Protection and treatment of hypothermia in prehospital trauma care

- with emphasis on active warming

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To be continued …

ABSTRACT

Background: In prehospital trauma care active warming is recommended to aid in protection from further cooling. However, scientific evidence of the effectiveness of active warming in a clinical setting is scarce. Also, evaluating the effectiveness of active warming, especially in harsh ambient conditions, by objective measures, is difficult.

Objective: To evaluate the effectiveness of field applicabe heat sources (**I**) and to evaluate active warming intervention in a prehospital clinical setting (**II** and **III**).

To evaluate reliability and validity of the Cold Discomfort Scale (CDS), a subjective judgement scale for assessment of the thermal state of patients in a cold environment (**IV**).

Methods: In a laboratory trial, non-shivering hypothermic subjects (n=5), were cooled in 8 ºC water followed by spontaneous warming, a charcoal heater, two flexible hot-water bags or two chemical heat pads, all applied to the chest and upper back (**I**). Oesophageal temperature, skin temperature, heat flux, oxygen consumption, respiratory rate and, heart rate were measured.

In two clinical randomized trials, shivering patients during road and air ambulance transport (**II**) and during field treatment (**III**) were randomized to either passive warming alone (n=22 and n=9) or to passive warming with the addition of a chemical heat pad (n=26 and n=11). Body core temperature, respiratory rate, heart rate, blood pressure (**II**) and the patients' subjective sensation of thermal comfort (**II** and **III**) were measured.

In a laboratory trial, shivering subjects were exposed to – 20 ºC (n=22). The CDS was evaluated regarding reliability, defined as test-retest stability, and criterion validity, defined as the ability to detect changes in cold discomfort due to changes in cumulative cold stress (**IV**).

Results: In non-shivering hypothermic subjects postcooling afterdrop was significantly less for the chemical heat pads, but not for the hot water bags and the charcoal heater, compared to spontaneous warming (**I**). Temperature drop during the entire warming phase was significantly less for all the heat sources respectively, compared to spontaneous warming (**I**).

During road and air ambulance transport, ear canal temperature was significantly increased and cold discomfort significantly decreased, both in patients assigned to passive warming only, and in patients assigned to additional active warming (**II**). During field treatment, cold discomfort was significantly reduced in patients assigned to additional active warming, but remained the same in patients assigned to passive warming only (**III**).

Weighted kappa coefficient, describing test-retest stability, was 0.84 (**IV**). CDS ratings were significantly increased during each 30 minutes interval (**IV**).

Conclusion: In non-shivering hypothermic subjects, heat sources were effective to attenuate afterdrop, when providing high heat content over a large surface area and effective to continue to increase body core temperature when providing sustained high heat content. In shivering trauma patients, adequate passive warming were sufficient treatment to prevent afterdrop, to slowly increase body core temperature, and to reduce cold discomfort. If inadequate passive warming, additional active warming was required to reduce cold discomfort. The CDS, a subjective judgement scale for assessment of the thermal state of patients in a cold environment seemed to be reliable regarding test-retest stability and valid regarding ability to detect change in cumulative cold stress.

LIST OF PUBLICATIONS

This thesis is based on the following studies, which will be referred to in the text by their Roman numerals:

I Lundgren JP, Henriksson O, Pretorius T, Cahill F, Bristow G, Chochinov A, Pretorius A, Bjornstig U, Giesbrecht GG. Field Torso Warming Modalities: A Comparative Study Using a Human Model. Prehosp Emerg Care 2009,3:371-378.

II Lundgren P, Henriksson O, Naredi P, Bjornstig U. The effect of active warming in prehospital trauma care during road and air ambulance transportation - a clinical randomized trial. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine 2011 19:59.

III Lundgren P, Henriksson O, Naredi P, Bjornstig U. The Effect of Active Warming on Cold Discomfort in Field Treatment of Trauma Patients – a Clinical Randomized Trial. Manuscript.

IV Lundgren P, Henriksson O, Kuklane K, Holmér I, Naredi P, Bjornstig U. Validity and Reliability of the Cold Discomfort Scale - a Subjective Judgement Scale for Assesssment of the Thermal State of Patients in a Cold Environment. Manuscript.

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SAMMANFATTNING

Bakgrund: En skadad person löper stor risk att bli nedkyld, men redan innan allmän nedkylning är ett faktum, aktiveras kroppens försvarsmekanismer i form av sammandragning av ytliga blodlärl för att minska värmeförlusterna samt huttring för att öka värmeproduktionen. Detta innebär, förutom ett ökat obehag, en stor fysiologisk belastning för kroppen som kan vara ödesdiger i kombination med andra yttre skador. Om allmän nedkylning ändå inträffar medför detta ökad blödningsbenägenhet, vätskeförluster och risk att drabbas av livshotande hjärtrytmrubbningar. Allmän nedkylning i samband med allvarliga kroppsskador har visat sig vara en negativ prognostisk faktor associerad med ökad dödlighet. Vid omhändertagande på skadeplats samt under transport in till sjukhus är det således av yttersta vikt att skydda skadade patienter mot ytterligare nedkylning och åtgärder för att förhindra detta är prioriterade. Isolering mot yttre påverkan av väta, blåst och kyla utgör grunden för behandling. Därtill rekommenderas i såväl nationella och internationella riktlinjer att någon form av extern värmekälla ska tillföras patienten redan på skadeplats och under transport som komplement till isolering i syfte att minska den fysiologiska belastningen på kroppen.

De förhållanden som råder utanför sjukhus sätter begränsningar avseende möjligheter att adekvat mäta hur kylan påverkar patienten. Det är svårt att med tillförlitliga medel mäta central kroppstemperatur på skadeplats eller under transport til sjuhus och det är än svårare att under dessa omständighetrer objektivt mäta graden av huttring.

Syfte: Utvärdering av extern värmetillförsel på skadeplats samt under transport, avseende inverkan på fysiologisk samt även psykologisk belastning på kroppen. Specifikt var syftet att, under kontrollerade former i laboratorium, utvärdera och jämföra effekt av fältmässigt anpassad materiel för värmetillförsel (studie I) och att i kliniska situationer (studie II och III) utvärdera utvärdera effekten av sådan materiel, som tillägg till ordinarie behandling med isolering. Utöver detta var syftet även att utvärdera en alternativ mätmetod i form av en skala för subjektiv skattning av upplevelse av kyla, Cold Discomfort Scale (CDS), i syfte att kunna bedöma graden av kylapåverkan redan tidigt i förloppet.

Metod: I ett laboratorium exponerades forskningspersoner (n = 5) för kyla i form av 8 ºC vatten, för att därefter erhålla behandling med en varm sovsäck och en av fyra olika behandlingsmetoder; en kolbricketdriven värmare, kemiska värmekuddar, varmvattensäckar, alternativt ingen värmebehandling alls (studie I). Försökspersonernas huttring hämmades med läkemedel. Central kroppstemperatur, värmeöverföring, syrgasförbrukning som ett mått på huttring samt andnings- och hjärtfrekvens mättes

I två kliniska studier av behandling på skadeplats (studie II) och behandling under transport till sjukhus (studie III) randomiserades lindrigt skadade patienter till antingen ordinarie behandling med endast isolering (n = 22 och n = 9) eller till behandling ordinarie med tillägg av extern värmekälla (n = 26 och n = 11).

Kroppstemperatur, andningsfrekvens, hjärtfrekvens och blodtryck (studie II) samt patienternas upplevelse av kyla (studie III) mättes.

Forskningspersoner (n = 22) exponerades vid två upprepade tillfällen med identiska förutsättningar för - 20 ºC i 60 minuter. CDS utvärderades för reliabilitet avseende test-retest stabilitet och för kriterievaliditet, definierad som förmåga att mäta skillnad i kumulativ kylapåverkan.

Resultat: Under förhållanden där forskningspersonernas huttring hämmades med läkemedel sjönk kroppstemperaturen mindre, avseende lägsta uppmätta kroppstemperatur (afterdrop), vid behandling med de kemiska värmekuddarna, men inte vid behandling med varmvattensäckar eller kolbrickettdriven värmare, jämfört med ingen värmebehandling alls. Under hela behandlingsfasen, sjönk kroppstemperaturen mindre vid behandling med såväl de kemiska värmekuddarna, varmvattensäckarna som den kolbricketdrivna värmaren.

Under transport till sjukhus ökade patienternas centrala kroppstemperatur, samtidigt som deras upplevelse av kyla minskade signifikant både vid behandling med endast ordinarie isolering och vid behandling med tillägg av extern värmekälla (studie II).

På skadeplats och under inledande transport utomhus minskade patienternas upplevelse av kyla signifikant vid behandling med tillägg av extern värmekälla till ordinarie isolering, men den kvarstod däremot oförändrad vid behandling med endast isolering.

Viktad kappa koefficient, som mått på test-retest stabilitet, var 0.84. CDS visade signifikant ökad niva för upplevelse av kyla vid jämförelse av mätningar med 30 minuters mellanrum.

Slutsats: Externa värmekällor som tillförde mycket värmeenergi över en stor kontaktyta var effektiva för att minska afterdrop och under förutsättning att de tillför denna värmeenergi under lång tid, även effektiva för att påbörja uppvärmning vid behandling av patienter som har nedsatt huttringsförmåga. Avseende patienter som har bibehållen huttringsförmåga var adekvat mängd isolering tillräckligt för att motverka afterdrop, påbörja uppvärmning, och minska upplevelsen av kyla, men då isoleringen, utifrån rådande omgivningsförhållanden, inte var adekvat krävdes tillägg av extern värmekälla för att minska upplevelsen av kyla. Subjektiv skattning av upplevelse av kyla enligt CDS uppvisade både god reliabilitet avseende test-retest stabilitet och god validitet avseende förmåga att påvisa skillnad i kumulativ kylapåverkan.

CONTENTS

ABBREVIATIONS

ASHRAE	American Society of Heating, Refrigerating, and Air-Conditioning Engineers
ANOVA	Analysis of Variance
C	Celsius
CDS	Cold Discomfort Scale
CI	Confidence interval
EMS	Emergency Medical Services
ICAR	International Commission for Alpine Rescue
IQR	Interquartile range
NRS	Numerical Rating Scale
PLSD	Protected Least Significant Differences
SaR	Search and Rescue
SD	Standard deviation
VAS	Visual Analoude Scale
VRS	Verbal Rating Scale

INTRODUCTION

In a prehospital rescue scenario, cold exposure poses a considerable risk for injured or ill patients. Admission hypothermia is associated with worse outcome and higher mortality in trauma patients (1-8). The cold induced stress response will also render considerable thermal discomfort which might increase the experience of pain and anxiety, even in still normothermic patients (9). In Sweden the average temperature in January during the period 1961 – 90 were between – 16 ºC in the northern part and – 1 ºC in the southern part of the country (10). In such environment, protection and treatment of hypothermia in prehospital trauma care is vitally important.

During the period 2001 – 2010, the median annual incidence of fatal accidental hypothermia in Sweden (about 9,5 million inhabitants) was 48 (range 37 – 63) (11). Hypothermia due to cold exposure as the primary cause (primary hypothermia) mainly affects two groups of patients; one group of elderly, most of them chronic abusers and under the influence of alcohol, and another group of younger, sober persons, performing outdoor leisure and sporting activities (12).

Although primary hypothermia is a rare diagnosis, secondary hypothermia, as a complication of systemic disorders, including trauma and sepsis, is common. In trauma patients, the overall medical condition and the administration of analgesic or anaesthetic drugs act to impair thermoregulatory mechanisms (13-16). In addition, wet clothing, contact with cold surfaces, large bleedings and administration of cold intravenous fluids contribute to the cold stress. Reported hypothermia incidence in the prehospital setting or upon arrival to hospital varies over a wide range (1, 4-8, 17-19). Severity of injury, the presence of haemorrhagic shock, prehospital induction of anaesthesia and protracted evacuation are predictive variables of admission hypothermia (1-5, 18, 20-22), reported hypothermia incidence is therefore dependent on inclusion criteria of the trauma registers and also dependent on whether hypothermia is being defined as body core temperature < 35 ºC or < 36 ºC. In one retrospective study using the US National Trauma Data Bank including more than 700000 patients, Martin et al. (4) found an hypothermia (< 35 ºC) incidence of about 2 %, whereas Helm et al (18), in a prospective study including 302 trauma patients treated during primary helicopter rescue missions, found a hypothermia (< 36 ºC) incidence of about 50%.

Induced hypothermia diminishes complications due to ischemia reperfusion injury during elective surgery (23). In laboratory studies, hypothermia has been shown to have beneficial effects during and after hemorrhagic shock and traumatic brain injury (23-25). The reduced physiological stress due to shivering prevention in induced hypothermia, compared to the increased physiological stress in accidental hypothermia, has been suggested a reason for these beneficial effects (23). In the clinical setting a few retrospective (19, 22) and prospective (17) observational

studies, investigating a total of about 1200 trauma patients, have found no difference in adjusted mortality for hypothermic versus normothermic patients. However, other retrospective (1, 3-8) as well as prospective (2) observational clinical studies, investigating more than 750000 trauma patients have revealed that hypothermia remains an independent determinant of mortality.

Accordingly, effective prehospital field protection and treatment of hypothermia, is considered vitally important to improve the medical condition upon admission to hospital, and active warming in the field is considered one important part of such treatment (13-15, 26-32). Because the heat sources need to be portable and easily handled by Search and Rescue (SaR) or Emergency Medical Services (EMS) personnel, there are limited treatment options in the field and during prehospital transport. Chemical heat pads, hot water bottles, carbon-fiber resistive heating blankets, and charcoal fuelled heat pacs are commonly used and advised (13, 14, 26, 28, 29, 32). There are some laboratory studies (33-37) evaluating such field-applicable devices (portable, not requiring external electrical power supply), but to this author's knowledge, only two randomized clinical trials have evaluated the effectiveness of such heat sources in the field (38, 39).

As part of primary trauma care, it is important to have accurate measures to evaluate the thermoregulatory state of the patient, both upon arrival of the rescue personnel and during prehospital treatment and transport. In the field, especially in harsh ambient conditions, this is often hard to achieve (14, 15). Measuring body core temperature as well as skin temperature might be difficult and measuring oxygen consumption to assess shivering is, in most clinical scenarios, not possible. Thus, alternative measures, such as subjective judgement scales for assessment of the thermal state of patients, might be of considerable importance in such scenarios, both for an initial assessment of the patient and for evaluation of the treatment provided. The judgement scales must be reliable and valid.

This thesis primarily focuses on protection and treatment of hypothermia in prehospital trauma care, the emphasis being evaluation of active warming intervention regarding impact on thermoregulation. Subjective judgement scales for assessment of the thermal state of patients in a cold environment is also studied.

Historical notes

Throughout history, accidental hypothermia is perhaps best documented in military history, where harsh ambient conditions have played a major role for the outcome of numerous military campaigns. The list is long and distinguished.

Hannibal lost about 20000 of his 46000 soldiers in 218 B.C when crossing the Pyrenees and Alps on his way towards Rome.

In 1718 Carl Gustaf Armfeldt and his army were caught in a blizzard crossing the mountains on their return from Norway to Sweden. Only 1700 of the 5100 soldiers survived.

In 1812 Napoleon lost much of his army because of the cold while attempting to invade Moscow.

During the First World War 115000 British soldiers suffered local cold injuries or trench foot.

During the Second World War 200000 German soldiers were disabled because of cold injuries.

When writing about hypothermia from a historical perspective, it is also important to mention the horrible crimes committed under the guise of medical experiments on prisoners in German concentration camps during World War II. To establish the most effective treatment for victims of immersion, Germans conducted hypothermia experiments at the Dachau concentration camp in 1942 and 1943. Immediately after, the American Chief of Counsel for War Crimes prepared a 228 page report after investigating the records of the experiments. This report, referred to as the Alexander report (author: the American psychiatrist Leo Alexander), was cited by some authors during the first decades after the war. This is considered by most authors, including this author, strongly, ethically reprehensible. In addition, citations are inappropriate on scientific grounds (40) [Berger 1990].

Definitions of hypothermia

Traditionally, hypothermia has been defined as body core temperature < 35 ºC and further classified into levels of severity based on the physiological changes that occur because of decreased body core temperature (13-16). The levels are mild (32 – 35 ºC), moderate (28 – 32 ºC), severe (20 – 28 ºC), and profound hypothermia (< 20 ºC). These definitions were introduced to describe hypothermia resulting from environmental exposure. However, more recently, due to the poor prognosis of the combination of trauma and hypothermia, a revised classification has been developed for use in trauma care (27). In this classification, hypothermia is defined as body core temperature < 36 ºC and subsequently as 34 – 36 ºC for mild, 32 – 34 ºC for moderate, and < 32 ºC for severe hypothermia. Furthermore, in this context, it is

important to stress that thermoregulatory responses are induced long before body core temperature declines below the level defined as hypothermia. Beyond the two classifications mentioned above, to be more applicable in a prehospital rescue scenario, yet another method of staging hypothermic patients is recommended by the International Commission for Alpine Rescue (ICAR) (28). Using this method, degree of consciousness, presence or absence of shivering, cardiac activity, and body core temperature are taken into consideration when deciding hypothermia level. Table 1.1.

Table 1. Classifications of hypothermia based on body core temperature.

Hypothermia level (ICAR level)	Traditional classification	Trauma classification	ICAR classification
Mild (I)	35 – 32 ºC	36 – 34 ºC	35 – 32 ºC
Moderate (II)	32 – 28 ºC	34 – 32 ºC	32 – 28 ºC
Severe (III)	28 – 20 ºC	< 32 ºC	28 – 24 ºC
Profound (IV)	< 20 ºC		24 – 15 ºC
(V)			< 15 ºC

Cold exposure

The human body maintains an average core temperature near 37 °C in various thermal conditions (41). However, extreme thermal exposure as well as certain medical conditions can lead rapidly to dangerous deterioration of body core temperature. Because the speed of chemical reactions vary with temperature and because the enzyme systems of the body have narrow temperature ranges in which their function is optimal, normal body function depends on finetuned temperature regulation. A deviation of about 2 °C above or below normal body core temperature is well tolerated but a deviation of about 3 °C begins to threaten normal body function.

Thermoregulatory mechanisms are not fully developed until after puberty and from about seventy years of age thermoregulatory capacity is decreased, having the consequence that children and elderly are more vulnerable to cold stress (41).

