential combustion of biomatter. An internal rotary valve that isolates the patient's airway from the heating element, if sensed to be greater than the safe allowable temperature, automatically provides a mix of cool ambient air. Together, these features are critical for STEAM's safe operation.

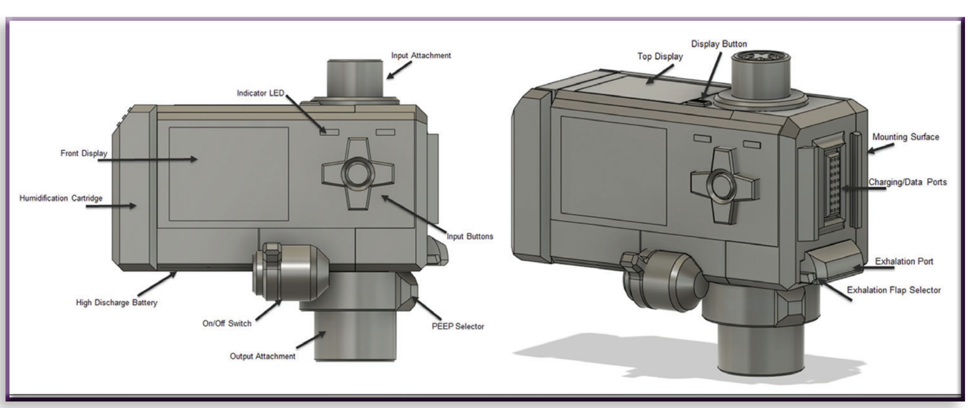

FIGURE 1 *External front and side view of STEAM (CAD, with labels illustrating the device's major external parts and controls.[35]*

CAD = computer-aided design, STEAM = System for Thermogenic Emergency Airway Management

Expanding on the above description, the STEAM device is comprised of five groups of components, all of which can be disassembled and reassembled in the prehospital environment for cleaning and sterilization or repair by the end-user (Figure 2). As such, the STEAM device can be reused. These groups include the outside shell which houses the internal components the heating coil and furnace apparatus, the humidifier element, the electronic control circuit, and a rechargeable battery system that is detachable to power the device. Furthermore, given the above-mentioned sensor technology STEAM can measure and display capnography, and barometric weather and altimeter functions. The device's valve system also allows for positive end-expiratory pressure (PEEP) control. In addition, the onboard computer and sensor network can provide ventilatory rate and volume control.

Discussion

We proposed, designed, and digitally prototyped STEAM to begin the effort to meet the needs of our prehospital and austere medical professionals, allowing them control of inspiratory air at physiologic temperatures and humidity levels. This innovation will bring the hospital standard, by medical guideline, far forward. We recognize that revolutionary advancements have been made to improve battlefield survival; however, there remains a need for innovation surrounding hypothermia prevention and management. Furthermore, this issue is compounded by an increasing battlefield reliance on PCC principals. STEAM is a novel solution that will integrate with existing hypothermia management systems to help reduce patient morbidity and mortality in the prehospital and austere environments.

The potential that STEAM holds for the future of battlefield. Austere medicine should not be underestimated and the need for such a device is long overdue. By doctrine STEAM is compatible with or incorporates all elements of the essential PCC capabilities regarding airway ventilation and oxygenation, and monitoring capability via capnography (Table 1). STEAM can operate to the maximum ("Best" rating) standards from ruck to plane (Role 1a–1d), and onward from Roles of Care 2–4.[22,24]

With near-peer threats rapidly developing and fielding advanced anti-access/area-denial, or A2/AD, it is likely that future high intensity conflicts will place tremendous logistical and operational burdens across the battlespace. One strategy to offset a unit's dependence on higher echelons for medical care is through the miniaturization of current technologies and making them easily portable. Additionally, developing new innovations that allow current capabilities previously delivered in-hospital to be employed close to the point of injury is another strategy. To enhance the performance of future medical devices and to serve as a framework to evaluate/develop innovative technologies, we propose that the principles of technological convergence and emergence enter the discussion.

We define technological convergence as the combination of multiple existing technologies into a single device in which the modern technology is more compact, portable, and lighter than the sum of the existing technologies, thus likely offering increased performance for the end user. STEAM adheres to the principle of convergence by design. STEAM integrates an airway heater, humidifier, PEEP valve, capnography, a barometric weather station, and a barometric altimeter. STEAM is estimated to weigh less than 100 grams, fully charged, significantly improving functionality based on size alone.

Technological emergence is a term denoting the capabilities that arise when multiple technologies work in conjunction with one another so that the overall capabilities and performance are greater than the sum of the individual parts. Because of its internal sensors and inherent design features, STEAM also adheres to the principle of emergence by enabling the use of medical telemetry to assist the medic or other health professionals. STEAM is also able to utilize its internal temperature, humidity, and pressure sensors to sense the input air volume, flowrate, and pressure entering the patient. By taking advantage of the internal rotating safety valve, STEAM has the emergent properties of allowing the end-user to set a rate limiting, volume, and pressure limiting function to prevent barotrauma and volutrauma (Table 1). If manual ventilation is replaced by an external pressure source, STEAM can also serve as a ventilator by automatically controlling the respiratory rate, flow, and pressure the patient receives as set by the end-user.

