Hypothermia Management, an Evaluation of a Novel Lightweight System.

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Background:

Accidental hypothermia is often defined in contemporary literature as body temperature below 35°C[1], and remains an important contributory factor to mortality in trauma, both in civilian and military environments[2]. Furthermore, even at 36°C, mortality of severely injured people has been shown to be 11% in civilian and 12% in military patients[2]. Healthy individuals may experience mild hypothermia as a transient and simply unpleasant phenomenon[3], yet for patients with traumatic injuries, hypothermia contributes to a much more significant pathophysiology[4].

Patients enter a hypothermic state when their core body temperature falls below the normal physiological parameters and the hypothalamus detects a change in temperature, initiating a feedback loop that increases skeletal muscle activity, thus generating heat[1]. This occurs via compensatory mechanisms, such as peripheral vasoconstriction and shivering[5]. The thermoregulatory mechanisms begin to fail as core temperature decreases further, resulting in the pathological effects of hypothermia: fatigue, bradycardia, arrythmias and eventually asystole[6]. Hypothermia is widely recognised alongside acidosis and coagulopathy as a component of 'the lethal triad' that results in poor outcomes for trauma patients[7].

This study focuses on methods to prevent and reverse hypothermia in critically unwell patients with the aim of diminishing the effects of this component of the lethal triad. To effectively combat heat loss and minimise the hypothermic element of the lethal triad cycle requires an understanding of the most significant mechanism of heat loss that occur in both healthy individuals and seriously injured people. People lose heat in four ways - conduction, convection, evaporation and radiation[10].

This study will investigate options for use in the field that has been designed to combat heat loss via these processes. A further challenge is faced when considering the use of hypothermia mitigation systems in the prehospital environment. The volume, shape and weight of a product allow its transportation and deployment in the field[13]. There are, some lightweight hypothermia management systems that are used by military and civilian rescue teams[13]. (See Figure 1). These systems can be easily carried on expeditions and are widely used, yet they primarily focus on loss of heat by radiation and may not be optimal in the management of trauma patients experiencing a large haemorrhage. This study focused on comparing these two systems with a new product: The Xtract™SR Heatsaver. This novel approach to a hypothermia mitigation system aims to provide optimal performance in the management of a hypothermic patient while remaining within a size:weight ratio acceptable to pre-hospital clinicians and medical care providers.

Limitations:

This pilot study was limited by the small cohort of volunteer subjects. It was sensible to use a small sample size in this preliminary trial as it took place in a location that was limited by size. The researchers only had access to a few prototypes of each system. Future trials will benefit from a larger cohort which will increase representation in the variables of sex, age and BMI to ascertain any potential influence of these factors on the rewarming process. An element of blinding for both the subjects and the researchers working in the environment may be difficult to achieve.

Aims and Materials:

For this study a total of seven normothermic healthy subjects were cooled and then rewarmed on four separate occasions, with the aim of demonstrating both the numerical decrease in the subjects' core temperature, and objective qualitative findings regarding comfort. The subjects were also invited to share their experience of both the cooling and rewarming stages. Three different heating systems were utilised in the rewarming stage of the trial, to investigate the performance of Xtract™SR Heatsaver in the rewarming of trauma patients when compared with systems currently used in austere environments.

Systems:
See Figure 1.

Subjects:
Seven subjects volunteered to participate in this initial trial (see Figure 2), over a three-day period. This trial additionally aimed to identify areas for further research; it was hoped that the heterogeneity of subjects might highlight any potential differences that might warrant future investigation.

Clothing and environment:
All subjects wore lightweight sports shorts, t-shirts, underwear, and shoes, and were soaked in water using a cold shower prior to entering the room. The clothes were identical on all days to minimise confounding factors. Subjects were exposed to an environment of 0 °C (+/- 1 degree) in a temperature-controlled cold room with a plastic and sediment flooring that imitated an artic setting (See Figure 3)..

System	***Name***	***Contents***	***Weight (g)***	***Pack Dimensions (cm)***
1	Blizzard Heat	Blizzard 3 Layer Blanket with Heat Cells contained in Blizzard Heat product	1900	30 x 25 x 5
2	North American Products Hypothermia Prevention and Management System (HPMK®)	External cover Ready Heat Cell Blanket	1588	26.67 x 17.15 x 13.97
3a	Xtract™SR Heatsaver *Prototype- Unwashed*	*Xtract™ SR Stretcher* *Xtract™ Insulate Mattress* *Xtract ™ HeatSeal Blanket* *Xtract ™ Element Protection Sheet.*	2400	40 x 18 x 18
3b	Xtract™SR Heatsaver *Prototype -Washed*	*As above,* *Heatseal blanket washed x 4 @ 60◦ with 10-minute contact time in a Bosch Excel 7 1200 Express domestic washing machine.*	2400	40 x 18 x 18

Figure 1: Table listing the products used to rewarm subjects and the components that make up each system.