There are also differences between men and women (41). Women, as a group, have, compared to men, a greater surface-area-to-mass ratio, a greater percentage of subcutaneous and total body fat, a greater resting vasoconstriction in hands and feet, a higher setpoint for cutaneous vasodilation and onset of sweating, and also cyclic hormonal changes that influence thermoregulation. However, when individual differences are accounted for, thermoregulatory gender differences are negligible.

Heat exchange

The human body maintains core temperature by a fine balance between heat gain and heat loss. When heat gain equals heat loss, a state of thermoneutrality exists, but if heat loss exceeds heat gain, there is a risk of whole body cooling and hypothermia (13, 14, 16, 41-43).

Factors governing heat exchange can be described by the heat balance equation:

$$H_{tot} = \pm H_d \pm H_c \pm H_r \pm H_e$$

where

H_{tot} = total metabolic heat production
H_d = conductive heat exchange
H_c = convective heat exchange
H_r = radiative heat exchange
H_e = evaporative heat exchange

Total metabolic heat production, which is about 70 W/m^2 (basal metabolism) in a resting 70 kg man, increases with voluntary physical activity and involuntary muscle contractions (shivering).

Conductive heat exchange means heat transfer by direct contact to a surrounding medium, for example air, water, or solid ground (13, 41, 44, 45). The amount of heat flow is dependent on physical characteristics of the surrounding medium, temperature gradients, and the contact surface area. Air conducts heat poorly. Water conducts heat approximately twenty five times, and metals up to ten thousand times, greater than air.

Convective heat exchange means heat transfer by movements of the boundary layer of the surrounding medium (air or water) (13, 41, 44, 45). The amount of heat exchange is mainly dependent on the relative velocity of the surrounding medium.

Radiative heat exchange means heat transfer by infrared electromagnetic waves to objects, for example, cold stone walls of a building (13, 41, 44, 45). The amount of heat transfer is dependent on the physical characteristics of the objects and temperature gradients.

Evaporative heat exchange means heat transfer from evaporation of water on the skin surface or the respiratory tract, where the amount of heat exchange is dependent on the amount of water evaporated (13, 41, 44, 45).

Heat loss is caused primarily by convection, which is greatly increased by wind or movements (13, 41, 44, 45). To a smaller extent, heat is also lost through radiation to cold objects in the surrounding environment, or to the clear sky, and by

evaporative and convective heat loss from the airways. Sweating and evaporative heat loss from the skin is often minimal in cold environments, but could be considerable in cases of wet clothing or skin due to immersion or previous physical activity. In addition, if immersed, lying on the ground or in direct contact with a cold surface, conductive heat loss will be significant.

Thermophysiological reactions to cold exposure

Thermal receptors are widely distributed, especially in the skin, but also in the abdominal viscera, the spinal cord, extrahypothalamic as well as hypothalamic portions of the brain (13, 16, 41-43). The information from both peripheral and central receptors is integrated in the preoptic nucleus – anterior hypothalamic area of the brain, which is considered the center of thermoregulation. In response to cooling of peripheral or central receptors or both peripheral and central receptors, a sympathetic mediated thermoregulatory response is evoked, rendering vasoconstriction to preserve heat within the body core and shivering to increase endogenous metabolic heat production.

Vasoconstriction is primarily due to the closing of the arteriovenous anastomoses of the hands and feet resulting in decreased blood flow in the entire extremity (13, 41, 42). During full vasoconstriction, blood flow through the fingers and toes can decrease up to one hundredfold, from 80 -90 ml/min/100ml of tissue during full vasodilation to 0,5 – 1,0 ml/min/100ml of tissue during massive vasoconstriction (13). In addition to central regulation, tissue cooling directly affects vasoconstriction by increasing cutaneous blood vessel sensitivity to cathecolamines.

In shivering, thermogenesis is due to involuntary and unsyncronized muscle contractions (13, 41, 42). At maximum shivering, endogenous heat production can be increased by as much as five times from resting levels (46). In mild hypothermia (32 – 35 ºC), thermoregulatory responses are still intact, but if body core temperature declines even further, thermoregulation, and thereby shivering, starts to fail and at about 30 - 32 °C the shivering response is lost.

As a consequence of cold-induced peripheral vasoconstriction, temperature in peripheral parts of the body starts to decline long before body core temperature is affected (14, 41). Following substantial cold exposure, there is temperature equalization between the warm body core and the cold peripheral parts, contributing to a continuous fall in body core temperature, designated the afterdrop phenomenon. Main contributing factors are conductive temperature equilibration between the colder periphery and the warmer body core and circulatory changes involving counter current cooling of warm blood circulating cold, previously vasoconstricted peripheral tissues. The magnitude of the afterdrop, which can be considerable and amount to several degrees, is dependent on temperature gradients in the tissues, peripheral circulation, and endogenous heat production.

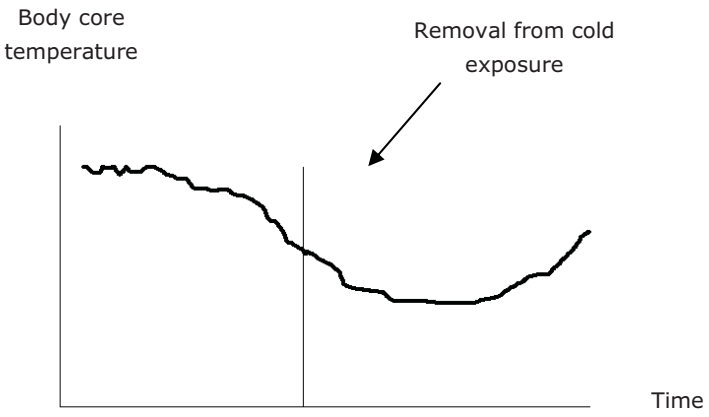

Figure 1. Afterdrop.

In trauma patients, thermoregulation is often impaired, resulting in an increased vulnerability to cold exposure (13, 14, 16, 41). Injuries to the nervous system might affect both vasoconstriction and shivering because of both central and peripheral effects. Muscle injuries locally affect shivering ability. The administration of analgesics, anaesthetics or both induces vasodilation and impedes shivering. Although lipid and protein work as alternative fuels to carbohydrates in shivering thermogenesis, malnutritive states reduce shivering capacity.

Psychological reactions to cold exposure

Psychological reactions to cold exposure is divided into thermal comfort or discomfort and thermal sensation, where the fomer drives behaviour, while the latter drives autonomic thermoregulation, described above (47). However, in clinical reality it is difficult to differentiate between those modalities. Because of thermal comfort is driven by both physiological and psychological variables, whereas thermal sensation is driven by only physiological variables, in this thesis, psychological reactions to cold exposure is described as thermal comfort.

According to the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), thermal comfort is described as a state of mind that expresses satisfaction with the surrounding environment. Physiological variables affecting thermal comfort include information from brain, body core and skin temperature sensors as well as vasoconstriction and shivering (48-52). The psychological variables include previous experience with cold exposure, state of mind, social context, and behaviour (53).

Patophysiology and clinical presentation of hypothermia

The following section outlines, the pathophysiological reactions and clinical picture due to cold stress and hypothermia. In this context, attentiveness to the occurrence of considerable individual differences is important. There are also differences dependent on whether hypothermia has developed rapidly (acute hypothermia) or over a longer period (chronic hypothermia) (14).

Respiratory and cardiovasculatory changes. In response to the cold-induced sympathetic mediated thermoregulatory stress response, respiratory and cardiac work is increased. Shivering thermogenesis increases oxygen demand and peripheral vasoconstriction raises systemic blood pressure which further escalates cardiac workload. (13, 16, 41, 42, 46).

As body core temperature declines, spontaneous depolarization of the pacemaker cells of the sinus node decreases, resulting in atropine-resistant bradycardia (16). Because hypothermia increases duration of action potentials, and because the His-Purkinje system of the heart is more sensitive to cold than the myocardium itself, decelerated conduction might cause re-entry currents, resulting in ventricular arrhythmias. PR, QRS, and QT intervals are prolonged (54-56). However, not pathognomonic of hypothermia, Osborn or J-waves, a distinctive deflection occuring at the QRS-ST junction, are common in hypothermic patients. Osborn waves might pose a diagnostic difficulty, because they, when pronounced, resemble the elevation of the ST segment also seen in transmural myocardial infarction. Atrial as well as ventricular arrhythmias are encountered at body core temperatures below 32 °C and spontaneous ventricular fibrillation is seen below 25 °C (15). The risk of developing cardiac arrhythmias is increased by hypovolemia, tissue hypoxia, electrolyte and acid balance disturbances, as well as rough handling of the hypothermic patient.

In chronic hypothermia, peripheral vasoconstriction, resulting in increased central blood volume, will lead to fluid extravasation and tissue oedema, including lung oedema and also to increased diuresis due to raised renal perfusion pressure (14). Thus, patients exposed to prolonged cold stress should be considered hypovolemic, which is important to account for when peripheral circulation returns to normal during rewarming.

As for the heart rate, respiratory rate also declines with body core tempreature. In severely hypothermic patients, breathing may be hard to detect since it is very slow and shallow.

Neurological changes. The cold-induced sympathetic mediated stress response results in an initial increase in cerebral metabolism, but as body core temperature drops by more than 1 °C, cerebral metabolism will decline (15). This will result in an increasingly deteriorated mental status, presented as impaired memory and judgement, slurred speech, and decreased level of consciousness. Most patients are unconscious at a body core temperature below 30 °C (16).

Muscle performance in the extremities is impaired both because of local tissue cooling as a consequence of vasoconstriction and neurological malfunction. These combined effects pose a substantial risk for development of local cold injuries (57, 58).

Blood chemistry changes. Haematocrit and also blood viscosity rises because of fluid extravasation and increased diuresis (15, 16). Platelet count is lowered due to bone marrow depression and sequestration in the spleen and liver. Platelet adhesion and aggregation is impaired. Coagulation enzyme activity is reduced to a level equivalent to 50 % of clotting factor deficiency at temperatures below 33 °C (59, 60). Already mild hypothermia induces a general coagulopathy (61, 62) which can be reversed by active warming (63).

Leukopenia, also due to bone marrow depression and sequestrian of leukocytes in the spleen and liver, together with a general immune system depression, weakens the resistance to infections(16).

Serum electrolytes fluctuate over time and with body core temperature during cooling and rewarming (14, 16). Hypokalaemia due to an intracellular redistribution of potassium, as well as hyperkalaemia, due to assumed cellular membrane dysfunction, is seen. Hyponatremia is common in chronic hypothermia due to osmolar diuresis.

Neutral pH varies with temperature and rises with body core cooling (14). Respiratory alkalosis due to initial hyperventilation is common after sudden immersion in cold water. This is followed by respiratory and metabolic acidosis due to respiratory depression and also ketogenesis and lactate formation from shivering, reduced cardiac output and tissue hypoxia due to impaired peripheral circulation.

Initially, blood glucose level rises because of glycogenolysis caused by the cold-induced stress response (14, 16). During prolonged cold stress glycogen stores will be depleted and hypoglycaemia might develop due to shivering and the cold-induced glycosuria.

Prehospital protection and treatment of hypothermia

Actions to reduce cold stress and prevent further heat loss are an important and integrated part of prehospital trauma care. Initial measures should be taken to shelter, remove wet clothing, and insulate the patient from ambient weather conditions and ground chill. Adequate windproof and waterproof insulation ensembles (passive warming) are imperative. In addition, depending on the physiological status of the patient including body core temperature, available resources and expected duration of evacuation, the application of heat (active warming) is recommended by most authors as protection from further cooling during treatment and transport to definitive care (13-15, 28-32). In a prehospital setting the primary objective of active warming is to reduce cold stress and further

cooling, not to rewarm the patient. Available, field applicable, heat sources all have limited heating capacity, rendering rapid rewarming in the field impossible. Too rapid rewarming, implying possible development of fluid, acid-base or electrolyte imbalances that would be difficult to control in the field, is therefore not considered a problem (14, 15, 29).

Several studies on mildly hypothermic shivering subjects have found that exogenous skin heating attenuates shivering heat production by an amount equivalent to the heat donated (34, 37, 64). Thus, in a mildly hypothermic, shivering patient, active external rewarming generally does not decrease afterdrop or increase the rewarming rate more than shivering thermogenesis. However, thermogenesis from shivering during passive warming alone can result in significant anaerobic metabolism and lactic acidosis, and active external warming might therefore present treatment advantages of decreased respiratory and cardiac workload, preserved substrate availability, and increased comfort. Overall, additional active warming should be considered also when treating mildly hypothermic trauma patients.

When shivering is diminished or absent, as in moderate to severe hypothermia, or is otherwise impaired because of the overall medical condition of the patient, active external or internal warming is required. Otherwise afterdrop will continue and little or no warming will occur (35, 36, 65, 66).

Active external warming

To be field applicable, warming modalities need to be portable and require no external electrical power supply. In a report summarizing survey responses from from 41 Mountain Rescue Association teams (67) the active warming methods most frequently used were warm IV fluids, chemical heat pads, body-to-body warming, charcoal heaters, and warm air or oxygen inhalation. Some of these methods are extensively studied, others are not. Regardless of the warming method, most of the studies are laboratory studies, only a few have been conducted in a prehospital environment, which might be a considerable limitation when making decisions about prehospital trauma care.

In the following section, field applicable warming methods, i.e. warming methods that are portable and require no external electrical power supply, are described.

Exercise. Moderately to severly hypothermic patients are likely to be physically and metabolically exhausted and have an altered level of consciousness. In these patients, movements might also induce ventricular fibrillation (13-16). Thus, excercise is not a treatment alternative. However, in mild hypothermia, increasing endogenous heat production by exercise has been suggested for warming purposes.

In one study on subjects cooled to 33 °C, Giesbrecht et al. (34) found that the post cooling rewarming rate for exercise was significantly higher than for shivering, but not higher than for external heat. However, exercise, as well as external heat,

significantly increased both length and amount of afterdrop compared to shivering, resulting in no difference between the three treatment alternatives regarding total recovery time. In another study on shivering subjects, Giesbrecht et al (68) postponed exercise until afterdrop was complete and found that during exercise there was a second afterdrop of similiar, but not greater, magnitude as during the initial shivering period.

Body-to-body warming. Direct body-to-body contact with a minimally clothed euthermic heat donor used to be widely recommended for warming hypothermic patients in the field (69-71). As it is also shown for other active external heat sources (34, 37), body-to-body warming has no beneficial effect on body core warming compared to shivering thermogenesis alone (64, 72). However, if shivering is diminished or absent, as in moderate to severe hypothermia, or otherwise impaired because of the overall medical condition of the patient, heat donated by body-to-body contact will, as other external heat sources, increase heat gain (36).

Heat packs. Warm water bottles, chemical heat pads, or the HeatPac®; a charcoal heater (Normeca AS, Oslo, Norway), are widely used (67) for active external warming in the field. Such devices are portable and easy to handle for the rescue personnel, but heat content is limited. In order facilitate heat transfer, heat sources should be applied in proximity (precautions should be taken to avoid burn injuries) to the skin on areas with high heat transfer such as the chest (36), neck, axillae, and groins.

In mildly hypothermic shivering subjects, laboratory studies of the Heat Pac® (34, 37) have shown no beneficial effect on body core rewarming compared to shivering thermogenesis alone. This is in accordance with studies on other active external warming modalities (64, 72). In one laboratory study on human subjects, where shivering was suppressed pharmacologically to resemble moderate to severe hypothermia, the HeatPac® was significantly more efficient than body-to-body rewarming in minimizing afterdrop and facilitating body core rewarming (36). The HeatPac® consists of a combustion chamber, charcoal fuel, and a branched; reinforced, but flexible, heating duct and produces 250 W of heat. It is placed on the patient's chest and the heating ducts are applied dorsally over the shoulders and then anteriorly under the axillae crossing over the lower chest. Total skin contact surface area of the chamber (23 x 12 x 6 cm, 1100 g) and ducts is about 1500 cm2. Because there are no clinical studies using the HeatPac®, practical aspects, such as ignition of the charcoal fuel in field conditions and the potential risk of the charcoal fuel burning in proximity to or even inside vehicles, has not been evaluated. However, a safety concern regarding carbon monoxide contamination has been presented (37).

In a prehospital clinical randomized trial by Watts et al (39), chemical heat pads were applied in at least two locations (on top of the head, under the patient against the lower back, or under either axilla with the hot pack against the chest wall) This treatment was compared to five other treatment alternatives (no intervention, passive rewarming, reflective blankets, warmed IV fluids, and warmed IV fluid plus

reflective blanket). Trauma patients who received hotpack warming showed a mean increase in body core temperature during transport (0.7 °C) (measure of variation not reported), while all other groups (no intervention, passive warming, reflective blankets, warmed IV fluids, warmed IV fluid plus reflective blanket) showed a mean decrease in temperature during transport (- 0.2 °C to - 0.4 °C), the difference was statistically significant. The chemical heat pad Hot Cycle 1 (Sign Manufacturing Corporation, Fairfield CA) is activated by breaking an internal chamber and it reaching a temperature of 54.5 °C. To avoid burn injuries of the skin the chemical heat pads were rolled in towels before application.

Resistive heating. In a laboratory study on human subjects by Greif et al (35), where shivering was suppressed pharmacologically to resemble moderate to severe hypothermia, a carbon-fiber resistive heating blanket was evaluated. Both total body heat content and body core rewarming rate were increased compared to passive warming alone. In contrast to the passive warming group that presented a small, although not statistically significant afterdrop, there was no afterdrop in the carbon-fiber resistive heating blanket group. The carbon-fiber resistive heating blanket measures 80 x 200 cm, with the actively heated section being 40 x 148 cm. The batteries weigh 0.5 kg, each lasting 30 – 40 minutes.

In a prehospital clinical randomized trial by Kober et al (38)[Kober 2001] the same carbon-fiber resistive heating blanket was compared to passive warming alone. In trauma patients receiving passive warming alone mean body core temperature decreased by 0.4 °C/h (95% CI; 0.3 – 0.5 °C/h), whereas in patients receiving additional carbon-fiber resistive heating, mean body core temperature increased by 0.8 °C/h (95% CI; 0.7 – 0.9 °C/h), the difference between groups being statistically significant.

Inhalation warming. The effectiveness of inhalation rewarming has been somewhat equivocal. In some studies (73-76), beneficial effects on body core temperature have been reported, whereas in other (37, 77, 78), including one study on non-shivering human subjects (66), no body core warming advantages have been found. Benefits of inhalation warming such as rehydration, stimulation of mucociliary activity in the respiratory tract and direct heat transfer from the upper airways to the hypothalamus, brain stem, and other brain structures have been suggested (75).