The major limitation to this work is that it is theoretical in nature. It is the proposed solution to an identified prehospital

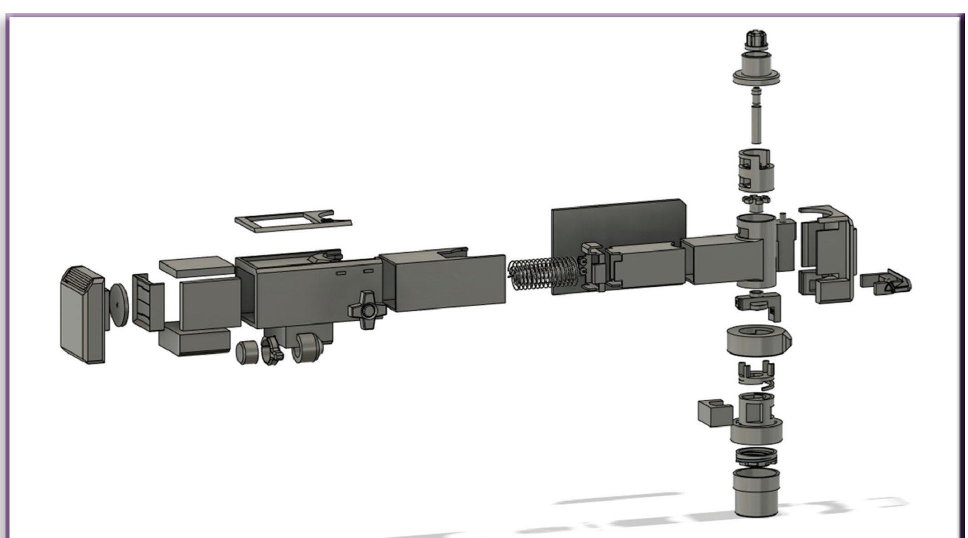

FIGURE 2 *Exploded view STEAM (CAD) illustrating the devices' ability to be disassembled and re-assembled in the pre-hospital environment for cleaning or repair.*[35]

CAD = computer-aided design, STEAM = System for Thermogenic Emergency Airway Management.

TABLE 1 *STEAM Capability Overlap and Integration With PCC Guidelines*

Convergent Properties	Emergent Properties
Ability to heat and humidify input air	Inspiratory air temperature and humidity control
ventilator and manual BVM compatibility	Telemetry capability
intermediate and advanced airway compatibility	Breath rate control function
CO_2 capnography	Breath volume control function
Barometric weather station	Output pressure limiting function
Barometric altimeter	
PEEP capability	

capability gap, which has just recently passed the digital prototype manufacturing and patenting phase of development. However, this milestone in itself should not be unacknowledged, considering we can now begin to have a profession-wide discussion regarding future advancements in this uncharted territory of medical technology.

Future planned works include physical device prototyping and development of the STEAM device's ability to heat and humidify ambient air to physiologic levels, per industry standard. As research and development continues to device fabrication and testing, we will be able to standardize the STEAM for use in future animal model studies. We estimate that the temperature and humidity of ambient air will increase as it passes through the STEAM device in proportion to the electrical power supplied to the heating and humidifier elements. A dose-response curve and power draw can then be measured to determine if/what improvements to the design are necessary to meet performance requirements.

Conclusion

Although the future of battlefield medicine is unknown, it is predicted that PCC will become commonly practiced requiring medical and technological innovation in prehospital care. Currently there are medical capabilities that can only be delivered in the hospital setting or in locations with more robust resources. We estimate that hypothermia management requires innovation to better combat the lethal triad, especially in the PCC setting. We have identified such a capability gap – the current inability to heat and humidify inspiratory air of ventilated patients in the prehospital setting. Through STEAM, we can bring the above capability far forward into the most austere environments. Thus, it can bring the in-hospital standard of care into the pre-hospital setting, likely reducing morbidity and mortality of the injured.

Author Contributions

BP conceived the invention concept and design. All authors contributed to the evolution of the concept and design. BP refined and created the design as filed. BP, RS, and LT obtained funding. RS wrote the first draft, and all authors contributed, edited, and approved the final manuscript.

Disclosures

The views expressed are solely those of the authors and do not reflect the official policy or position of the Uniformed Services University, US Army, Department of Defense, or the US Government.

Financial Disclosure

The authors Pierce, Stevens, and Tilley are listed as inventors for the STEAM device, patent pending. These authors are entitled to future royalties related to STEAM.

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