Project: pIVot

From: Olivia Conroy, Shipra Khatri, Biola Ogunfuyi, Manit Sabharwal, Bené Woods

Date: April 10, 2020

Title: Clinical Literature Assessment

Rev: 2

Goal: Provide an analysis of relevant clinical and academic literature on the subject of pre-hospital patient warming theory, techniques, and risk.

Overview of Relevant Literature:

Per the Center for Disease Control and Prevention, accidents (unintentional injuries) are the third leading cause of deaths in the United States of America[1]. Hypothermia is one of the most important physiological predictors for early and late mortality in trauma patients[2]. Being so, the need to address heat loss in trauma patients in pre-hospital environments in order to foster core body temperature in the normothermic range is substantial.

Normothermia is defined as 37 ± 0.5 °C[4]. Hypothermia is conventionally defined as a temperature below 35°C[4]. Trauma patients lose heat at an increased rate than non-trauma patients, resulting in redefined ranges for hypothermia (table 1). Heat loss occurs at a rate of 60-75 kcal/hr; however, trauma patients lose heat at an increased rate of 400 kcal/hr, increasing mortality overall[4]. In trauma patients, mortality rates increase to 100% at 32°C, the border temperature between moderate and severe hypothermia[14]. Heat is loss by four different methods: radiation, conduction, convection and evaporation (table 2).

Table 1. Classification of Hypothermia[3]

Classification	Conventional	Trauma patient
Mild hypothermia	35–32 °C (95.0–89.6 °F)	36–34 °C (96.8–93.2 °F)
Moderate hypothermia	32–28 °C (89.6–82.4 °F)	34–32 °C (93.2–89.6 °F)
Severe hypothermia	28–20 °C (82.4–68.0 °F)	32 °C (89.6 °F)
Profound hypothermia	20–14 °C (68.0–57.2 °F)	

Table 2. Mechanisms of Heat Transfer in Trauma[3]

Mechanism	Rate (kcal/h)	Description
Radiation	10–50	Transfer of heat energy via electromagnetic waves down a concentration gradient without direct contact according to Boltzmann's equation:[a] $Q = K(T1 - T2)$
		Methods to reduce losses include:
		• warming blankets
		• increasing environmental temperature
		• radiant heaters
		• avoid unnecessary anesthesia
Conduction	16–30	Transfer of energy between two solid objects in contact according to Fourier's equation:[b] $Q = KA\ dt/dx$
		Methods to reduce losses:
		• removal of wet clothing
		• avoid prolonged contact with cold surfaces
Convection	10–20	Transfer of heat energy during the mass movement of gas or liquid.
Evaporation	12–16	Heat energy transferred during change of phase (water to gas): 58 kcal/g water evaporated from skin, respiratory tract, and viscera
		Methods to reduce losses for convection and evaporation:
		• avoid prolonged surgery with an open abdomen
		• warming blankets

[a] Q = rate of radiant heat transfer, K = a constant, $T1$ = temperature of the first object, $T2$ = temperature of the second object
[b] Q = rate of heat transfer by conduction, K = thermal conductivity, A = area in contact, dt/dx = thermal gradient

Hypothermia is a contributor to the trauma "triad of death". The triad of death- hypothermia, metabolic acidosis, and coagulopathy, feed one another in synergistically leading to the demise of many trauma patients. Acidemia, a blood pH of less than 7.35, was proven to progressively worsen clot formation deficiency by Engström et al6. In a study conducted by Brohi et al, it was found that trauma-induced coagulopathy (TIC) presented in 25% of all severely injured patients and carried a 46% mortality rate[7]. TIC becomes even more detrimental when combined with acidemia and hypothermia.

In "Non-Therapeutic Intraoperative Hypothermia: Prevention and Treatment (Part II)" Zaballos Bustingorri highlights the important considerations in patient warming: General and regional anesthesia alter the physiological mechanisms of thermoregulation, and unintentional intraoperative hypothermia develops during most surgical procedures that last more than 1 hour. Monitoring of central temperatures among other vital signs is advisable in such interventions in order to detect temperature changes and check the efficacy of measures to prevent or treat hypothermia. Passive insulation reduces heat loss through the skin but most patients require active warming to maintain a normal temperature. Various skin surface warming systems prevent hypothermia from developing and provide effective warming. The most often used are forced-air or warm water circulation devices. When large volumes of fluids must be infused intravenously, they must be warmed to body temperature to avoid heat loss13. For the purpose of pIVot entering the pre-hospital setting, this article further supports the use of warmed intravenous fluids. In the case of future considerations on pIVot entering the hospital-setting where surgical procedures lasting more than 1 hour occur, this article also supports the use of warmed intravenous fluids, reinforcing the potential for pIVot to enter the peri-operative space.