Warm intravenous fluids. Intravenous fluids should be heated to 40 - 42 °C during hypothermia resuscitations (32). Cold fluid resuscitation of hypovolemic patients can induce hypothermia, infusion warming devices are therefore mandatory during massive volume resuscitations (79, 80).

Prehospital monitoring

To have accurate measures to evaluate the thermal state of patients in the prehospital setting is vitally important. In the field, especially in harsh ambient conditions, this is often hard to achieve (41). Adequate measurements of body core temperature as well as skin temperature might be difficult to obtain (14, 41), and measuring oxygen consumption for assessment of shivering is, in most rescue scenarios, not possible.

Thus, alternative measures such as subjective judgement scales for assessment of the patient's thermal state might be of considerable importance, both for an initial assessment of the patient and for evaluation of the treatment provided.

Body core temperature

The temperature of the pulmonary artery is considered the best reference temperature for deep body core temperature (41). However, pulmonary artery catheterization is not an option in the field.

In the following section, non-invasive generally accepted sites for measuring body core temperature are listed, all of various degrees of usefulness in the field.

Oesophagus. Oesophageal temperature is obtained by placing a temperature probe into the distal portion of the oesophagus, usually via nasal passage, to the level of the heart (81). The proximity of the oesophagus to the descending aorta and the left auricle is the anatomical basis for an accurate measurement of deep body core temperature. It is an accurate method for deep body core temperature (82, 83). However, this method is, for educational and practical reasons, also not an option in many prehospital rescue scenarios.

Closed ear canal. Closed ear canal temperature is obtained by placing a temperature probe in the mid to distal portion of the ear canal, which is then sealed from the ambient environment by insulation covering the ear. The proximity of the ear canal to the internal carotid artery makes it an ideal site for measuring body core temperature. This method has been shown to correlate well with oesophageal temperature (84, 85). Although these results are mainly based on data from indoor operating theatre environments, Walpoth et al. (84) have shown that, if properly sealed from the ambient air, closed ear canal temperature is also reliable in sub-zero and wind conditions. As the reliability of closed ear canal temperature is dependent on positioning within the ear canal, there is a risk of false low recordings. However, if measurements are made over a period of time with the probe left in position in the ear canal, which is standard procedure, temperature change over that period of time should be reliable.

Tympanic membrane. Tympanic membrane temperature is obtained by reflecting infrared electromagnetic waves from the tympanic membrane and the ear canal. It is a simple field applicable method but has been shown not reliable (86-88).

Rectum. Rectal temperature is an accurate method for measuring deep body core temperature in steady state conditions (41). However, when deep body core temperature changes, there is a delay in rectal temperature change.

Urinary bladder. Urinary bladder temperature is an accurate method for measuring deep body core temperature and as many patients need a urinary catheter, the catheter can be used for measuring temperature (89).

Oral cavity. Oral temperature is obtained by placing the probe in the sublingual pocket which is well perfused. Provided that the patients can keep their mouths closed, it is a simple field applicable method, but has also been shown not reliable (88).

Subjective judgement scales for assessment of the thermal state of the patient

The most common single item judgement scales are Visual Analouge Scales (VAS), Numerical Rating Scales (NRS) and Verbal Rating Scales (VRS). A VAS consists of a visual line, usually 100 mm long, where the ends of that line are labeled with descriptions for the extremes of the studied modality. The respondent places a mark on the line representing his or her level of experienced intensity in relation to the described extremes. Instead of a visual line, a NRS consists of a range of numbers, usually 0 – 10, and a VRS consists of a list of words or phrases, describing various degrees of the studied modality.

The international standard BS EN ISO 10551:2001 (90) outlays general principles for construction of subjective judgement scales for assessment of the influence of the environment on the thermal state of the patient. These general principles, mainly used for indoor or near isothermal environments, recommend symmetrical 7 to 9-degree rating scales comprising a central indifference point and two times 3 or 4 degrees of increasing intensity for both hot and cold. The two most well-known scales are the Bedford scale (91) and the ASHRAE scale (92). In 1936 Bedford (91) collected data on almost 2000 industrial workers to correlate subjective judgements of their thermal comfort to objective measurements of the thermal environment. The responses of the workers were measured according to a seven degree VRS, called the Bedford scale, and to be able to use statistics on the data, numerical values were assigned to the different levels of the scale. In 1971 Rohles et al. (92) collected data on 1600 college students to correlate subjective judgement of thermal comfort to ambient air temperature, humidity, length of exposure and gender. The scale developed for those studies is also a VRS, called the ASHRAE scale.

OBJECTIVES

The overall objective of this thesis was to evaluate prehospital active external warming intervention regarding impact on thermophysiological and psycological reactions. Reliability and validity of the Cold Discomfort Scale (CDS), a subjective judgement scale for assessment of the thermal state of patients in a cold environment was also studied.

Specific objectives were to evaluate:

the warming effectiveness of three different portable heat sources, none of them requiring external electrical power supply, and spontaneous warming (control condition) regarding their impact on post-cooling body core temperature including afterdrop in a laboratory setting (study I).

external warming intervention, using a previously evaluated (study I) heat source as additional treatment to a standard protocol of passive warming in a prehospital clinical setting, both during transport and treatment in a heated road ambulance or helicopter (study II) and during outdoor field treatment and transport (study III), regarding impact on body core temperature (study II) and thermal comfort (study II and III).

the CDS, a subjective judgement scale for assessment of the thermal state of patients in a cold environment, regarding reliability, defined as test – retest stability, and criterion validity, defined as ability to detect changes in cumulative cold stress (study IV)

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METHODS

Because of small study populations, especially in the laboratory studies, where study populations also are relatively homogenous, the limited external validity must be considerd when conclusions are drawn based on the results of these studies.

Table 2. Overall methods.

	Study I	*Study II*	*Study III*	*Study IV*
Environment	Laboratory	Prehospital transport	Prehospital scene of injury	Laboratory
Study design	Experimental controlled trial	Randomized clinical trial	Randomized clinical trial	Experimental controlled trial
Study population	n = 5	n = 48	n = 20	n = 22
Intervention	Comparison of three different heat sources and spontaneous warming	Passive warming alone vs. Passive warming + active warming	Passive warming alone vs. Passive warming + active warming	
Primary outcome	Body core temperature	Body core temperature, cold discomfort	Cold discomfort	Cold discomfort
Statistical analysis	Non-parametric statistics	Non-parametric statistics	Non-parametric statistics	Non-parametric statistics

Laboratory trials

Measurements on shivering subjects

Study design

The CDS was evaluated in a laboratory environment regarding reliability, defined as test-retest stability and criterion validity, which is defined as the ability to detect changes in cold discomfort due to changes in cumulative cold stress (study IV). Twentytwo healthy subjects participated in two trials each, on two separate occasions, at about the same time of day, approximately one week apart. Conditions were identical during both trials, subjects were exposed to -20 °C for 60 minutes wearing only light clothing. CDS ratings were recorded every five minutes, both during 10 minutes of base line data collection and during the 60 minutes of cold exposure. The CDS is a subjective judgement scale for assessment of the thermal state of patients in a cold environment. It is designed as a NRS, where the subjects assess the thermal state of their whole body, not specific body parts, and provide integer values from 0 to 10, where 0 means not being cold at all and 10 means being unbearably cold.

Statistical analysis

Pre-study calculations indicated a minimal sample size of 18 to detect a difference in Cold Discomfort Scale ratings of 2 or more IQR; 2) presupposed 80% statistical power at an α-level of 0.05. Reliability of the CDS was analysed for test-retest stability using weighted kappa coefficient, comparing median CDS ratings between the two trials. This included all the measurements made every five minutes and also, separately, every single measurement.

Criterion validity was analysed by comparing median CDS ratings over a moving 30 minutes interval (5-35 minutes; 10-40 minutes; 15-45 minutes etc) using Wilcoxon signed ranks test. Statistical significance was defined as $p < 0.05$, and, in analysis of criterion validity, after correction for multiple comparisons according to Bonferroni as $p < 0.008$ (two-sided).

Methodological considerations

Because the test and retest were conducted in a laboratory environment, ambient conditions were controlled and identical for both the test and retest. Subjects also served as their own controls. However, it is always difficult to achieve identical conditions in a test-retest design when measuring subjective parameters. Even though all arrangements are made to match, the subjects might react differently to the same cold exposure at two different occasions. There might also be a habituation which can either increase or decrease the sensitivity to the exposure.

Evaluation of criterion validity is dependent on how it is defined and conclusions about criterion validity therefore, must be based on that definition. It might

sometimes be hard to appraise if the chosen definition is relevant, which then complicates interpretation of results.

In this study, criterion validity was defined as the ability to detect changes in cold discomfort due to changes in cumulative cold stress by subjects exposed to -20 °C wearing only light clothing, over a moving 30-minute interval. The time interval was chosen based upon what, under prevailing conditions, was appraised a clinically significant change in cumulative cold stress. A moving 30-minute interval was chosen in attempt to cover early as well as late changes within the evaluation period of 60 minutes.

Measurements on non-shivering hypothermic subjects

Study design

In a laboratory environment, three different portable exogenous heat sources, none of them requiring external electrical power supply, and spontaneous warming (control condition) were compared (study I). Five human subjects participated in four trials each, one trial for every condition, thereby serving as their own controls. To mimic moderate to severe hypothermia and also to achieve equal conditions of endogenous heat production for each condition, shivering was suppressed pharmacologically using a human model previously evaluated in several studies (36, 65, 66). An initial cooling phase, in which subjects were exposed to 8 º C water for 10-30 minutes, was followed by a 120-minutes treatment phase including passive warming with the addition of either one of three exogenous heat sources or spontaneous warming. Prior to the trials, 30 mg of orally administered buspirone, and during the last 10 minutes of the cooling phase, and also if needed during rewarming, intravenously administered meperidine to a maximum cumulative dose of 3,5 mg/kg, was used to supress shivering. Oesophageal temperature (81-83), skin heat transfer, skin temperature, oxygen consumption, respiratory rate and heart rate were continuously monitored and recorded during the trials. The exogenous heat sources applied to the chest and upper back, were a charcoal heater, HeatPac®, (Normeca AS, Oslo, Norway), two chemical heating pads (Dorcas AB, Skattkarr, Sweden) and two flexible water bags (Mountain Safety Research, Seattle, WA) each filled with 2 litres of 55 °C water replenished every 20 minutes.

Statistical analysis

Continuous data, considered normally distributed, were initially compared using repeated measures analysis of variance (ANOVA). If statistical significance was revealed, Student´s t-test for pair-wise post hoc analysis with Fisher's protected least significant difference (PLSD) for multiple comparisons test was used to identify and quantify differences between individual conditions. Statistical significance was defined as $p < 0.05$ (two-sided).

Methodological considerations

The human model, in which shivering is suppressed pharmacologically, is designed to thermophysiologically mimic a scenario of moderate to severe hypothermia. It has been evaluated in several studies (36, 65, 66). Beyond the ability to evaluate different treatment alternatives in a thermophysiologically hypothermic subject, which, for safety reasons, would otherwise be impossible, this model also makes comparisons between treatment alternatives almost perfectly fair regarding influence of endogenous heat production. This is because endogenous heat production is kept at a constantly low rate and also is controlled for. If there are differences in endogenous heat production, this will be revealed and impact on the overall result will be possible to analyse.

The human model for severe hypothermia eliminates and controls for shivering. However, it does not account for other physiological or psychological changes that come with moderate to severe hypothermia such as, respiratory, circulatory, neurological, and blood chemistry changes.

In this study, because of safety considerations, the amount of meperidine administered to inhibit shivering was limited to a cumulative dose of 3.5 mg/kg for each trial. Therefore, the cooling phase had to be adjusted for the subjects' body composition, resulting in a relatively longer cooling phase in subjects with a higher percentage of body fat. However, because subjects served as their own control and the cooling phase was identical for each subject for all conditions, this should have very limited impact on the results.

Parametric statistical tests were used for ratio and interval scale data, despite small study population, because data were considered normally distributed. However, considering the small study population, the use of parametric statistics is controversial and therefore, results are also presented for non-parametric statistics using Friedman test and Wilcoxon signed rank test instead of ANOVA and PLSD respectively.

Clinical trials

Study design

In two randomized clinical trials, chemical heat pads (Dorcas AB, Skattkarr, Sweden), the same chemical heat pads as previously evaluated on non-shivering subjects (study I) were used to evaluate the impact of active warming on thermoregulation in mildly hypothermic trauma patients with preserved shivering capacity during transport and treatment in a heated road ambulance or helicopter (study II) or during outdoor field treatment and transport by ski patrol units (study III). Sequential trauma patients, age $\geq$ 18 years, who had sustained an outdoor injury, were enrolled. Patients were excluded if initial level of consciousness was affected, (Glasgow Coma Scale < 15), if duration of transport or treatment was expected to be shorter than 10 minutes, if active warming already had been initiated,

if they had been taken indoors for more than 10 minutes before ambulance or ski patrol unit arrival or had an initial cold discomfort rating ≤ 2.

If enrolled, patients were randomized to either passive warming with blankets according to an existing protocol alone (study II: n = 22, study III n = 9) or to passive warming with blankets according to the existing protocol with the addition of one chemical heat pad applied on the anterior chest (study II: n = 26: study III: n = 11). In study II, after loading into the ambulance or helicopter, initial measurements of closed ear canal temperature (84, 85), respiratory rate, heart rate, blood pressure, and patients' subjective sensation of thermal comfort according to the CDS were made. In study III, at the scene of injury, an initial measurement of patients' subjective sensation of thermal comfort according to the CDS was made. In both studies initial measurements were made before eventual application of the chemical heat pad. Measurements were then continuously made every 30 minutes and at the receiving hospital (study II), first aid centre or EMS unit arrival (study III).

Statistical analysis

Pre-study sample size calculations, estimating a difference in body core temperature of ≥ 0.5 °C and in CDS ratings of ≥ 2 between the two intervention groups, an alpha of 0.05 and a beta of 0.10 revealed a minimum study population of 42 patients. This was for both studies II and III since CDS was the restricting variable.

For comparison between groups the Mann Whitney U test was used for interval and ordinal data and Chi square or Fisher's exact test for nominal data. In addition, CDS ratings were characterized as increased, unchanged or decreased and the difference between groups was analysed using Fisher's exact test. For comparisons within groups, Wilcoxon signed rank test was used for interval and ordinal data. Statistical significance was defined as $p < 0.05$ (two-sided).

Methodological considerations

The rescue personnel used the standard protocol for all patients; participation in the studies involved no interfering instructions. Application of the chemical heat pad to the anterior thorax for those assigned to additional active warming was the only difference between groups. This study design thus enables a fair comparison between study groups. The active warming intervention being evaluated in a proper environment must also be considered a great strength of the study. A laboratory environment results in a high degree of control when conducting the study, including control of evaluated intervention and recordings. This might be more difficult to achieve in a prehospital clinical setting and it is important to be aware of such possible sources of errors when interpreting results. Although, if considered, that must not entail a limitation.

Closed ear canal temperature (84, 85) was used for measurement of body core temperature. Because the absolute value of closed ear canal temperature is somewhat dependent on placement within the ear canal, those values might not be

completely accurate. However, if the ear canal is properly insulated from the ambient environment and if the temperature sensor is kept in the same place during the entire trial, recordings of temperature changes will be accurate.

CDS was used for assessment of thermal comfort. The reliability (defined as test – retest stability) and criterion validity (defined as ability to detect an increase in cumulative cold stress) of CDS is discussed below.

In study II, fourteen day and night manned road ambulance units and one helicopter ambulance unit participated during the entire, or part, of an inclusion period of two and a half years. There are 125 000 inhabitants in the catchment area of the participating ambulance units and, due to tourism, the population increases during winter time. In study III, ski patrols from three ski resorts in the northern parts of Sweden participated in the study during two consecutive winter seasons. There were a total number of 1 803 000, person-ski days during that period. Still, the study population was relatively small, which might be due to several factors. The compliance of the rescue personnel to include patients in the study might have been low. The doctors in charge of the studies, Lundgren and Henriksson, visited every unit about twice a year and above that carried out monthly phone calls to make sure the study proceeded as planned, but that might not have been adequate.

The inclusion and exclusion criteria were also somewhat narrow, which also might have had an influence on the size of the study population. Reports from the ambulance personnel indicated that many of the patients injured outside had already been moved inside, while waiting for the ambulance to arrive and, due to long distances, the time limit of ten minutes of indoor stay or active warming treatment was exceeded. Reports from ski patrol units indicated that many of the patients injured and in need of treatment on the ski slopes were rapidly transported to an indoor medical facility, thereby outdoor treatment and transport time were less than the required 10 minutes.

Patients having an initial CDS rating of ≤ 2 were also excluded since they were not considered cold stressed.

However, presented inclusion and exclusion criteria were considered necessary to limit the study population to those actually considered cold stressed, even if some patients who also could have been considered cold stressed might have been left out, and the resulting consequenses was a small study population.

Study II was terminated when the required number of included patients had been reached according to prestudy sample size calculation. Statistical analysis of outcome variables was performed until the second measurement, at an average of 26 ± 7 minutes, since at that point, all 48 subjects were included, whereas at the third measurement, performed at an average of 58 ± 5 minutes only 12 subjects remained.

Study III was terminated before the required number of included patients had been reached according to pre-study sample size calculations, since differences in CDS between groups proved to be larger than expected when making those calculations.

CDS data was considered ordinal scale data. In study II, non-parametric statistics wass used also for interval scale data as the study population was small.

RESULTS

Reliability and criterion validity of the Cold Discomfort Scale

In total, forty-four trials were completed; all twenty-two subjects participated in two trials each. Median CDS increased from 0 (IQR; 0 – 0) during base line to 7 (IQR; 5 – 7) at the end of the first trial (test) and to 6 (IQR; 5 – 7) during the second trial (retest) (Figure 2).

