Technical Report

Use of the ThermoSuit® System for Treatment of Severe Hyperthermia

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Current medical guidelines recommend cold water immersion as the preferred treatment for heat stroke. The ThermoSuit System is the only FDA-cleared patient cooling device that uses this approach to cool the patient. This report discusses some of the data related to the use of this device in the treatment of severe hyperthermia [LRS Technical Report, June 2015).

Background

Severe hyperthermia is increasingly recognized as a critical health issue. Record high temperatures have been reported in many parts of the world in recent years, and these in turn have been associated with significant increases in rates of death. Thousands of people die each year due to heatstroke, according to the World Health Organization[1]. Military personnel operating in high-temperature environments are at a particularly high risk for heat-related disability or injury, and a number of heat related fatalities have occurred[2]. Over 1,600 heat casualties were reported in 2012 within the US Army active component that required medical attention and/or lost duty time[3].

Heatstroke is a condition resulting from prolonged exposure to intense heat, characterized by high fever and in severe cases convulsions, coma, and death. It is a medical emergency requiring immediate measures to rapidly reduce the core temperature. It has been reported that immersion in ice water is superior to all other cooling methods for treatment of severe hyperthermia, including i.v. fluids, cold air, and ice packs[4,5,6]. A research study conducted by the University of Ottawa and Defense R&D Canada[7] studied the use of immersion in circulating cold water in hyperthermic volunteers. This study demonstrated that cooling was most effective if the water was at 2°C; cooling was less effective for water temperatures of 8, 14, and 20°C.

Current Guidelines

Current evidence-based medical guidelines, issued in 2014[8] recommend the use of cold water immersion as the preferred treatment of heat stroke. The expert panel which developed these guidelines gave cold water immersion a *Recommendation Grade 1A* rating, both for treatment of patients in the field and within the hospital (the only cooling treatment to receive the 1A rating). Other cooling methods, such as ice packs, evaporative cooling, and cold intravenous fluids all received inferior ratings (see Tables 1 and 2 below)

Table 1: 2014 Guidelines for Field Treatment of Heat Stroke[8]

Treatment Method	Recommendation Grade
Cold-water immersion	**1A**
Evaporative Cooling	1C
Chemical Cold packs/ice packs	1C
Ice-towel application	2B
Antipyretics	2B

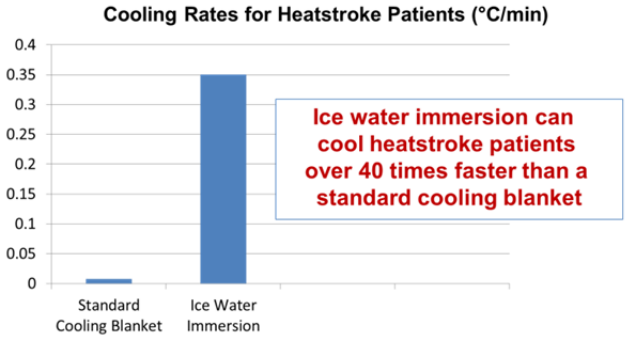
Table 2: **2014 Guidelines for In-Hospital Treatment of Heat Stroke**[8]	
Treatment Method	Recommendation Grade
Cold-water immersion	**1A**
Evaporative and Convective Cooling	1C
Cold intravenous fluids,	1C
Body cavity lavage or intravascular cooling devices	2C
Pharmacological Treatment	1B

The cold water immersion method, while highly effective, has until recently not been practical for use while performing other emergency medical treatments such as cardiopulmonary resuscitation. The introduction of the LRS ThermoSuit System has changed that.

Cooling Methods

The ThermoSuit System is the *only* product that provides controlled patient cooling by ice water immersion. It delivers a rapidly flowing thin layer of ice water directly over the body in a contained system, rapidly lowering the body's core temperature in minutes. It is designed to be used on a supine patient on a stretcher, facilitating the delivery of CPR and other medical treatments and monitoring procedures simultaneously with cooling. The water is above the freezing point, and thus does not introduce the risk of frostbite that ice-based cooling methods carry.

Ice water immersion[7] cools victims of severe hyperthermia significantly faster than standard cooling blankets[9].