Methodology:

All three days followed the same conceptual methodology. Once the volunteers had an aural temperature reading of 35ºC (+/- 0.5ºC) they were placed into different hypothermia systems and the rewarming effects of each system was monitored over time. Heat cells were added in order to aid rewarming. In the HMPK® and Xtract™SR Heatsaver heat cells were configured around the abdomen and axillary region. In the Blizzard Heat system, the heat cells were placed only in the locations permitted by the product's design. Due to the size constraints of the cold room and the limited space for both subjects and those collecting data, different systems were tested and compared on each day of the trial.

On days one and two respectively the Blizzard Heat and HMPK® were compared with the Xtract™SR Heatsaver. On Day Three a further investigation was carried out on both the Blizzard Heat and the Xtract™SR Heatsaver to assess the practicality of carrying out a suitable and comprehensive clinical assessment in the cold room environment. The assessments were undertaken in the cold room by an emergency medicine consultant with extensive experience of pre-hospital care in both military and civilian environments.

The clinician wore clothing appropriate for artic conditions, including mitts, to ensure the assessment carried out reflected those challenges faces by medics in cold pre-hospital environments. Each system was reviewed by the clinician against a set of predetermined criteria. These included the ability to communicate with the subject, as well as access to lower limbs, chest and the antecubital fossa. Access to each area corresponded with the necessity to carry out clinical interventions such as tourniquet placement, chest examination and venous access respectively. The clinician's experiences were recorded as qualitative data and provide a comparison of the two systems' clinical functionality.

Day one					
Subject	Sex	Age (Years)	Weight (kg)	Height (m)	BMI (kg/m^2)
1	Male	54	86	1.80	26.5
2	Female	24	80	1.65	32.9
Day two					
Subject	Sex	Age (Years)	Weight (kg)	Height (m)	BMI (kg/m^2)
3	Male	54	86	1.80	26.5
4	Male	53	71	1.76	22.9
Day three					
Subject	Sex	Age (Years)	Weight (kg)	Height (m)	BMI (kg/m^2)
5	Male	54	87	1.80	26.9
6	Male	53	73	1.76	23.6
7	Female	23	57	1.57	23.1

Figure 2: A table providing specific details about each subject.

Results:

Figure 4: Graphs of results from Day One, comparing Blizzard Heat with Xtract™SR Heatsaver.

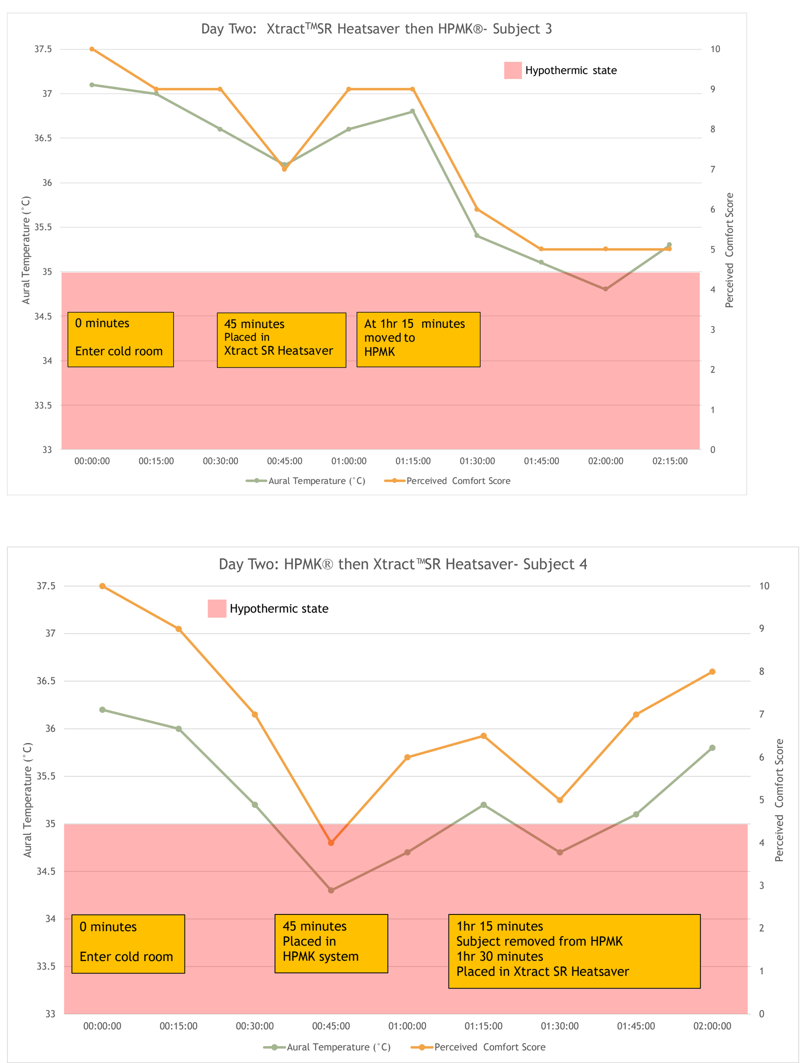

Figure 5: Graphs of results from Day Two comparing HPMK with Xtract™SR Heatsaver.