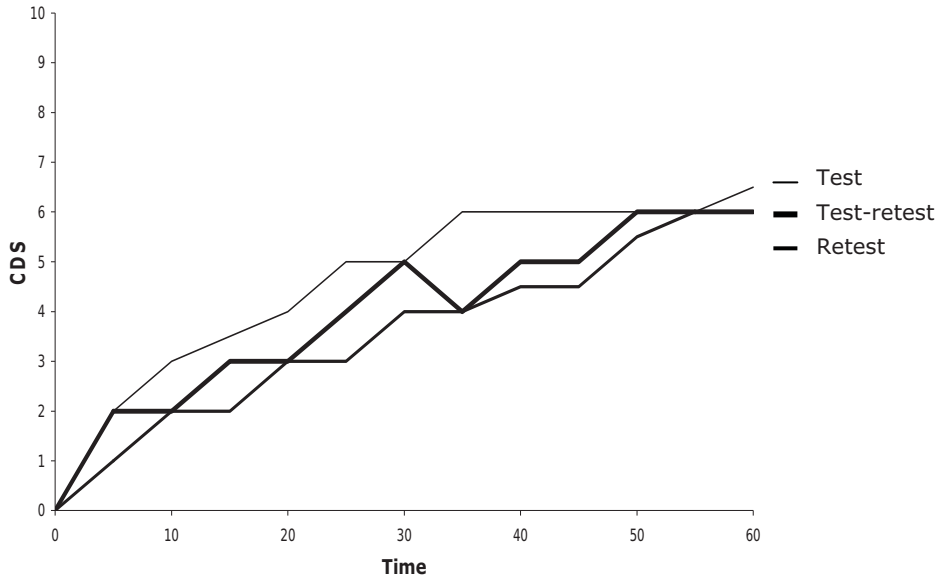

Figure 2. Median CDS ratings of test (n = 22), retest (n = 22) and merged median CDS ratings of test-retest (n = 22).

Reliability analysed for test-retest stability, using weighted kappa coefficient, which included all the measurements made every five minutes, was 0.84 and separated for every single measurement between 0.48 and 0.86 (Table 3).

Table 3. Test-retest stability of CDS ratings at 5 minutes intervals.

Time (min)	Test * (n=22)	Re-test * (n=22)	Weighted kappa coefficient** (n=22)
5	2 (1.25 - 3)	1 (1 - 2)	0.56 (0.25 - 0.86)
10	3 (2 - 3)	2 (1 - 2)	0.48 (0.20 - 0.77)
15	3.50 (3 - 4)	2 (1.25 - 3.75)	0.56 (0.31 - 0.81)
20	4 (3.25 - 4)	3 (2 - 4)	0.60 (0.38 - 0.83)
25	5 (4 - 5)	3 (2.25 - 4.75)	0.53 (0.30 - 0.76)
30	5 (4 - 6)	4 (3 - 5)	0.68 (0.48 - 0.87)
35	6 (4 - 6)	4 (3 - 5)	0.64 (0.40 - 0.88)
40	6 (4 - 6)	4.5 (6 - 4)	0.70 (0.49 - 0.90)
45	6 (4.25 - 6)	4.5 (6 - 4)	0.72 (0.51 - 0.92)
50	6 (5 - 7)	5.5 (5 - 7)	0.76 (0.57 - 0.96)
55	6 (5.25 - 7)	6 (5 - 7)	0.86 (0.72 - 1.0)
60	6.5 (5.25 - 7)	6 (5 - 7)	0.85 (0.81 - 0.99)

Values are median (IQR) * and weighted kappa coefficient (95% CI) **.

Criterion validity analysed by comparing median CDS ratings (n = 22) over a moving 30-minute interval, revealed that CDS ratings were significantly increased during each 30-minute interval (5-35 minutes; 10-40 minutes;15-45 minutes etc) (Table 4).

Table 4. CDS ratings change over a 30 minutes moving interval.

Time (min)	Test and retest*(n=22)	Test and retest**(n=22)	*Wilcoxon signed rank test*
5 vs. 35	2 (1 - 2.25)	5 (3.75 - 6)	P < 0.001
10 vs. 40	2 (2 - 3)	5.5 (4 - 6)	P < 0.001
15 vs. 45	3 (2 - 4)	6 (4 - 7)	P < 0.001
20 vs. 50	4 (2 – 4)	6 (5 - 7)	P < 0.001
25 vs. 55	4 (3 - 5)	6 (5 - 7)	P < 0.001
30 vs. 60	5 (3 - 6)	6 (5 - 7)	P < 0.001

Values are median (IQR).
*First time in interval, **second time in interval.

Effectiveness of exogenous heat sources for active warming intervention in non-shivering hypothermic subjects

Metabolic heat production increased from 116 ± 17 W (mean ± SD) during baseline to 195 ± 51 W during the last 10 minutes before meperidine injection. Meperidine suppressed shivering and heat production returned to 114 ± 21 W during the first 40 minutes of treatment and subsequently fell to 97 ± 17 W throughout the remaining 80 minutes of treatment (Figure 3). There were no significant differences in metabolic heat production for the different conditions either during the cooling or the treatment phase.

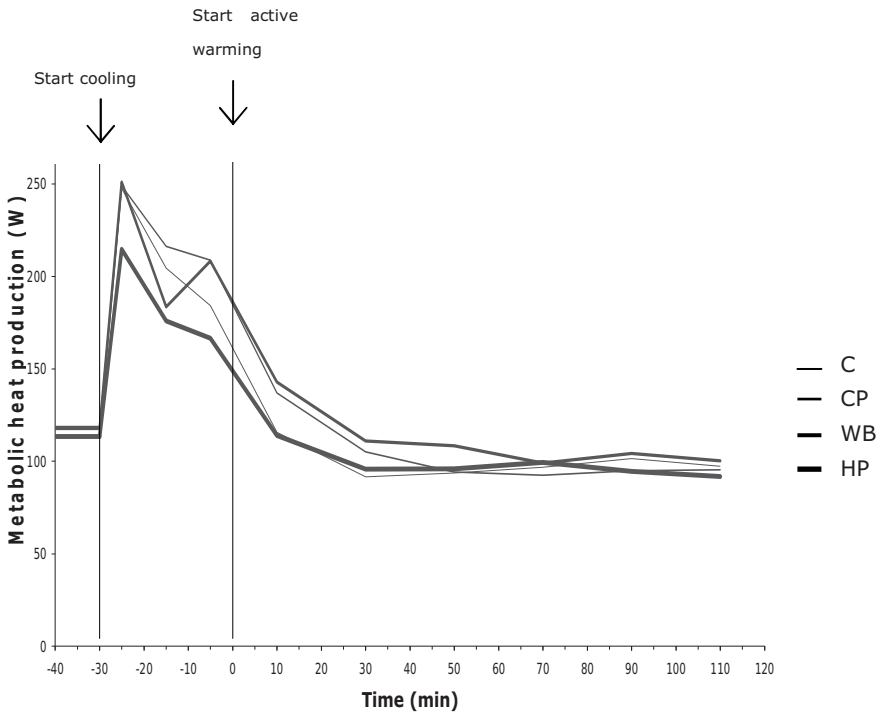

Figure 3. Mean metabolic heat production during four warming protocols (n=5).
WB = Hot water bags; CP = Chemical heat pads; HP = Charcoal heater;
C = Spontaneous warming.

Parametric statistics: The post-cooling afterdrop was significantly less for the chemical heat pads and the hot water bags, but not for the charcoal heater, compared to spontaneous warming. Time to temperature nadir and temperature drop during the entire treatment phase (0 to 120 minutes) was significantly less for all three heat sources compared to spontaneous warming.

Non parametric statistics: The postcooling afterdrop was significantly less for the chemical heat pads, but not for the hot water bags or the charcoal heater, compared to spontaneous warming. Time to temperature nadir and temperature drop during the entire treatment phase (0 to 120 minutes) was significantly less for all three heat sources compared to spontaneous warming. (Table 5)

Table 5. Post-cooling body core temperature and time to temperature nadir during treatment phase.

	Spontaneous warming (n=5)	Charcoal heater (n=5)	Chemical heat pads (n=5)	Hot water bags (n=5)
Maximum temperature drop (afterdrop) amount (°C)	-2.2 (0.3)	-1.9(0.5)	-1.5 (0.4) [a]	-1.6 (0.2)
Time to temperature nadir	88 (38)	53 (31) [a]	46 (23) [a]	44 (23) [a]
Total temperature drop amount (°C)	-1.7 (0.8)	-1.1 (0.6) [a]	-0.9(0.7) [a]	-0.6 (0.6) [a]

Values are mean (± SD).
*Significantly less than spontaneous warming[a] (Wilcoxon signed rank test, $p < 0.05$).

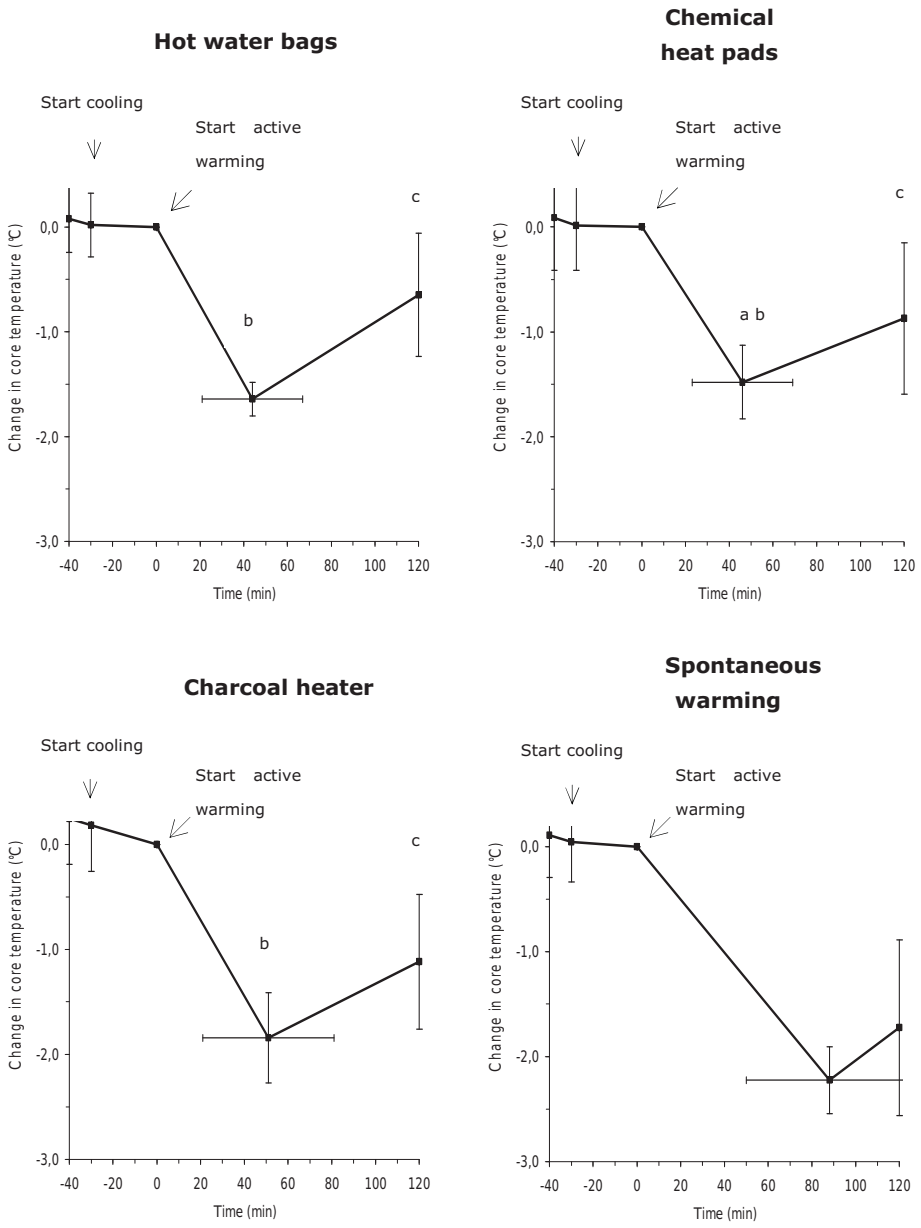

Figure 4. Body core temperature change for each condition (mean; SD; n = 5). [a] Afterdrop amount, [b] time to temperature nadir and [c] total temperature drop amount significantly less than spontaneous warming (Wilcoxon signed rank test, $p < 0.05$) .

Effectiveness of active warming intervention in shivering trauma patients

The mean time from injury to the arrival of ambulance personnel arrival was 64 (95 % CI; 41 – 88) minutes in patients assigned to passive warming only and 81 (95 % CI; 61 – 101) minutes in patients assigned to additional active warming with no significant differences between the two groups.

During road and air ambulance transport ear canal temperature was significantly increased and CDS ratings was significantly decreased, both in patients assigned to passive warming only, and in patients assigned to additional active warming (Table 6).

Table 6. Body core temperature and cold discomfort within treatment groups during prehospital transport.

		1st measurement	2nd measurement
Passive warming (n = 22)	Body core temperature	35.1 (34.7 – 35.5)	36.0 (35.7 – 36.3)*
	Cold discomfort	5 (4 – 7)	3 (0 – 5)*
Active warming (n = 26)	Body core temperature	35.6 (35.2 – 36.0)	36.4 (36.1 – 36.7)*
	Cold discomfort	7 (5 – 8)	2 (1 – 3)*

Values are mean (95% CI) or median (IQR).
* Significantly different from first measurement (Wilcoxon signed rank test, $p < 0.05$).

However, when change in cold discomfort was characterized as increased, unchanged or decreased, 15 out of 21 in the group assigned to passive warming only presented a decrease in CDS rating, whereas all 26 patients in the group assigned to additional active warming presented a decrease in CDS ratings. This difference in CDS rating change between groups was statistically significant ($p < 0.05$).

The time from injury to ski patrol arrival was 11 ± 7 minutes (mean ± SD) in patients assigned to passive warming only and 16 ± 9 minutes in patients assigned to additional active warming, with no significant differences between the two groups.

During field treatment, CDS ratings were significantly reduced in patients assigned to additional active warming, but remained the same in patients assigned to passive warming only (Table 7).

Table 7. Cold discomfort within treatment groups during prehospital field treatment.

	1st measurement	2nd measurement
Passive warming (n = 9)	5 (2 – 5)	5 (3 – 6)
Active warming (n = 11)	4 (3 – 8)	1 (0 – 3)*

Values are median (IQR).
* Significantly different from first measurement (Wilcoxon signed rank test, $p < 0.05$).

In addition, when change in cold discomfort was characterized as increased, unchanged, or decreased, 9 of 11 patients assigned to additional active warming presented a decrease in cold discomfort and two remained at their initial cold discomfort whereas only 3 of 9 patients assigned to passive warming alone presented a decrease in cold discomfort; one remained at initial cold discomfort and 5 presented an increase in cold discomfort, this difference in cold discomfort change between groups being statistically significant ($p < 0.05$).

DISCUSSION

Active external warming

Admission hypothermia is an independent risk factor associated with worse outcome in trauma patients, retrospective (1, 3-8) as well as prospective (2) observational clinical studies have revealed that hypothermia remains an independent determinant of mortality after correction for severity of injury. Actions to reduce cold exposure and prevent further heat loss are therefore an important and integrated part of prehospital trauma care. Active warming is by most authors recommended to aid in protection from further cooling during treatment and transport to definitive care (13-15, 28-32). Prehospital active external warming treatment, aims primarily at reducing further heat loss and to counteract the post cooling afterdrop.

Exogenous heat sources for active warming intervention

Chemical heat pads and warm water bottles are commonly used and advised for prehospital active warming treatment. However, unlike the HeatPack® charcoal heater, these heat sources have never before been evaluated regarding their impact on thermoregulation in non-shivering hypothermic subjects. Although all the evaluated heat sources were applied on the chest and upper back, providing their heat content conductively to the skin and underlying tissues, they displayed some important differences that affected warming effectiveness.

Chemical heat pads were most effective in attenuating afterdrop amount. This was most likely due to their high initial heat delivery to a relatively large surface area. The charcoal heater, also with a high initial heat production but a relatively small surface area, had less effect on afterdrop amount compared to spontaneous warming than the chemical heat pads.

The charcoal heater, like the hot water bags (replenished every 20 minutes), provided high continuous heat delivery. The heat delievery of the chemical heat pads declined over time. Therefore, the charcoal heater also, like the chemical heat pads and the warm water bottles, presented a significant difference in body core temperature change over the entire warming phase, compared to spontaneous warming. Thus, all heat sources presented a statistical significant lower body core temperature drop compared to spontaneous warming during the warming phase and this is also in accordance with findings of large afterdrop amounts and little or no warming, when exogenous heat is left out (35, 36, 65, 66).

In summary, heat sources applied on the chest and upper back were effective to attenuate afterdrop when providing high heat content over a large surface area, and

effective to continue to increase body core temperature when providing sustained high heat content.

However, it could be discussed whether recorded differences in body core temperature of about 1˚C is clinically relevant. Nevertheless, prehospital active warming aims primarily at reducing heat loss and to reverse a continuing fall in body core temperature. Thus, especially at critical temperature levels at about 30 ˚C where the heart becomes susceptible to arrhythmias, every degree might be important or even lifesaving.

All of the evaluated warming modalities are portable, require no external power supply and are easily used by laypersons, Search and Rescue (SaR) personnel, or Emergency Medical Services (EMS) crew members without significant training. They are suitable for different clinical scenarios.

The charcoal heater, which is lightweight and provides heat over 8–12 hours, has advantages in protracted evacuation and rescue operations because of sustained heat production.

Water bags, which often are lightweight and easy to bring during backcountry excursions are better suited for scenarios in which the patient will remain on the scene of the accident waiting for evacuation, because an external heat source and significant effort are required for replenishing the water bags.

Chemical heating pads, although heavier and requiring more space than the other modalities can be easily transported in a vehicle such as in ground or air ambulance units. As they are effective in reversing the initial fall in body core temperature, they might prove valuable for initial thermal stabilization of a cold patient, and if replaced at sufficient intervals, also for continuous heat delivery.

Effectiveness of active warming intervention in a prehospital clinical setting

Passive warming according to standard treatment protocol was effective in preventing afterdrop and slowly increasing body core temperature during transport to definitive care (study II). Additional active warming composed no beneficial effect on body core temperature in this study on cold stressed trauma patients with an initial body core temperature of about 35°C and preserved shivering capacity. This is in accordance with previous laboratory studies on mildly hypothermic shivering subjects, where exogenous skin heating has been shown to attenuate shivering heat production by an amount equivalent to the heat donated (34, 37, 64, 72). Passive warming was also effective in reducing cold discomfort. However, only 2/3 of the patients assigned to passive warming, whereas all patients assigned to additional active warming presented a decrease in cold discomfort during transport. This beneficial effect on thermal comfort by application of a chemical heat pad to the upper torso is probably explained by a combination of reduction of shivering thermogenesis and increased skin temperature.