Case Examples

Listed below are several case examples of the use of the ThermoSuit as a treatment for severe hyperthermia.

Case 1 - Severe Heatstroke: A 47 year old male was found unconscious on the side of a road at midday in Louisiana with the ambient solar exposure + heat index estimated at 101°F. His body temperature was 108 °F. He was brought to a nearby hospital. After attempts at surface cooling produced marginal results, the patient was placed in the ThermoSuit System (TSS) with a starting core temperature of 105° F and cooled to 90.8 °F in 26 minutes, then removed from the TSS and gradually rewarmed. The patient's impending acute renal failure, rhabdomyalysis, and coma completely resolved. Because of elevated cardiac enzymes he underwent cardiac catheterization which was normal and the patient was discharged fully recovered on hospital day five.

Case 2 - Malignant Hyperthermia: A male patient in his 30's developed malignant hyperthermia during surgery (108°F). The anesthesiologist requested that patient be cooled with ThermoSuit. The patient was rapidly cooled to normothermia, and was later discharged with full recovery.

Case 3 - Severe Fever: A female patient in her 50's with non-hodgkins lymphoma arrived in the emergency department with a fever of 105°F, with altered mental status, and hemodynamically unstable. Physicians were unable to control her fever as it rapidly climbed to 107°F. An emergency department physician elected to deploy the ThermoSuit. Upon treatment the patient temperature dropped from 106.7°F to 96.8°F in 45 minutes. The next day the patient was awake and was extubated. The patient recovered rapidly, and was later discharged with excellent outcome and full neurologic recovery.

Case 4 - Fever (obese patient): A 44 year-old 298 lb female patient developed a 107.7°F fever. Obese patients tend to be difficult to cool due to the large body mass in relation to surface area. She was cooled with the ThermoSuit to 100° F in only 30 minutes. After being removed from the ThermoSuit, her temperature continued to decrease to 98°F in 5 more minutes.

Discussion

The heatstroke patient described in case 1 above was treated to a level of therapeutic hypothermia (TH) instead of normothermia. His rapid and complete recovery suggests that thermal cell injury may respond to TH in similar manner to ischemic injury and deserves scientific study. It is well known that rapid reversal of core hyperthermia will stop thermal injury to the cells.

The ThermoSuit System uses circulating cold water to cool approximately 90% of the body's surface area, giving it an advantage in terms of heat transfer area vs. all other cooling methods. Furthermore, the

ThermoSuit System operates with water that is colder than 10°C (the ThermoSuit usually cools with circulating water at about 2°C). Clinical research by Proulx et al[7] demonstrated that colder water significantly increased the cooling rate of immersed human volunteers. This is in part due to the increased thermodynamic advantage of using colder water, but a physiological effect is also a factor: Proulx et al reported that only one of seven volunteers shivered when immersed in 2°C water, while six of seven shivered in 8°C water. Thus, the colder water suppressed the shivering response in most subjects. Correspondingly, this study reported that subjects in 2°C water lost heat approximately 50% more rapidly than those in 8°C water.

Shivering raises metabolic rate significantly and adds to the stress on the body. If the goal of cooling is to bring the core temperature to a safe level while minimizing the stress of the cooling process, a rapid cooling induction is desirable. Rapid cooling has also been shown to be desirable when therapeutic hypothermia is indicated[10,11,12,13,14].

The LRS ThermoSuit® System*: The only patient cooling device that provides cold water immersion therapy. This produces the highest noninvasive patient cooling power available.*

In summary, the ThermoSuit System has a cooling power greater than any other noninvasive cooling method. This is due to a highly efficient liquid convection heat exchange mechanism that maximizes thermal transfer while minimizing shivering. It uses liquid above the freezing point and does not introduce a risk of frostbite. It enables simultaneous use of medical treatments such as CPR. The ThermoSuit System should be considered as the standard of care for treatment of severely hyperthermic patients.

FDA-Cleared Indications for The LRS ThermoSuit System:

Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients.

Health Canada – Cleared Indications for the LRS ThermoSuit System:

Temperature reduction in patients where clinically indicated, e.g., to induce hypothermia in patients to preserve cardiac and brain function in victims of cardiac arrest, stroke, heart attack, traumatic brain injury.

References

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