Figure 6: Graphs of results from Day Three comparing HPMK with Xtract™SR Heatsaver.

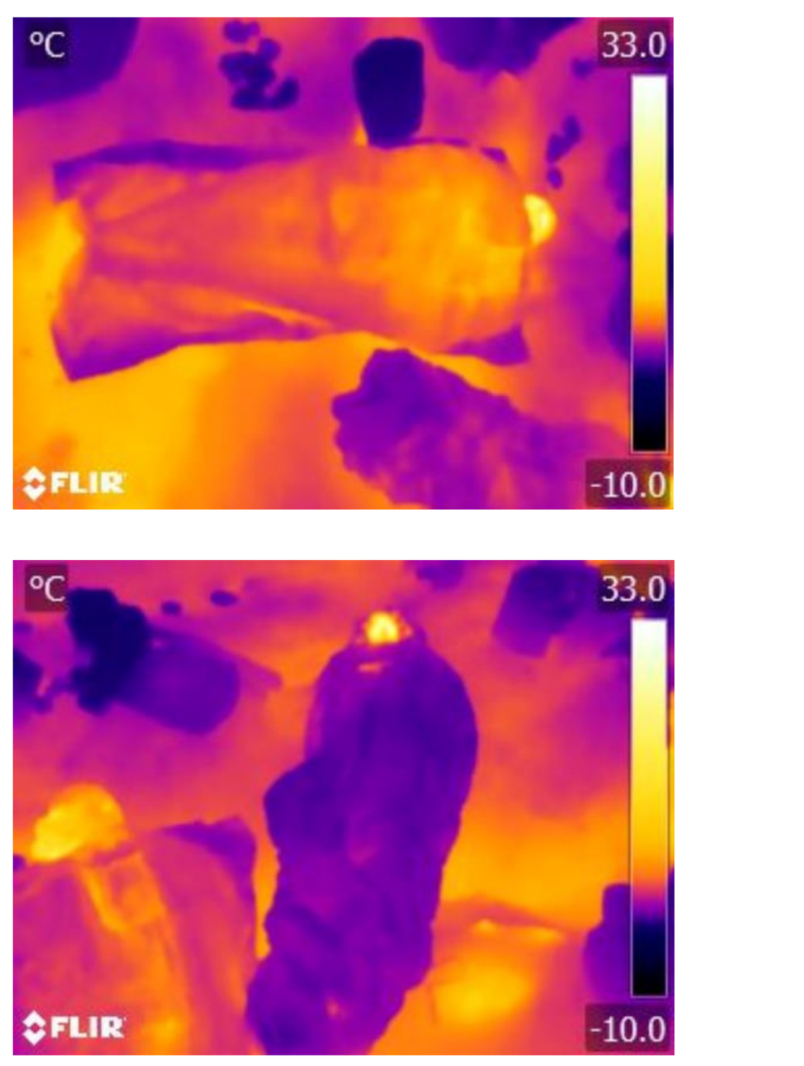

Figure 7: Examples of thermal camera images of the systems tested throughout the pilot study. HPMK (top) and Xtract™SR Heatsaver (bottom). Temperature key provided on right side of image.

Conclusions:

Results demonstrate that the new Xtract™SR Heatsaver system offers improved performance with regards to reducing heat loss, increasing patient comfort and allowing for clinical assessment. The study also reinforces the importance of the use of adjuncts such as heat cell blankets and insulation mats alongside hypothermia mitigation systems and provides scope for future research into individual nuances surrounding the effects and onset of hypothermia.

The trial improved knowledge regarding the use of active rewarming equipment in the field. It found that the Xtract™SR Heatsaver provided a higher level of comfort and a more immediate relief from hypothermia than other systems currently on used prehospitally. Additionally, it was found that heat cells are most effective when pre-warmed in a warm environment and placed over the abdomen and axilla. With further investigation this could change best practice in the pre-hospital environment.

Finally, the investigation resulted in several findings that would support further research regarding the mechanisms of hypothermia. It is possible that individual factors such as sex, age and BMI may affect the process of heat loss. Qualitative data showed a decrease in comfort and mood of subjects as temperature dropped. An interesting phenomenon was the initial increased baseline comfort level on the second day of the trial. This could be attributed to the anticipation of the decrease of comfort, adding reserve to the initial comfort rating.

Conflicts of interest:

Participating researchers contributed to the design of the Xtract™SR Heatsaver. Independent researchers were present to oversee the deployment of the equipment and data collection to minimise any elements of vested interest. Two of the volunteer subjects were involved in writing up this report and poster presentation.

Contacts:

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For further information about the study design or the Xtract™SR Heatsaver please email: info@tsgassociates.co.uk

Figure 3: Images showing the cold room test environment and clothing worn by the subjects.

References:

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