Contrary to this study, two other randomized clinical trials found a decrease in body core temperature with passive warming only, whereas with additional active warming using either resistive heating blankets (38) or multiple chemical heat pads (39), body core temperature was increased during transport. Because effective passive warming requires adequate insulation materials in relation to ambient conditions and intact shivering thermogenesis, differences regarding these factors might explain differences between studies.

During field treatment additional active external warming rendered improved thermal comfort, whereas passive warming alone did not (study III).

This is a difference compared to study II, where passive warming alone was enough to reduce cold discomfort, even though additional active warming was even more efficient. In both studies, the number of blankets used for passive warming was about the same, but in study II, the evaluation was conducted during treatment and transport in a heated ambulance or helicopter, whereas in study III evaluation was conducted during treatment and transport in the outdoors. This probably resulted in a greater cold stress during the evaluation period for patients in study III than in study II, and thereby, probably also in increased shivering thermogenesis and lower skin temperature. Although, an equal amount of insulation was present in both studies, the realative cold stress seemed to be greater in study III. If cold stress increases, demands on shivering thermogenesis during passive warming also increases. In a scenario with trauma patients injured on the ski slopes, where extensive shivering might be harmful, additional active warming seemed to be beneficial.

Increased thermal comfort of patients in both study II and study III indicates a beneficial effect on thermoregulation of additional active warming compared to passive warming alone. This is most probably due to an increase of skin temperature and to a reduction in demands on shivering thermogenesis and also consistent with previous studies demonstrating that exogenous skin heating attenuates shivering by an amount equivalent to the heat donated (34, 37, 64, 72).

Future research

Clinical randomized trials presented in this thesis indicate beneficial thermophysiologic effects from active warming intervention. However, since body core temperature remains stable if shivering and adequate passive warming are intact, these results were based on subjective judgements of included patients. Clinical studies, that, besides body core temperature, also investigate other objective parameters and early predictors of cold induced stress, such as oxygen consumption, are desirable.

Although probably due to different degrees of severity of injuries of included patients as well as different heat sources and different amounts of passive warming,

results from these and the few prior studies on active warming intervention in a prehospital clinical setting (38, 39) are diverging. Therefore, and also because all studies are relatively small, more and larger studies are desirable.

Future prehospital studies should also address more severely injured patients suffering from moderate or severe hypothermia to evaluate effects of active warming intervention regarding requirements of hospital treatment, morbidity and mortality.

Prehospital monitoring

To have accurate measures to evaluate the thermal state of patients in the prehospital setting is vitally important. In the field, especially in harsh ambient conditions, this is often hard to achieve (14, 41). Thus, alternative measures to body core temperature, skin temperature, and oxygen consumption, such as subjective judgement scales for assessment of the patient's thermal state, might be of considerable importance in such scenarios, both for an initial assessment of the patient and for evaluation of the treatment provided. Such assessment of the thermal state of the patient might also be an early predictor of cold stress, and therefore may be used to evaluate the risk of developing hypothermia.

It is important not to underestimate evaluation of the patient's subjective experience of medical care. Improved thermal comfort might have the potential of relieving psychological stress such as the experience of pain and anxiety (9), which might comprise a considerable physiological stress to the patient by increasing respiratory and cardiovascular workload.

Reliability and criterion validity of the Cold Discomfort Scale

In a laboratory setting the test-retest stability of median CDS ratings showed moderate to very good agreement. CDS ratings were generally somewhat higher during test compared to retest, this difference might be a result of a decreased sensitivity to the cold exposure from previous experience, and therefore being less anxious, about exposure to the cold the second time, compared to the first time. This tendency to habituation from repeated exposure might be a weakness of reliability of the CDS. However, there was only one week between test and retest and if a longer period would have passed between test and retest, reliability might have been even better.

Criterion validity, when defined as the ability to detect changes in cold discomfort due to increased cumulative cold stress from 30 minutes in - 20°C wind still conditions, was good. CDS ratings proved to be statistical significantly increased for every 30 minutes of cold exposure. However, during the last 20

minutes it seemed that CDS ratings did not increase as much as during the first 40 minutes. This tendency to habituation during exposure might be an indication of a limitation to detect differences in cumulative cold stress when cold exposure is protracted.

Bedford (91) and also Rholes (92) evaluated subjective judgement scales for assessment of the thermal environment regarding construct validity, trying to correlate subjective judgements of thermal comfort to objective measurements of the thermal environment. Different from that, the CDS is evaluated for criterion validity, defined as the ability to detect changes in cold discomfort due to changes in cumulative cold stress, and therefore should be used to monitor changes in cold discomfort over time. The CDS can not be used to measure and rank the level of cold stress the patients are exposed to and that is the reason, why it is not possible to make any comparisons between CDS ratings at different occasions.

Future research

This study is the first to evaluate reliability and criterion validity of a subjective judgement scale for assessment of the thermal state of patients in an extreme cold environment. Further studies including larger study populations, to confirm these results would be desirable. Evaluating the CDS in different ambient conditions and when using warming intervention would also be desirable.

CONCLUSION

Active external warming

Active external warming is recommended for protection from further cooling and treatment of hypothermia in prehospital trauma care.

In non-shivering hypothermic subjects, heat sources applied on the chest and upper back were effective to attenuate afterdrop, when providing high heat content over a large surface area and effective to continue increasing body core temperature when providing sustained high heat content.

In cold stressed, shivering trauma patients, adequate passive warming was sufficient treatment to prevent afterdrop and slowly increase body core temperature. Adequate passive warming also seemed sufficient to reduce cold discomfort, even though additional active warming was even more efficient. When passive warming was inadequate, additional active warming was required to reduce cold discomfort.

Prehospital monitoring

In a prehospital rescue scenario subjective judgement scales might be a valuable measure for assessment of the thermal state of conscious patients.

The Cold Discomfort Scale, a subjective judgement scale for assessment of the thermal state of patients in a cold environment seemed to be reliable, regarding test-retest stability, and valid, regarding ability to detect change in cumulative cold stress.

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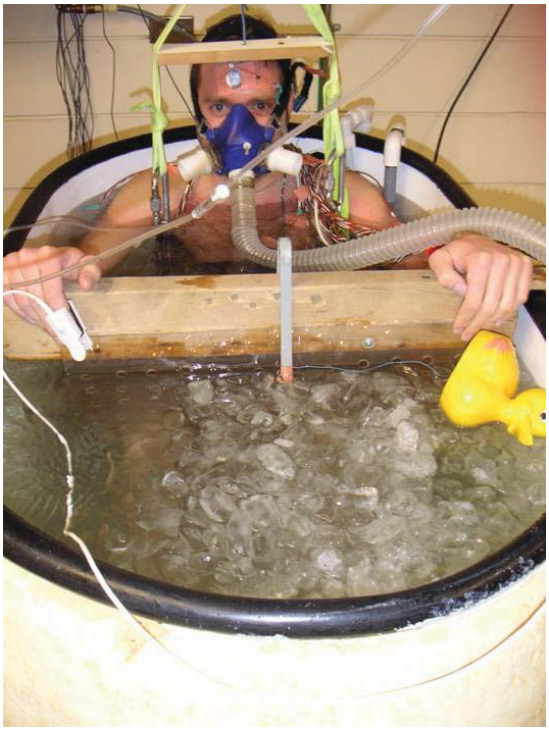
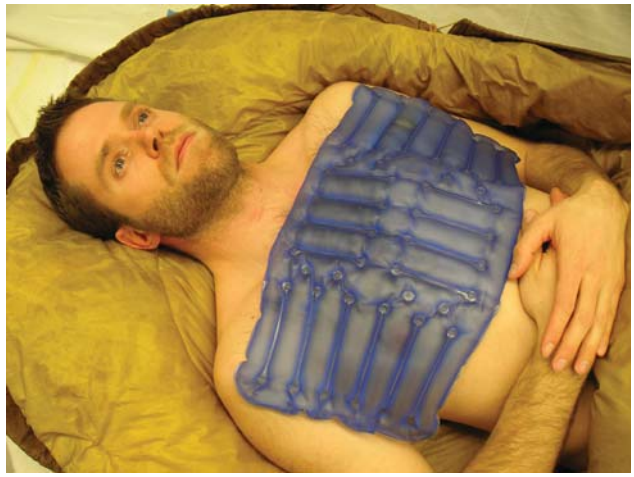
1: Volunteer subject wearing light clothing in - 20°C (Study IV)


2: Volunteer subject immersed in 8 ˚C water (study I)



3: Chemical heat pad (study I)

4: Hot-water bag (study I)

5: Charcoal heater (study I)

6: The author in a prehospital setting

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I

PRELIMINARY REPORT

FIELD TORSO-WARMING MODALITIES

A COMPARATIVE STUDY USING A HUMAN MODEL

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ABSTRACT

Objective. To compare four field-appropriate torso-warming modalities that do not require alternating-current (AC) electrical power, using a human model of nonshivering hypothermia. **Methods.** Five subjects, serving as their own controls, were cooled four times in 8°C water for 10–30 minutes. Shivering was inhibited by buspirone (30 mg) taken orally prior to cooling and intravenous (IV) meperidine (1.25 mg/kg) at the end of immersion. Subjects were hoisted out of the water, dried, and insulated and then underwent 120 minutes of one of the following: spontaneous warming only; a charcoal heater on the chest; two flexible hot-water bags (total 4 liters of water at 55°C, replenished every 20 minutes) applied to the chest and upper back; or two chemical heating pads applied to the chest and upper back. Supplemental meperidine (maximum cumulative dose of 3.5 mg/kg) was administered as required to inhibit shivering. **Results.** The postcooling *afterdrop* (i.e., the continued decrease in body core temperature during the early period of warming), compared with spontaneous warming (2.2°C), was less for the chemical heating pads (1.5°C) and the hot-water bags (1.6°C, $p < 0.05$) and was 1.8°C for the charcoal heater. Subsequent core rewarming rates for the hot-water bags (0.7°C/h) and the charcoal heater (0.6°C/h) tended to be higher than that for the chemical heating pads (0.2°C/h) and were significantly higher than that for spontaneous warming rate (0.1°C/h, $p < 0.05$). **Conclusion.** In subjects with shivering suppressed, greater sources of external heat were effective in attenuating core temperature afterdrop, whereas sustained sources of external heat effectively established core rewarming. Depending on the scenario and available resources, we recommend the use of charcoal heaters, chemical heating pads, or hot-water bags as effective means for treating cold patients in the field or during transport to definitive care. **Key words:** hypothermia; body temperature regulation; rewarming; emergency medical services

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INTRODUCTION

A major concern in the prehospital care of patients exposed to a cold environment, either through cold air or cold water immersion, is to reduce cold stress and avoid further heat loss, thereby diminishing the risk of cold-induced cardiac or respiratory failure. Initial measures should be taken to insulate the patient from the ground, remove wet clothing if possible, and contain endogenous heat production within a vapor barrier and adequate wind- and waterproof insulation. Application of some form of exogenous heat should then be considered to reduce the depth and duration of the core temperature (T_{co}) *afterdrop* (i.e., the continued decrease in body temperature during the early period of rewarming) and establish a steady moderate rate of T_{co} rewarming.[1–7]

For the mildly hypothermic victim (T_{co} = 35–32°C) who is physiologically stable, spontaneous warming due to shivering heat production provides reduction of afterdrop and establishes a safe and efficient rewarming rate.[2,3,8–13] Several studies on mildly

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hypothermic shivering subjects have found that exogenous skin heating attenuates shivering heat production by an amount equivalent to the heat donated.[8–13] Accordingly, body-to-body warming,[9,11] forced-air warming,[10] application of electrical and hot-water-perfused heating pads,[11,12] and charcoal heaters[8,13] have produced reduction of afterdrop and established rewarming rates similar to that of spontaneous shivering alone. Thus, in a mildly hypothermic shivering victim, external warming generally does not decrease afterdrop or increase the rewarming rate; however, it might provide other advantages, including increased comfort, decreased cardiac work, and preserved substrate availability.

When shivering is diminished or absent in moderate (T_{co} = 32–28°C) to severe (T_{co} < 28°C) hypothermia or otherwise impaired because of the overall medical condition of the patient (i.e., old age, alcohol or drug ingestion, head or spinal injury, severe trauma, or depleted metabolic energy substrates), some form of exogenous external or internal heat is required; otherwise, afterdrop will continue and little or no rewarming will occur. This was demonstrated using a human model of nonshivering hypothermia, where meperidine was administered to inhibit shivering in mildly hypothermic subjects.[14–16] With metabolic and thermal responses similar to those in actual severe hypothermic conditions, subjects using spontaneous warming only experienced an increased afterdrop, with rewarming either attenuated or eliminated compared with that in subjects receiving an exogenous heat supply.

In a summary of survey responses from 41 Mountain Rescue Association teams, the most common protocols for treatment of hypothermia were chemical heating pads (46%), body-to-body warming (39%), and hot-water bottles applied to the trunk (32%).[17] Although chemical heating pads and hot-water bottles are commonly used and recommended, scientific verification of their effectiveness is minimal or nonexistent. In fact, these measures are recommended in some prehospital treatment guidelines[4,6] but discouraged in others.[7,18] Effective prehospital field warming is considered of utmost importance to improve the medical condition of severely hypothermic patients on admission to the emergency department.[1–7] It is therefore important to quantify the thermal effectiveness of those modalities that could be used in the field by laypersons, search and rescue (SAR) personnel, or the emergency medical services (EMS) system.

We therefore decided to use a human model for nonshivering hypothermia[14,15] to evaluate the thermal effectiveness of chemical heating pads and hot-water bottles. To increase the surface area in contact with the skin, flexible nylon water bags were used instead of rigid bottles. For comparative reasons, the previously evaluated charcoal heater and spontaneous warming were selected. These torso-warming modalities, being portable and requiring no external electrical power, are all suited for prehospital field care.

TABLE 1. Characteristics of the Subjects

Subject	Gender	Age, years	Height, cm	Weight, kg	Body fat*, %	BSA†, m^2	BMI‡, kg/m^2
1	Male	35	174	78	26	1.9	26
2	Male	27	173	91	29	2.1	31
3	Male	40	175	110	30	2.2	36
4	Male	29	180	73	21	1.9	22
5	Male	28	175	68	13	1.8	22
Mean		32	175	84	24	2.0	27
SD		6	3	17	7	0.2	6

*Calculated according to Durnin and Womersley.[19]
†Calculated according to Dubois and Dubois.[20]
‡Calculated according to McArdle et al.[21]
BSA = body surface area; BMI = body mass index; SD = standard deviation.

METHODS

Design, Setting, and Subjects

The study was approved by the Education/Nursing Research Ethics Board of the University of Manitoba. Five male subjects volunteered for participation (Table 1). They had no history of allergy to or current use of narcotics. Written informed consent was obtained from all patients. Studies were conducted in the Laboratory for Exercise and Environmental Medicine at the University of Manitoba in February and March 2006.

Monitoring

Esophageal temperature (T_{es}),[22,23] oxygen consumption (Vo_2), respiratory exchange ratio (RER), electrocardiography (ECG), heart rate (HR), and arterial oxygen saturation were continuously monitored and recorded during the trials as described previously.[14,15] Endogenous heat production (M) in watts (W) was calculated from V_{O_2} and RER according to the following equation:

$$M\ (W) = VO_2\ (L/\min) \times 69.7(4.686 + [(RER - 0.707) \times 1.232])$$

where M represents heat production and W represents watts.

Skin heat transfer (Q_{skin}; $W \cdot m^{-2}$) and skin temperature (°C) were measured from 12 sites using thermal flux transducers (Concept Engineering, Old Saybrook, CT). Skin heat transfer for a specific body part ($Q_{body\ part}$; W) was then calculated using heat flux values for each transducer (W/m^2) according to the following equation:

$$Q_{body\ part}(W) = \text{transducer flux}\ (W/m^2) \times BSA(m^2) \times \text{body part percentage}$$

where BSA represents body surface area; the body part percentage was estimated according to Layton et al.[24]

Intravenous (IV) access was obtained in the right forearm or hand for the purpose of drug and/or saline administration.

Protocol

Each subject served as his or her own control for comparative evaluation of each of the warming modalities, and was cooled at the same time of day on four separate occasions. The order of the trials followed a balanced design. Subjects dressed in a bathing suit and sat quietly at an ambient temperature of approximately 22°C for 10 minutes of baseline data collection after monitors were applied. To enhance the effect of meperidine, the subjects took buspirone (30 mg orally) during the instrumentation period. They were then immersed to the level of the sternal notch in a stirred water bath. The temperature of the water was lowered, by rapid inflow of 2°C water from a large reservoir, from 21°C to 8°C over a period of 5 minutes. Subjects were immersed for 10 to 30 minutes depending on their body mass, with their immersion time being based on the results of prior pilot studies. Immersion time was the same for all conditions for each subject and was limited by the highest amount of body cooling that could occur for which the subject's shivering could be successfully inhibited by the prescribed maximal dose of meperidine.

During the last 10 minutes of immersion, subjects were given 1.25 mg/kg of IV meperidine (diluted in five 2-mL aliquots and injected over successive 2-minute intervals). Subjects were then hoisted out of the water, towel dried, and placed in a sleeping bag, with the head covered, for 120 minutes of warming. Postimmersion supplemental injections of meperidine to a maximum cumulative dose of 3.5 mg/kg were administered based on $\dot{V}o_2$ and the subject's sensation of shivering in order to maintain shivering suppression. Each trial was terminated after 120 minutes of warming, a duration sufficient to establish a steady rate of core temperature change. Subjects were then immersed in 42°C water until their T_{es} rose to a normothermic level.

Warming Modalities

No exogenous heat source was used in the spontaneous warming trials. The materials and protocols for the warming modalities are as described in the sections that follow.