A majority of the current patient warming devices on the market are listed in table 3, however not all of these devices are compatible with the prehospital setting. Each current device also has its own shortcomings. In a study conducted by Tjoakarfa et al, it was demonstrated that after **adequate prewarming**, there were no significant differences between the temperature of patients warmed by reflective blankets versus forced air warming[5]. Here it can be inferred that adequate prewarming is the most impactful in maintaining normothermia, while any method of warming following proper prewarming will serve as a secondary means of maintenance.

Table 3. Warming Methods[3]

Warming device	Manufacturer	Description	Heat transfer
Warming blanket	Bair Hugger 750, 505 (Arizant Healthcare Inc., Eden Prairie, MN, USA)	Air delivered to variety of blankets (upper, lower, full, torso, surgical access, pediatric, cardiac) at three settings: high (43 °C), medium (38 °C), low (32 °C)	Convection
	Equator (Smiths Medical ASD, Rockland, MA, USA)	Air delivered to adult and pediatric blankets. Settings: high (44 °C), medium (40 °C), low (36 °C)	Convection
	Thermacare TC3000 series (Gaymar Industries, Inc., Orchard Park, NY, USA)	Air delivered to adult and pediatric quilts: low (32 °C), medium (38 °C), high (43 °C), maximum (46 °C)	Convection
	WarmTouch 5200 (Nellcor, Pleasanton, CA, USA)	Air delivered to adult and pediatric blankets: high (42–46 °C), medium (36–40 °C), and low (30–34 °C)	Convection
Circulating water garment	Medi-Therm III (Gaymar Industries, Inc.)	Circulates water from the control unit to polymer hyper/hypothermia blankets. Manual settings: 4–42 °C; automatic: 30–39 °C	Conduction
	Blanketrol II Hyper–Hypothermia Water System (Cincinnati SubZero Products, Cincinnati, OH, USA)	Circulates water from the control unit to specialized blankets (adult and pediatric). Temperature range, 4–42 °C	Conduction
Heated air mattress	Polar Air (Augustine Medical, Inc., Eden Prairie, MN, USA)	Has not been shown to be effective [73] because only a limited amount of body surface area comes into contact with the mattress. Trauma patients may be vulnerable to burn injury	Conduction
Hot packs	Hot Cycle 1 (Sign Manufacturing Corporation, Fairfield, CA, USA)	Temperature at approximately 54.5 °C. Mean increase in temperature of 1.4 °C compared with a mean decrease of 0.3–0.6 °C in controls. Further research is necessary [64]	Conduction
Humidified gases	Heated Anesthesia Circuit (ANAPOD Westmed, Inc., Tucson, AZ, USA)	Delivery of warm, humidified gas can increase core temperature by 0.5–0.65 °C/h in injured patients [74]	Evaporation
Fluid warmer	General	Warmed fluids were found to increase temperature to 36.8 °C compared with 35.5 °C in nonwarmed patients [75]	Conduction
	Level 1 System H-1200, H-1000, H-1025, H-525, H-500, H-275, H-250 (Smiths Medical ASD, Rockland, MA, USA)	Aluminum heat exchanger with countercurrent 42 °C circulating water bath. Air detector/clamp	Conduction
	Hotline (Smiths Medical ASD)	Water bath heat exchange. Surrounds patient line with layer of 42 °C circulating fluid	Conduction
	FW600 Medi Temp III (Gaymar Industries, Inc.)	Dry heat exchange. Plastic disposable with aluminum heating plates (set point, 41 °C)	Conduction
	Thermal Angel TA-200 (Estill Medical Technologies, Dallas, TX, USA)	Battery-powered, portable in-line warmer. Outlet temperature, 38 ± 3 °C at flow rate 2–150 ml/min	Conduction
	Warmflo FW538 (Nellcor)	Dry heat exchange. Single-use metal cassette. Maximum flow rate, 500 ml/min	Conduction
Other	AV-300: CAVR – continuous	Rapid core rewarming. Circulates colder blood of patient through Level 1 heat exchanger and returns it to patient at Smiths Medical ASD	Conduction
	CairCooler (Pentatherm Ltd, Wakefield, UK)	Forced-air cooling system. Connects to forced-air blanket to deliver 10 °C air	Conduction
	Arctic Sun 2000 (Medivance, Louisville, CO, USA)	Circulating water temperature is controlled between 4 °C (39.2 °F) and 42 °C (107.6 °F) to achieve a preset target patient temperature	Conduction
	Lavage	The specific heat and rate of heat transfer in water is 32-fold greater than air, which permits effective hypothermia management [76]. The rate of rewarming is 1–3 °C per hour if done continuously	Conduction
	CPB	Hemodialysis (rate of rewarming is 2–3 °C/h), CPB using a heat exchanger (8–15 °C/h), and extracorporeal venovenous rewarming are other options for rewarming [77–79]. CPB is therefore the only technique that can also correct the hemodynamic stability of the patient and provides the greatest heat transfer	Conduction