Charcoal Heater

The heater consisted of a combustion chamber, charcoal fuel, and a branched, reinforced, but flexible, heating duct (Normeca AS, Oslo, Norway) and produced 250 W of heat (1,800 kJ over 120 minutes). The combustion chamber was placed on the subject's chest and the heating ducts were applied dorsally over the shoulders, and then anteriorly under the axillae to cross over the lower chest (Fig. 1, top). The total skin contact surface area of the chamber (23 × 12 × 6 cm, 1,100 g) and

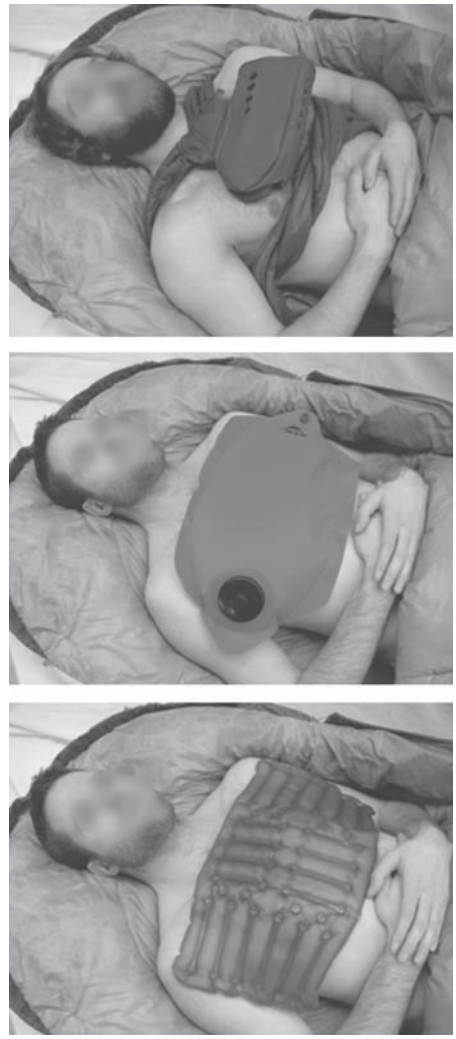

FIGURE 1. *Top*: charcoal heater in use; *middle*: hot-water bags in use; and *bottom*: chemical heating pads in use.

ducts was about 1,500 cm^2. The heater was ignited and set to the "high" setting 15–30 minutes before being applied to the subject. The heater could produce maximum heat for approximately eight hours. Subjects laid their hands on the heater during warming.

Hot-Water Bags

Two 6-liter flexible water bags (Mountain Safety Research, Seattle, WA) were each filled with 2 liters of 55°C water. This volume of water was used because a total of 4 liters was considered a realistic volume that could be heated in the field, and, filled with this volume of water, the water bag lay flat, allowing virtually all of one side of it to contact the skin. Each bag (45 × 25 cm, 120 g) had a skin-contact surface area of about 1,100 cm^2. A towel was placed between each bag and the skin to prevent burn injury. Subjects lay with one of the bags placed under their upper back, while the other bag was placed on the upper chest (Fig. 1, middle). Every 20 minutes, both bags were refilled with 55°C water. Subjects laid their hands on the top of the chest water bag as soon as it was comfortable.

Chemical Heating Pads

Two chemical heating pads (Dorcas AB, Skattkarr, Sweden) were activated 2 minutes prior to use. Each pad (42 × 25 × 2 cm, 1,400 g) had a skin contact surface area of about 1,100 cm^2. Subjects lay with one of the pads placed under their upper back, while the other pad was placed on the upper chest (Fig. 1, bottom). Surface temperature on the skin side of the pads reached approximately 50°C within 2 minutes after activation and then gradually declined. Initially a towel was placed between each pad and the skin to prevent burn injury. The towel was removed after 30 minutes, as pad surface temperature had decreased to a level where skin temperature could remain below the threshold (~43°C) for burn injury.[25] Subjects laid their hands on the chest pad during warming.

Data Analysis

Data were compared using a repeated-measures analysis of variance (ANOVA) with post hoc analysis with Fisher's protected least significant difference (PLSD) test to identify significant differences. Results are reported as means ± standard deviation (SD), and $p < 0.05$ was the threshold defined for statistically significant differences.

RESULTS

Endogenous Heat Production

Metabolic heat production increased from 116 ± 17 W during baseline to 195 ± 51 W during the last 10 minutes before meperidine injection. Meperidine suppressed shivering, with heat production returning to 114 ± 21 W during the first 40 minutes after cooling and then subsequently falling to 97 ± 17 W throughout the remaining 80 minutes of warming. There were no differences in heat production for the different conditions.

Heart Rate, Respiratory Rate, and Skin Temperature

Heart rate and respiratory rate increased during cooling from baseline values of 74 ± 13 beats/min and 19 ± 5 breaths/min to 87 ± 19 beats/min and 21 ± 7 breaths/min, respectively, just before meperidine administration. Postimmersion heart rate and respiratory rate declined to 66 ± 13 beats/min and 17 ± 6 breaths/min, respectively. There were no significant differences between the different conditions.

Skin temperature on the chest and upper back reached maximum values of 41.6°C for the charcoal heater, 42.3°C for the hot-water bags, and 42.8°C for the chemical heating pads.

Body Core Temperature

There were no significant differences in initial cooling rate (−10 to 0 min) for the different conditions (Table 2 and Fig. 2). The postcooling afterdrop compared with spontaneous warming (2.2°C) was significantly less for the chemical heating pads (1.5°C) and the hot-water bags (1.6°C, $p < 0.05$), but not for the charcoal heater (1.8°C). The time to T_{es} nadir was significantly less for all other modalities compared with spontaneous warming ($p < 0.05$). Subsequent core rewarming rates for the hot-water bags (0.7°C/h) and the charcoal heater (0.6°C/h) tended to be higher than that for the chemical heating pads (0.2°C/h) and were significantly greater than that for spontaneous warming (0.1°C/h, $p < 0.05$).

Exogenous Heat Delivery

The heat gain during active warming on the chest and upper back (each being 9% of body surface area) is shown in Figure 3. The charcoal heater provided a steady heat gain primarily to the chest. The water bottles donated heat to both the chest and upper back, with heat transfer being slightly greater on the back than the chest; the amount of heat transferred transiently increased each time water was replaced. The chemical heating pads also donated heat to both the chest and upper back, with the amount of heat transferred decreasing for the initial 30 minutes. Once the towels were removed, heat transfer transiently increased and then again decreased to minimal levels

TABLE 2. Core Temperature Responses*

Modality	Cooling Rate (−10 to 0 min), °C/h	Afterdrop Amount, °C	Time to T_{es} Nadir, min	Rewarming Rate (60–120 min), °C/h	Change in T_{es} (0–120 min), °C
Charcoal heater	−0.8 (1.4)	−1.8 (0.4)	51 (30)†	0.6 (0.5)†	−1.1 (0.6)†
Hot-water bags	−0.8 (1.3)	−1.6 (0.2)†	44 (23)†	0.7 (0.3)†	−0.6 (0.6)†‡
Chemical heating pads	−0.4 (1.6)	−1.5 (0.4)†	46 (23)†	0.2 (0.3)	−0.9 (0.7)†
Spontaneous warming	−0.9 (1.7)	−2.2 (0.3)	88 (38)	0.1 (0.8)	−1.7 (0.8)

*Values are mean ± standard deviation.
†Significantly different from spontaneous warming ($p < 0.05$).
‡Significantly different from charcoal heater ($p < 0.05$).
T_{es} = esophageal temperature.

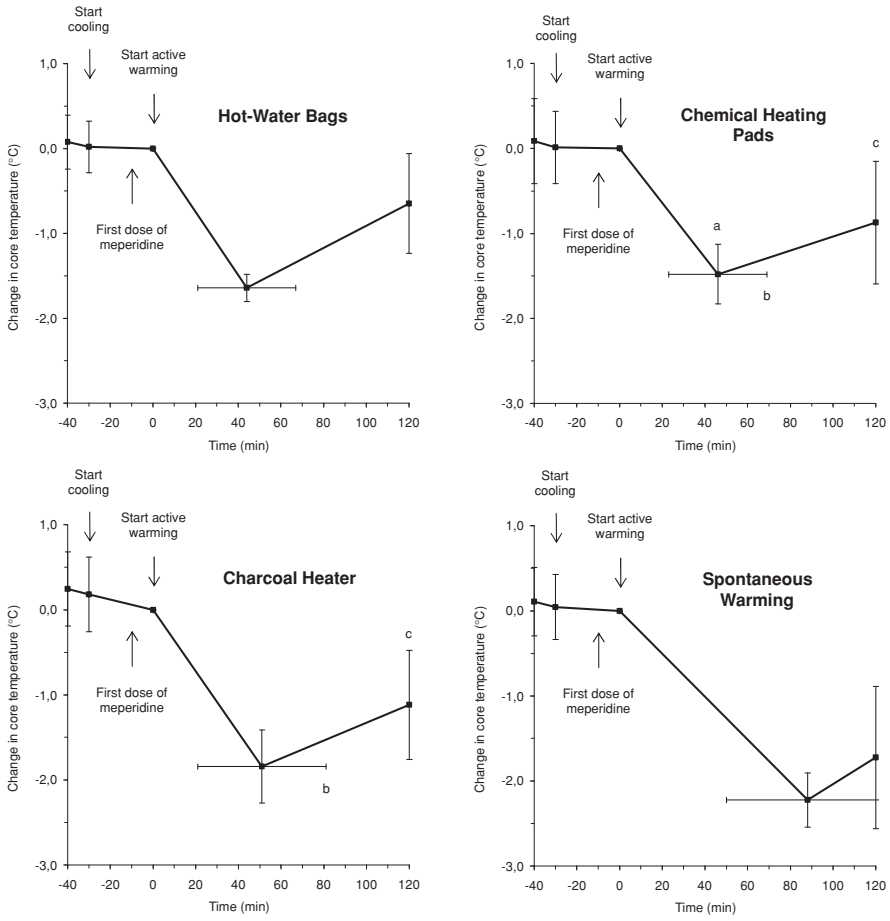

FIGURE 2. Change in esophageal temperature (T_{es}) during four warming protocols (mean, $n = 5$). [a]Afterdrop amount and [b]time to T_{es} nadir less than spontaneous warming; [c]final T_{es} significantly greater than spontaneous warming; [d]final T_{es} significantly greater than charcoal heater ($p < 0.05$). CP = chemical heating pads; HP = charcoal heater; SP = spontaneous warming; WB = hot-water bags.

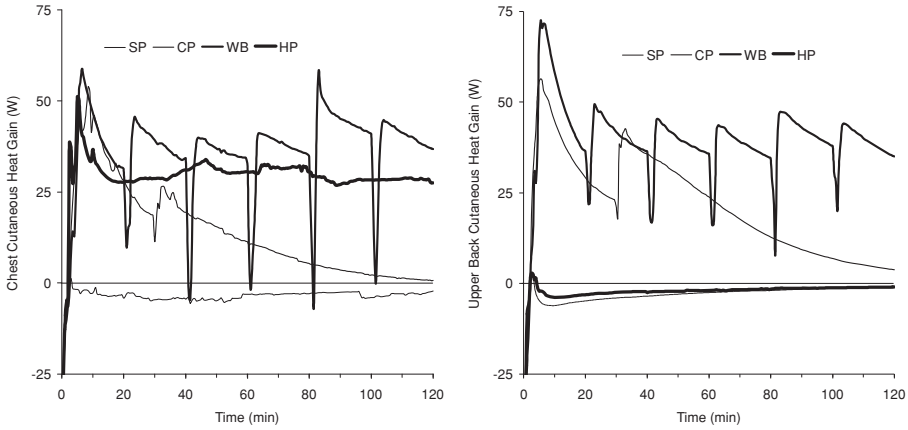

FIGURE 3. Cutaneous heat gain on the chest and upper back during four warming protocols (mean, $n = 5$). CP = chemical heating pads; HP = charcoal heater; SP = spontaneous warming; WB = hot-water bags (note the sawtooth pattern due to replenishing the water).

over the next 90 minutes. During spontaneous warming there was a small, continuous steady heat loss from the upper torso. Total cumulative energy transfer to the chest and upper back during 120 minutes of warming was 536 ± 56 kJ for the hot-water bags, 246 ± 71 kJ for the chemical heating pads, 230 ± 50 kJ for the charcoal heater, and -50 ± 28 kJ for spontaneous warming, and this was significantly different for each of the warming modalities except chemical heating pads vs. charcoal heater ($p < 0.05$).

DISCUSSION

This study was unique in that it used a human model for nonshivering hypothermia to evaluate relative efficacy of torso-warming procedures that could be used in the field and during transport to the hospital. Hot-water bags and chemical heating pads, which to our knowledge have not been quantified before, reduced both the amount and the duration of the subsequent afterdrop following removal from cold stress. The charcoal heater had little effect on afterdrop amount compared with spontaneous warming, although it significantly shortened the duration of the afterdrop. Hot-water bags and the charcoal heater then both provided efficient and steady rewarming rates, whereas the rewarming rate was small with chemical heating pads and almost negligible with spontaneous warming.

Possible Mechanisms for the Findings

When the amount of heat accessible is limited such as in a prehospital setting, external heat should be applied to the torso and areas with high surface heat transfer (axillae, neck, and groin).[4–7,11,12,16] In a previous torso-warming study, where different modalities of forced-air warming were compared with a charcoal heater and body-to-body rewarming, application of heat to the torso effectively decreased afterdrop and increased core rewarming.[16] This is likely due to the close proximity of the heat source(s) to the heart and lung circulation, and the fact that skin blood flow on the torso is generally unaffected by temperature, unlike the distal arms and legs. In this present study all heat sources were therefore applied to the upper torso. Although the evaluated heat sources were similar in providing their heat content conductively to the skin and underlying tissues, there were some important differences, which affected warming effectiveness. Hot-water bags and chemical heating pads, with their high initial heat delivery to a relatively large surface area, were both effective in attenuating afterdrop amount and duration. The charcoal heater, with its similarly high heat production but smaller surface area, had less effect on afterdrop amount compared with spontaneous warming, although it too significantly shortened the duration of the afterdrop. Heat delivery from the chemical heating pads then gradually declined and, therefore, the subsequent core rewarming rate was small. Hot-water bags and the charcoal heater, on the other hand, provided high continuous heat delivery and rendered effective rewarming rates. Conclusively, high initial heat delivery to a large surface area effectively decreased the afterdrop, whereas consistent high heat delivery was required for core rewarming.

Practical Implications

Several prehospital guidelines and review references recommend active prehospital warming of cold patients, especially if the patient is severely hypothermic and endogenous shivering heat production is inhibited.[1–7] Previous studies have shown that nonshivering moderately to severely hypothermic patients have a distinct thermal disadvantage because their shivering heat production defense is abolished and their basal metabolic rate is lower than normal, thus the postcooling afterdrop will be large and protracted.[14–16] In mildly hypothermic shivering patients, exogenous skin heating attenuates shivering heat production by an amount equivalent to the heat donated. In these patients, the application of external heat, although it might not decrease afterdrop or increase the core rewarming rate,[8–13] might provide other important advantages, including increased comfort, decreased cardiac work, and preservation of substrate availability. Accordingly, the application of external heat might also be beneficial for initially normothermic victims exposed to a cold environment.

In nonshivering hypothermic subjects, this study demonstrated that chemical heating pads and hot-water bags significantly decreased afterdrop at an amount of about 0.6–0.7°C and that the charcoal heater and hot-water bags significantly increased the rewarming rate compared with spontaneous warming by 0.5–0.6°C/h. All of the torso-warming modalities also significantly decreased the time to T_{es} nadir and the reversing of core cooling from about 88 minutes with spontaneous warming to about 46–51 minutes with active warming.

Previous retrospective analyses of trauma registries[26,27] as well as prospective clinical studies[28–30] have reported significant changes in physiologic variables, such as increased oxygen consumption, depletion of energy stores, disruption of blood clotting mechanisms, increased fluid resuscitation requirements, immune suppression, and development of organ failure already at mild hypothermic states compared with normothermic trauma victims. Mild hypothermia is also demonstrated to increase the risk of death in trauma patients, independent of injury severity.[26,27,31] A significant correlation between decreased duration of hypothermia by active core rewarming and increased likelihood of successful resuscitation and survival after trauma has also been demonstrated.[28] Thus, diminishing or even reversing a fall in core temperature, in an efficient yet safe manner, is desirable in the field and during prehospital care and transportation in order to improve the patient's condition upon admission to the emergency department. Accordingly, although the clinical significance of the differences in core temperature afterdrop or subsequent rewarming rate measured in this study is not yet fully known, we believe the impact of these prehospital torso-warming modalities might be of great benefit for an already compromised patient. To confirm the clinical significance of our findings, we encourage further prospective interventional clinical trials.

All of the evaluated torso-warming modalities are portable, require no external power supply, and can easily be used by laypersons, SAR personnel, or EMS crew members without significant training. The charcoal heater has a durable design yet is lightweight, is easy to handle even under harsh conditions, and provides heat over 8–12 hours using only one charcoal fuel cell at high (250-W) settings. In protracted evacuation and rescue operations, the charcoal heater therefore has the advantage of sustained heat production.

Water bags are often available during backcountry excursions or expeditions and do not take extra space or effort to transport. Although it is certainly possible and realistic for one person to reheat 4 liters of water every 20 minutes as in this study, an external heat source and significant effort are required for replenishing the water bags. They would therefore be more appropriate for scenarios in which the patient will remain on the scene of the accident, waiting for evacuation.

Chemical heating pads are somewhat heavier and take up more space than the other modalities but can easily be transported in a vehicle such as in ground or air ambulance units. Being effective in reversing the initial fall in body core temperature, chemical heating pads might prove valuable for initial thermal stabilization of a cold victim. However, since the energy content is limited, for continuous heat delivery we would recommend that the chemical heating pads be replaced about every 30 minutes.

Limitations

In order to limit the amount of meperidine necessary to inhibit shivering, we had to try to expose the subjects to the same relative cold stress depending on their physical constitution, and, therefore, based on experiences from prior pilot studies, immersion times differ between the subjects. However, since each subject served as his or her own control and immersion times were exactly the same for each subject for all the warming modalities, this should not have any impact on our data.

CONCLUSIONS

In nonshivering hypothermic subjects, all warming modalities significantly reduced the time to reversing of core cooling. Greater sources of external heat, such as chemical heating pads or hot-water bags, were effective in attenuating the amount of core temperature afterdrop, whereas sustained sources of external heat, such as hot-water bags or the charcoal heater,

effectively established steady, efficient core rewarming. Depending on scenario and available resources, these promising results support the recommendation to use charcoal heaters, hot-water bags, or chemical heating pads as effective means for treating cold patients in the field or during transport to definitive care.

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The effect of active warming in prehospital trauma care during road and air ambulance transportation - a clinical randomized trial

Peter Lundgren*, Otto Henriksson, Peter Naredi and Ulf Björnstig

Abstract

Background: Prevention and treatment of hypothermia by active warming in prehospital trauma care is recommended but scientifical evidence of its effectiveness in a clinical setting is scarce. The objective of this study was to evaluate the effect of additional active warming during road or air ambulance transportation of trauma patients.

Methods: Patients were assigned to either passive warming with blankets or passive warming with blankets with the addition of an active warming intervention using a large chemical heat pad applied to the upper torso. Ear canal temperature, subjective sensation of cold discomfort and vital signs were monitored.

Results: Mean core temperatures increased from 35.1°C (95% CI; 34.7-35.5°C) to 36.0°C (95% CI; 35.7-36.3°C) ($p < 0.05$) in patients assigned to passive warming only ($n = 22$) and from 35.6°C (95% CI; 35.2-36.0°C) to 36.4°C (95% CI; 36.1-36.7°C) ($p < 0.05$) in patients assigned to additional active warming ($n = 26$) with no significant differences between the groups. Cold discomfort decreased in 2/3 of patients assigned to passive warming only and in all patients assigned to additional active warming, the difference in cold discomfort change being statistically significant ($p < 0.05$). Patients assigned to additional active warming also presented a statistically significant decrease in heart rate and respiratory frequency ($p < 0.05$).

Conclusions: In mildly hypothermic trauma patients, with preserved shivering capacity, adequate passive warming is an effective treatment to establish a slow rewarming rate and to reduce cold discomfort during prehospital transportation. However, the addition of active warming using a chemical heat pad applied to the torso will significantly improve thermal comfort even further and might also reduce the cold induced stress response.

Trial Registration: ClinicalTrials.gov: NCT01400152

Keywords: hypothermia, body temperature regulation, thermal comfort, active warming, passive warming, prehospital trauma care, emergency medical services (EMS)

Background

In a cold, wet or windy environment, an injured or ill person is often exposed to a considerable cold stress. Heat loss is often aggravated due to exhaustion, light, torn or wet clothing, major bleeding, entrapment or the administration of cold intravenous fluids or sedative drugs and admission hypothermia is an independent risk factor associated with worse outcome and higher mortality in trauma patients [1-6]. The cold induced stress response will also render great thermal discomfort which might increase the experience of pain and anxiety, even in still normothermic patients [7]. Thus, in addition to immediate care for life threatening conditions, actions to reduce cold exposure and prevent further heat loss is an important and integrated part of prehospital primary care. Initial measures should be taken to get the patient into shelter, remove wet clothing and insulate the patient from ambient weather conditions and ground chill within adequate wind- and waterproof insulation ensembles (passive warming). In addition, depending on the victim's physiological status, body core temperature, available resources and expected

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duration of evacuation, the application of external heat (active warming) is in most guidelines recommended to be considered to aid in protection from further cooling during evacuation and transport to definitive care [8-12].

Several studies on mildly hypothermic (body core temperature, T_{co} = 32-35°C) shivering subjects have found that exogenous skin heating attenuates shivering heat production by an amount equivalent to the heat donated [13-15]. Thus, in a mildly hypothermic shivering victim, external warming generally does not decrease afterdrop or increase rewarming rate, however it might provide other advantages including increased comfort, decreased cardiac work and preserved substrate availability. When shivering is diminished or absent, as in moderate (T_{co} = 28-32°C) to severe (T_{co} < 28°C) hypothermia or otherwise impaired due to the overall medical condition of the patient (i.e. old age, alcohol or drug ingestion, head or spinal injury, severe trauma or depleted metabolic energy substrates) some form of exogenous external or internal heat is required, otherwise afterdrop will continue and little or no rewarming will occur [16,17].

Accordingly, effective prehospital field treatment of patients exposed to cold stress is considered of utmost importance to improve the medical condition on admission to the emergency room and active warming already in the field is considered one important part of such treatment. Since the warming modalities need to be portable and easily handled by Search and Rescue (SAR) or Emergency Medical Services (EMS) personnel there are limited treatment options in the field or during transport to definitive care. Chemical heat pads, hot water bottles, plumbed water filled blankets, charcoal fueled heat pacs, forced air warming and resistive heating devices are commonly used and advised [8-12], but the lack of studies in field conditions is noticed [18] and to the authors' knowledge, only two randomized clinical trials have evaluated the effectiveness of such modalities in the field [19,20].

We therefore decided to evaluate the effect of an active warming intervention on cold stressed trauma patients using chemical heat pads, previously evaluated in a laboratory study [17], as one possible field applicable warming device during road or air ambulance transportation of trauma patients. Primary outcome measures were body core temperature, cold discomfort and vital signs.

Methods

Design and settings

The study was designed as a randomized, clinical trial of prehospital active warming intervention for trauma patients, where enrolled patients were assigned to either passive warming with blankets (routine care) or passive warming with blankets with the addition of an active warming intervention using a large chemical heat pad applied to the upper torso. Ethical approval was obtained from the Regional Ethical Review Board at Umeå University. The study was conducted from December 2007 until May 2010. Fourteen road ambulance units and one helicopter unit, serving a primarily suburban area in the northern parts of Sweden with about 125 000 inhabitants, were selected for the study. After given both written and verbal instructions, the participating EMS personnel carried out the study as a part of their normal duty, without interference by the investigators.

Population

Subjects were sequential trauma patients, age ≥ 18 years, who had sustained an injury outdoors and were transported by one of the participating EMS units. Patients were excluded if initial level of consciousness was affected, (Glasgow Coma Scale < 15), or if duration of transportation was expected to be shorter than 10 minutes. As the aim of the study was to investigate the effect of active warming intervention in cold stressed patients, those patients who had already received active warming or had been taken indoors for more than 10 minutes before EMS unit arrival or had an initial cold discomfort rating ≤ 2 were also excluded.

Protocol

At the scene of injury event, all patients initially received routine trauma care, including passive warming with blankets. After loading into the ambulance or helicopter, informed consent to be part of the study was obtained. Enrolled patients then were selected for either passive warming or passive warming with the addition of active warming by opening of sequentially numbered and sealed envelopes containing randomized study protocols. A tympanic sensor was placed in the patient's ear canal and the outer ear sealed with a soft insulation cover. After 5 minutes an initial recording of ear canal temperature, cold discomfort, heart rate, blood pressure and respiratory rate, was obtained before active warming was begun if assigned. Apart from air temperature set to 25°C in the transportation unit, no other regulations were appointed. The number of blankets applied and specific care, such as immobilization or intravenous fluids and medications were provided according to standard trauma protocols. Repeated recordings of ear canal temperature, cold discomfort and vital signs were obtained every 30 minutes and upon arrival to the receiving hospital or health care center.

Passive warming

The participating ambulance units all had polyester blankets (200 × 135 × 0.4 cm, 1.200 g, 2.4 clo), woollen blankets (190 × 135 × 0.5 cm, 1.900 g, 2.7 clo) and one rescue blanket (nylon outer with synthetic filling and cotton inner, 275 × 125 × 0.7 cm, 2.300 g, 3.6 clo) as part of

their standard equipment. The type and number of blankets applied in each case were selected according to the EMS crew judgement without any regulations by the investigators. For comparative reasons the polyester blanket was accounted for as 1.0 blanket whereas the woollen blanket was accounted for as 1.1 blankets and the rescue blanket was accounted for as 1.5 blankets depending on their thermal insulation value (clo) determined according to European Standard for assessing requirements of sleeping bags [21].

Active warming intervention

A chemical heat pad (Dorcas AB, Skattkärr, Sweden), was selected as the active warming device. In a previous laboratory study this chemical heat pad, applied both to the anterior and posterior upper torso, was appreciated for its effectiveness in transferring heat to a cold person [17]. To simplify for the EMS crew, in this study the chemical heat pad on the posterior upper torso was left out. After activation, the heat pad (42 × 25 × 2 cm), reaching about 50°C within 2 minutes, was applied across the anterior upper torso, leaving only one layer of thin clothing between the heat pad and the skin. If the clothing had to be removed to gain necessary access to the patient, the heat pad was placed in an ordinary pillow-case to prevent burns to the skin. Following the initial chemical reaction, the surface temperature of the heat pad gradually declines [17]. To maintain effective heat transfer during longer transportations, the heat pad was thus replaced every 30 minutes.

Monitoring

A closed ear canal temperature sensor (Smiths Medical, Ltd., UK) was selected to monitor core temperature changes (± 0.2°C) during transportation. Ear canal temperature has been shown to correlate well with oesophageal temperature [22,23]. If properly sealed from the ambient air, closed ear canal temperature is also reliable in subzero and wind conditions [22] and thus considered the most accurate non invasive method of measuring body core temperature in the field [10-12]. After visual inspection of the outer ear to rule out any injuries, the sensor was gently placed in the middle of the ear canal. In addition to the outer soft cell foam cylinder that conforms to the ear canal and seals out ambient air, a soft insulation cover was placed on the outer ear and secured with Velcro around the head. The ear canal sensor was then connected to a temperature monitor (Novamed, Inc., USA) and left in place during the whole transportation.

Cold discomfort was monitored using a numerical rating scale [24], whereby the subjects estimated their sensation of cold to the whole body, not specific body parts, providing values from 0 to 10, where 0 indicated no sensation of cold and 10 indicated unbearable sensation of cold.

Vital signs were monitored using routine equipment and data collection sheets were filled out during transportation by the EMS personnel. In addition to ear canal temperature, vital signs, cold discomfort and overall satisfaction of care, the following information was recorded: time from injury to EMS unit arrival, on-scene duration, transportation time, outdoor temperature, wind speed, ambulance unit indoor temperature, patient characteristics, clothing characteristics, the type and number of blankets applied, immobilization and the administration of warm intravenous fluids and medications.

Data analysis

According to pre-study power calculations, with an estimated difference in core temperature of ≥ 0.5°C or cold discomfort rating of ≥ 2, an alpha of 0.05 and a power of 0.90, the minimum number of patients required to achieve statistical significance was 21 in each group and the study was ended after, with some margin, a sufficient number of patients had successfully been enrolled. Groups were compared using Mann-Whitney U-test for interval and ordinal data and Chi-2 or Fisher's exact test for nominal data, whereas pair wise related variable comparisons was made using the Wilcoxon Signed-Rank test. In addition, change in cold discomfort rating was characterized as increased, unchanged or decreased and the difference between groups was analyzed using Fisher's exact test. Statistical significance was defined as $p < 0.05$.

Results

Patient characteristics

Fifty-one trauma patients were enrolled in the study. Of these, one patient wished to end the study prior to arrival to the receiving hospital and two were excluded because of breach of protocol (assigned intervention was not given). Thus, a total of 48 patients, all subjected to blunt trauma, with a mean coded Revised Trauma Score (RTS) [25] of 7.83 (range 7.55 - 7.84), successfully completed the study, being randomized to either passive warming with blankets (n = 22) or passive warming with blankets with the addition of active warming (n = 26). The included patients were 19 male and 29 female and there were no significant differences between the two groups on morphometric or demographic characteristics (table 1).

Environment

The average ambient air temperature at the scene of accident was -4 ± 7°C (mean ± SD) and the average time from the injury until the patient was loaded into the EMS unit (cold exposure) was 73 ± 53 minutes with no significant differences between the two groups. The mean

Table 1 Patient characteristics and confounding factors

	Passive warming (n = 22)	Active warming (n = 26)
Patient characteristics		
Gender (male/female)	9/13	10/16
Age (years)	45 (34 - 55)	43 (36 - 50)
Body Mass Index	25.0 (22.8 - 27.3)	25.4 (23.6 - 27.3)
Environment		
Outdoor temperature (°C)	-6 (-9 - -2)	-3 (-6 - -1)
Outdoor wind speed (m/s)	2 (1 - 3)	2 (1 - 4)
Interior unit temperature (°C)	20 (19 - 21)	20 (19 - 21)
Cold exposure (min)	64 (41 - 88)	81 (61 - 101)
Time to 2nd measurement (min)	24 (21 - 28)	27 (24 - 29)
Total transportation (min)	33 (25 - 41)	37 (25 - 49)
Clothing (light/medium/heavy)	5/6/9	4/9/13
Clothing (dry/moist/wet)	13/2/4	21/3/1
Treatment during transport		
No. of blankets	2.7 (2.2 - 3.2)	2.3 (1.9 - 2.7)
Undress (none/partial/total)	12/8/2	14/10/1
Whole body fixation (yes/no)	8/13	8/17
Intravenous fluids (ml)	91 (31 - 151)	50 (0 - 107)
Intravenous opioids (yes/no)	10/12	14/12
Intravenous sedatives (yes/no)	2/20	5/21

Values are mean (95% confidence interval) or number of patients. The internal drop-out of any variable was ≤ 3 patients and there are no significant differences between groups ($p < 0.05$).

interior unit temperature during transport was 20 ± 3°C and the mean number of blankets applied was 2.5 ± 1.1 with no significant differences between the two groups. There were also no significant differences between the two groups in distribution of clothing thickness or wetness, the extent of undressing, the incidence of whole body fixation, the amount of intravenous fluids transfused or the incidence of intravenous opioids or sedatives administered during transport (table 1).

Primary outcome

The average transportation time to the receiving hospital or health care centre was 35 ± 26 minutes (mean ± SD) with no significant differences between the two groups. Thus, at the second measurement, performed at an average of 26 ± 7 minutes all 48 subjects were included, whereas at the third measurement, performed at an average of 58 ± 5 minutes only 12 subjects remained. The analysis of primary outcome variables was therefore terminated after the second measurement.

Mean initial ear canal temperature was 35.1°C (95% CI; 34.7 - 35.5°C) in patients assigned to passive warming only and 35.6°C (95% CI; 35.2 - 36.0°C) in those assigned to additional active warming with no significant differences between the two groups. At the second measurement, mean ear canal temperatures in both groups were significantly increased to 36.0°C (95% CI; 35.7 - 36.3°C) and 36.4°C (95% CI; 36.1 - 36.7°C) respectively with no significant differences between the two groups (table 2).

The initial median cold discomfort rating in patients assigned to passive warming only was 5 (IQR; 4 - 7) and the initial median cold discomfort rating in patients assigned to passive warming with the addition of active warming was 7 (IQR; 5-8) with no significant differences between the two groups. At the second measurement, cold discomfort was significantly reduced in both groups. However, in the group assigned to passive warming only, 15 out of 22 patients presented a decrease in cold discomfort, whereas in the group assigned to additional active warming all 26 patients presented a decrease in cold discomfort ratings, the difference in cold discomfort change being statistically significant (table 2).

There were no statistically significant differences in initial vital signs between the two groups. At the second measurement, the vital signs were statistically unchanged for the patients assigned to passive warming only, whereas patients assigned additional active warming presented a small but statistically significant reduction in mean heart rate and respiratory frequency (table 2).

Discussion

Overview

This study evaluates the effectiveness of active warming in prehospital trauma care using a large chemical heat

Table 2 Primary outcome

	Passive warming (n = 22)	Active warming (n = 26)
Body core temperature (°C) *		
1st measurement	35.1 (34.7 - 35.5)	35.6 (35.2 - 36.0)
2nd measurement	36.0 (35.7 - 36.3) †	36.4 (36.1 - 36.7) †
Cold discomfort **		
1st measurement	5 (4 - 7)	7 (5 - 8)
2nd measurement	3 (0 - 5) †	2 (1 - 3) †
☒ increased	1	0
☒ unchanged	5	0
☒ decreased	15	26 ‡
Vital signs *		
Heart rate		
1st measurement	83 (77 - 90)	84 (78 - 90)
2nd measurement	82 (76 - 87)	80 (75 - 86) †
Systolic blood pressure		
1st measurement	138 (129 - 147)	136 (127 - 145)
2nd measurement	134 (124 - 143)	131 (124 - 139)
Respiratory rate		
1st measurement	17 (16 - 19)	18 (16 - 20)
2nd measurement	17 (15 - 18)	16 (14 - 18) †
Revised Trauma Score	7.84 (7.84 - 7.84)	7.83 (7.80 - 7.84)

Values are * mean (95% confidence interval) or ** median (interquartile range) and number of patients. The internal drop-out of any variable was ≤ 2 patients.
† Significant difference within the same group (Mann-Whitney U-test, $p < 0.05$)
‡ Significant difference between groups (Fisher's exact test, $p < 0.05$)

pad applied to the upper torso in addition to passive warming with blankets during transportation to definitive care. Over the first 30 minutes of prehospital transportation, both patients receiving passive warming only and patients receiving passive warming with the addition of active warming presented a statistically significant increase in body core temperature as well as improved cold discomfort. However, in the group assigned to passive warming only, 2/3 of the patients presented a decrease in cold discomfort, whereas all patients in the group assigned to additional active warming presented a decrease in cold discomfort ratings, the difference in cold discomfort change being statistically significant.

Possible mechanism for findings

In previous laboratory studies on mildly hypothermic shivering subjects, exogenous skin heating has been shown to attenuate shivering heat production by an amount equivalent to the heat donated [13-15]. Accordingly, in this study, enrolling trauma patients with an initial body core temperature of about 35°C and preserved shivering capacity, active warming had no additional effect on body core temperature compared to passive warming only. In contrast, two previous randomized clinical trials found a decrease in body core temperature with passive warming only, whereas with additional active warming using either electrically heated blankets [19] or multiple chemical heat pads [20], body core temperature was increased during transportation. Since passive warming only as an adequate treatment alternative presupposes intact shivering capacity and enough insulation in relation to cold stress and ambient environmental conditions, differences regarding these factors might explain differences between studies.

Although body core temperature was increased, only 2/3 of the patients assigned to passive warming only presented a decrease in cold discomfort whereas all patients assigned to additional active warming presented a decrease in cold discomfort during transportation. This beneficial effect on thermal comfort by application of a chemical heat pad to the upper torso is probably explained by a combination of reduction in shivering thermogenesis and increased skin temperature. Although shivering was not monitored per se in this study, a reduction of the cold induced stress response was indicated by a small but statistically significant decrease in respiratory frequency and heart rate in patients assigned to active warming, whereas patients assigned to passive warming presented no significant change in these parameters during transportation.