Warm intravenous fluids (39°C) can increase the core temperature by 0.5-0.7°C and lower the incidence of hypothermia. In a study conducted by Goyal et al., patients received intravenous fluids via fluid warmer where core body temperature was recorded tympanically at every 1 minute for the first 5minutes, followed by 10minute intervals until the end of surgery. As a result, a statistically significant difference occurred in mean core temperatures at times 5, 50, 60, 70, 80 and 90 min and immediately on arrival in the recovery room between warmed groups and the control. The mean decrease in core temperature in group I that received room temperature IV fluids (22°C) was -2.184 ± 0.413 and -1.934 ± 0.439 in group II who received the warmed IV fluids (39°C). And incidence of shivering also decreased in the warmed group, but was not of statistical significance. It was concluded that infusion of warm intravenous fluids resulted in a lesser degree of fall in core temperature, thereby providing a significant temperature advantage; however, this did not translate to prevention of postoperative shivering[9].

In further considering the maximum heating limit and consequences to the contents of the heated intravenous fluids, it was found that the recommended maximum temperature of heated IV fluids is 42°C[10]. A paper published by Anshus et al titled “Microwave Heating of Intravenous Fluids” heated lactated Ringer's solution, normal saline solution, 1/2 normal saline solution, and 5% dextrose in water heated in a microwave oven from room temperature to 40-42°C in 3 minutes. Samples were taken before and after heating to assess any potential alterations in sodium, potassium, chloride, calcium, glucose, and lactate levels; differences were within the range of variation of the methods used. Though the plasticizer in the polyvinyl chloride containers is stable to microwave heating, data on other components is incomplete11. In the future, the stability of PVC should be assessed when heated to 42°C as well.

In comparing the effects of pre-warmed fluids to active fluid warming mechanisms (such as is the aim with pIVot), a randomised single blinded study of the administration of pre-warmed fluid vs active fluid warming on the incidence of peri-operative hypothermia in short surgical procedures was performed by Andrzejowski et. al. This study again supported that those who received fluid at room temperature had lower core body temperatures (0.4 °C) on arrival in recovery when compared with those receiving pre-warmed fluids. A lower incidence of hypothermia was recorded in patients who received either type of warm fluid (14%) compared to the patients who received fluid at room temperature (32%). The administration of 1L warmed fluids to patients having short duration general anaesthesia results in higher postoperative temperatures. Pre-warmed fluid, administered within 30 min of its removal from a warming cabinet, were as efficient at preventing peri-operative hypothermia as that delivered through an in-line warming system[12].

Pre-warmed fluids, like those warmed in a microwave, have their limitations as well. In the clinical study “Reliability of Modern Microwave Ovens to Safely Heat Intravenous Fluids for Resuscitation” conducted by Anthony Delaney, the increased output power of modern microwave ovens can lead to overheating of resuscitation fluids and potentially serious complications. Microwave heating of intravenous fluid could be a safe, simple, cheap and effective means of heating intravenous fluids for resuscitation, but care needs to be taken to calibrate individual machines to ensure a safe temperature is reached[10]. The increased output of power, need to follow an algorithm and special care needed for calibration of individual machines lends to additional steps and work for emergency medical services personnel who already have many considerations to take into account for every trauma patient they encounter.

Conclusion:

WIth accidents and unintentional injuries being the third leading cause of mortalities in the US, the need of a non-invasive way to address heat loss in trauma patients in pre-hospital settings, in order to manage patient core body temperature is a clinically relevant and impactful one. Hypothermia has been proven to significantly impact and even increase the rate of mortality in trauma patients. Current devices, such as force air warming systems, were not created suitable for the prehospital setting. Warming of patients with any device shows no significant difference if the patient is not adequately pre-warmed first. Being so, clinical literature supports the importance of addressing heat loss of trauma patient in pre-hospital settings. Studies also recommend that the intravenous fluids be warmed to 37 - 42°C to encourage normothermia, decrease the incidence of hypothermia, and maintain stability of the contents of the intravenous fluids.

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