Practical implications

Admission hypothermia is an independent risk factor associated with worse outcome in trauma patients and previous retrospective analysis of trauma registries as well as prospective clinical studies have reported significant changes in physiologic variables, such as increased oxygen consumption, depletion of energy stores, disruption of blood clotting mechanisms, increased fluid resuscitation requirements, immune suppression and development of organ failure already at mild hypothermic states compared to normothermic trauma patients [1-6].

Owing to peripheral vasoconstriction, the temperature in the periphery of the body starts to decline long before body core temperature is affected. After removal from the cold environment there is a temperature equalisation between the warm body core and the cold peripheral parts contributing to a continuous fall in body core temperature, designated the afterdrop phenomenon. The magnitude of the afterdrop, which can be considerable and amount to several degrees, is dependent on temperature gradients in the tissues, peripheral circulation and endogenous heat production. Thus, initial measures in prehospital care of cold stressed patients are aiming at avoiding further heat loss to the environment and reducing the amount and duration of the afterdrop [8-12].

According to this study on cold stressed trauma patients with an initial body core temperature of about 35°C and preserved shivering capacity, passive warming, if adequate, is an effective treatment to prevent afterdrop, establish a steady rewarming rate and reduce cold

discomfort during transportation to definitive care. However, additional active warming had a beneficial effect in improving thermal comfort and indicated a small reduction of the cold induced stress response. Even in these mild hypothermic states, active warming might be of considerable clinical importance, especially in scenarios with diminished to absent shivering or inadequate passive warming. In a sustained cold outdoor environment, such as in prolonged extrications or in multiple casualty situations where available insulation often is inadequate, shivering will then be maintained in order to prevent afterdrop, thereby increasing respiratory and circulatory demands which might be detrimental for an already compromised patient. The application of external heat would therefore be even more important to reduce shivering strain. Also, if shivering is diminished or absent due to moderate or severe hypothermia or due to the patient's overall medical condition some form of exogenous heat is most likely required, otherwise afterdrop will continue and little or no rewarming will occur [16,17]. Improved thermal comfort might also relieve the experience of pain and anxiety and contribute to the physiological well-being of the patient during prehospital care.

Limitations

In addition to body core temperature, subjective sensation of cold discomfort and vital signs, other parameters such as oxygen consumption (as a measure of shivering) and skin temperature would have been important and useful supplements as indicators of cold stress.

Further research

The thermal effectiveness of active warming in prehospital trauma care has only been evaluated in a few previous clinical trials [19,20] and the results are diverging. Various degrees of injuries as well as different warming modalities and different amounts of passive warming might explain differences between the studies. All studies are also relatively small and included patients suffering from not more than mild hypothermia. Thus, thermal effectiveness of active warming in prehospital trauma care deserves further research, especially including more severely injured patients suffering from moderate or severe hypothermia.

Conclusion

In mildly hypothermic trauma patients, with preserved shivering capacity, adequate passive warming is an effective treatment to establish a slow rewarming rate and to reduce cold discomfort during prehospital transportation. However, the addition of active warming using a chemical heat pad applied to the torso will significantly improve thermal comfort even further and might also reduce the cold induced stress response.

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Authors' contributions

The authors contibuted in the following way to the paper:
PL: Design of the study, aquisition of data, analysis and interpretation of data and writing of the manuscript.
OH: Design of the study, aquisition of data, analysis and interpretation of data and writing of the manuscript.
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Competing interests

The authors declare that they have no competing interests.

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III

The Effect of Active Warming on Cold Discomfort in Field Treatment of Trauma Patients – a Clinical Randomized Trial

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Running head: Active External Warming in Field Trauma Care

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Key words: hypothermia, prehospital trauma care, field treatment, emergency medical services (EMS), active warming, passive warming, thermal comfort

Abstract

Background: Adequate field treatment to reduce cold exposure is considered of vitally important to improve the medical condition of the trauma patientn upon admission to hospital, and the application of active warming in the field is considered an important part of such treatment.

Objective: The objective of this study was to evaluate the effect of active warming intervention on cold discomfort during rescue and transport of patients with skiing injuries in a cold outdoor environment.

Methods: Patients were assigned to either passive warming alone, or passive warming with the addition of active warming, using a large chemical heat pad applied to the anterior upper torso. Subjective sensation of cold discomfort was monitored at the scene of injury event and upon arrival to the recieving first aid center or EMS unit.

Results: In patients assigned to passive warming alone (n = 9), initial median cold discomfort, 5 (IQR; 2 – 5), remained at the same level, 5 (IQR; 3 – 6), during rescue and transport, whereas in patients assigned to additional active warming (n = 11) initial median cold discomfort, 4 (IQR; 3 – 7), decreased significantly, 1 (IQR; 0 – 3), ($p < 0.05$).

Conclusions: Additional active warming using a chemical heat pad applied to the anterior upper torso significantly improved thermal comfort during field treatment and transport of cold stressed trauma patients in a cold outdoor environment.

Introduction

In a prehospital rescue scenario an injured or ill person is often subject to a considerable cold stress, especially in remote areas, where the search for and where the evacuation of the victim might be prolonged and also where the first assessment and treatment take place outdoors. Harsh weather conditions, insufficient or wet clothing, immobilization, contact with cold surfaces, significant blood loss, and the administration of cold intravenous fluids or sedative drugs might all aggravate cold stress and contribute to a subsequent decrease in body core temperature (1). Admission hypothermia, defined as a body core temperature below 35°C, is an independent risk factor associated with worse outcome in trauma patients (2 - 4) The cold induced stress response causes great thermal discomfort which might increase pain and anxiety, even in normothermic patients (5).

Actions to reduce cold exposure and prevent further heat loss are important and integrated parts of prehospital primary care. Shelter and adequate wind- and waterproof insulation ensembles (passive warming) are imperative. In addition, the application of external heat (active warming) is recommended to protect from further cooling, during evacuation and transport to definitive care. Active warming has the benefit of attenuating cold induced shivering and thereby decreases cardiac and respiratory demands and preserves substrate availability. When shivering is absent or diminished some form of external heat is required, otherwise cooling will continue and little and no core rewarming will occur. (1, 6 - 9)

Since the warming modalities need to be portable and easily handled, treatment options the field are limited. Chemical heat pads, hot water bottles, plumbed water filled blankets, charcoal fueled heat packs, electrical heating pads and blankets are commonly used or advised (1, 6, 7), but to the authors' knowledge, only two previous randomized clinical studies have evaluated the effectiveness of such modalities in the field (10, 11).

In a recent study we evaluated the effect of prehospital active warming during road or air ambulance transportation of cold stressed trauma patients with preserved shivering capacity (12). The addition of a large chemical heat pad applied to the upper torso significantly improved thermal comfort compared to passive warming alone, but had no additional effect on core warming. As this study was conducted during transport in a heated environment we decided to address another part of the prehospital setting, evaluating the effect of the same active warming device regarding sensation of cold discomfort, when applied at the scene of accident and during transport in a cold outdoor environment.

Methods

The study was designed as a randomized clinical trial of prehospital active warming intervention on trauma patients with skiing injuries. Patients were assigned to either passive warming alone (routine care) or passive warming with the addition of active warming by a large chemical heat pad applied to the anterior upper torso. Ski patrol units at three minor ski resorts in the northern parts of Sweden were selected for the study, which was conducted during two consecutive winter seasons. After being given both written and verbal instructions, the participating ski patrol personnel carried out the study as a part of their normal duty, without interference by the investigators. Ethical approval was obtained from the Regional Ethical Review Board in Umeå..

Subjects were sequential patients, age $\geq$ 18 years, who had sustained an injury on the ski slopes and were attended and transported by one of the participating ski patrols. Patients were excluded if initial level of consciousness was affected (Glasgow Coma Scale <15), if on scene duration and transportation were expected to be shorter than 10 minutes, or if the patient had already received active warming or had been taken into a warm sheltered area for more than 10 minutes before ski patrol unit arrival.

At the scene of injury event all patients initially received routine care, including passive warming with blankets. As soon as possible, informed consent to be part of the study was obtained and enrolled patients were assigned to either passive warming (routine care) or passive warming with the addition of active warming by opening of sequentially numbered and sealed envelopes containing randomized study protocols. Initial cold discomfort was determined and if the patient was assigned to active warming,a large chemical heat pad (Dorcas AB, Skattkarr, Sweden) was applied across the anterior upper torso, leaving only one layer of thin clothing between the heat pad and the skin. The heat pad (42x 25x 2 cm, 1400 g), previously evaluated in transferring heat to a cold person (13), reaches about 50 °C within 2 minutes after activation. To maintain effective heat transfer during longer transportations, the heat pad was replaced every 30 minutes. Upon arrival to the receiving first aid center or Emergency Medical Service (EMS) unit, final recordings of cold discomfort were obtained before unloading the patient.

Cold discomfort was monitored using a numerical rating scale (14, 15), where the subjects estimate the cold discomfort to their whole body, not specific body parts, providing integer values from 0 to 10, where 0 indicates no cold discomfort and 10 indicates unbearable cold discomfort. The scale was designed to assess both thermal (dis)comfort and sensation since

they are hard to separate in a practical situation. After unloading the patient the ski patrol personnel filled out the data collection sheets. In addition to cold discomfort, the time of injury event, on-scene duration, transport time, outdoor temperature and wind speed, patient characteristics, clothing characteristics, and number of blankets applied was recorded.

Groups were compared using the Mann-Whitney U-test for nonparametric continuous data and Chi-square test for nominal data, whereas pair-wise related variable comparisons was made using the Wilcoxon Signed Rank test. In addition, change in cold discomfort was characterized as increased, unchanged or decreased and the difference between groups was analyzed using Fisher's exact test. Statistical significance was defined as $p < 0.05$ (two-sided).

Results

A total of twenty patients were enrolled in the study, and they were randomized to either passive warming (n = 9) or passive warming with the addition of active warming (n = 11). There were no significant differences between the two groups regarding patient characteristics or environmental factors (table 1). The mean ambient air temperature at the scene of accident was -6 ± 4 °C (mean ± SD) and the mean wind velocity was 4 ± 3 m/s. The average time from the injury until ski patrol arrival and first cold discomfort rating was 13 ± 9 minutes followed by an average treatment and transport time to the receiving first aid center or EMS unit of 23 ± 10 minutes. There were also no differences in distribution of clothing thickness or moisture or the number of blankets applied between the two groups.(Table 1).

At the scene of injury, the initial median cold discomfort was 5 (IQR; 2 – 5) in patients assigned to passive warming and 4 (IQR; 3 – 8) in patients assigned to additional active warming with no significant differences between the two groups. When patients were unloaded at the receiving first aid center or EMS unit, cold discomfort was significantly reduced to 1 (IQR; 0 – 3) in patients receiving additional active warming but remained at 5 (IQR; 3 – 6) in patients receiving passive warming alone (Fig 1). In addition when change in cold discomfort was characterized as increased, unchanged or decreased, 9 of 11 patients assigned to additional active warming presented a decrease in cold discomfort and two remained at their initial cold discomfort, whereas only 3 of 9 patients assigned to passive warming alone presented a decrease in cold discomfort, one remained at initial cold discomfort and 5 presented an increase in cold discomfort. The difference between groups in cold discomfort change was statistically significant.

Discussion

This study evaluated the effect on cold discomfort of active field warming of trauma patients injured on the ski slopes, where patients were assigned to either passive warming alone (routine care) or passive warming with the addition of active warming by a large chemical heat pad applied to the anterior upper torso. During rescue and transport, patients receiving additional active warming experienced statistically significantly improved thermal comfort, whereas patients receiving passive warming alone experienced sustained cold discomfort.

Reducing cold exposure is considered of utmost importance to prevent further cooling during rescue and transport to definitive care, and the application of external heat in the field is considered an important part of prehospital treatment (1, 6-9). This study demonstrated that additional active field warming rendered statistically significantly improved thermal comfort compared to passive warming alone during treatment and transport in a cold environment. Improved thermal comfort might have the potential of relieving psychological stress such as the experience of pain and anxiety (5), which is an important but easily forgotten part of medical care. Such psycological stress might also comprise a considerable physiological stress to the patient by increasing respiratory and cardiac work. The combined physiological and psychological benefits of active field warming might therefore be of great importance.

In order not to intervene with the work of the ski patrol units, we did not measure body core temperature, skin temperature, vital signs or oxygen consumption, which together with a small study population are obvious limitations of this study.

The thermal effectiveness of active external warming in prehospital trauma care has only been evaluated in a few previous clinical trials (10 - 12) and the results are diverging. Various degrees of injuries, as well as different warming modalities and different amounts of passive warming, might explain differences between the studies. All studies are also relatively small and included patients suffering from not more than mild hypothermia. Thus, thermal effectiveness of active warming in prehospital trauma care deserves further research, especially including more severely injured patients suffering from moderate or severe hypothermia.

Conclusion

Additional active external warming using a chemical heat pad applied to the anterior upper torso significantly improved thermal comfort during field treatment and transport of cold stressed trauma patients in a cold outdoor environment.

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TABLE 1. Patient characteristics and confounding factors

	Passive warming (n=9)	Active warming (n=11)
Patient characteristics		
Gender (male/female)	5 / 4	3 / 7
Age (years)	32 ± 13	34 ± 11
Body Mass Index	25 ± 3	25 ± 4
Environment		
Outdoor temperature (°C)	-5 ± 5	-6 ± 4
Outdoor wind velocity (m/s)	5 ± 4	4 ± 3
Total cold exposure time (min)	11 ± 7	16 ± 9
Total transportation time (min)	23 ± 11	23 ± 10
Clothing (light/medium/heavy)	0 / 6 / 0	1 / 6 / 3
Clothing (dry/moist/wet)	6 / 2 / 0	9 / 1 / 0
No. of blankets applied	2 ± 1	2 ± 1

Values are mean ± SD or number of patients. The internal drop-out of any variable was ≤ 3 patients and there are no significant differences between groups ($p < 0.05$).

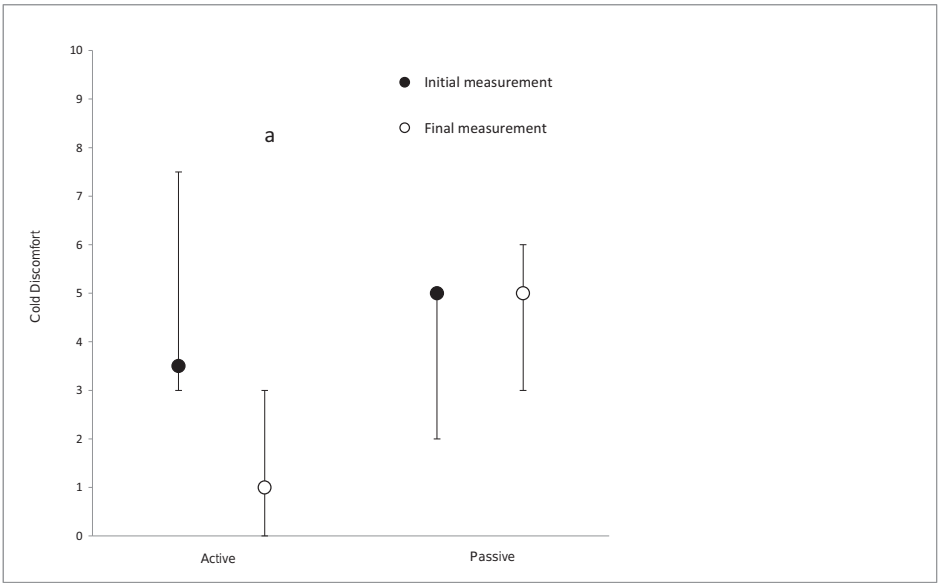

Figure 1. Cold discomfort in patients assigned to additional active warming (n = 11) and in patients assigned to passive warming only (n = 9) at initial measurement and at final measurement (median; IQR). [a] Cold discomfort significantly lower than initial measurement ($p < 0.05$).

IV

Validity and Reliability of the Cold Discomfort Scale - a Subjective Judgement Scale for Assesssment of the Thermal State of Patients in a Cold Environmemt

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Key words: hypothermia, prehospital trauma care, emergency medical services, reliability, validity, subjective judgement scale, thermal comfort

Abstract

Introduction: Alternative measures for assessmentof the thermoregulatory state of the patient, such as subjective judgement scales for assessment of personal thermal state, might be of considerable importance in field rescue scenarios, where objective measures such as body core temperature and skin temprature, as well as oxygen consumption are hard to obtain.
Objective: To evaluate the Cold Dicomfort Scale (CDS), a subjective judgement scale for assessment of the thermal states of patients in a cold environment, regarding reliability, defined as as test-retest stability and criterion validity, defined as the ability to detect changes in cumulative cold stress.
Methods: Twentytwo healty subjects performed two consecutive trials (test-retest).They dressed in light clothing and stayed in a climatic chamber set to - 20º C for 60 minutes. CDS ratings were obtained every five minutes.
Results: Reliability was analyzed by test-retest stability, using weighted kappa coefficient, and was 0.84, including all the measurements made every five minutes and was 0.48 to 0.86 separated for every single measurement. Criterion validity, defined as sensitivity to detect a difference in cumulative cold stress over a 30 minutes interval, was analyzed by comparing median CDS ratings for a moving 30 minutes interval, which revealed that CDS ratings were significantly increased during each 30 minutes interval ($p < 0.001$).
Conclusion: In a prehospital scenario subjective judgement scales might be a valuable measure for assessment of the thermal state of concious patients. The results of this study indicated that the CDS is both reliable and valid for such purpose.

Introduction

Admission hypothermia is an independent risk factor associated with worse outcome and higher mortality in trauma patients (1 – 6) and initial actions to reduce cold exposure and prevent further heat loss is an important and integrated part of prehospital primary care (7 – 11). The cold induced stress response will also render great thermal discomfort, which might increase the experience of pain and anxiety even in still normothermic patients (12 - 16).

Conseqeuently, as part of primary medical care, it is important to have accurate measures to evaluate the thermoregulatory state of the patient, both upon arrival of the rescue team and during treatment and evacuation. In the field, especially in harsh ambient conditions this is often hard to achieve. Measuring body core temperature as well as skin temperature might be difficult (9) and measuring oxygen consumption for assessment of shivering is, in most clinical scenarios, not possible.

Thus, alternative measures such as subjective judgement scales for assessment of the thermal state of the patient might be of considerable importance in such scenarios both for an initial assessment and for evaluation of the treatment provided. It is of utmost importanance that those subjective judgement scales are reliable and valid.

Reliabilility refers to a measure´s lack of errors of measurement. (17) Validity can be divided into content, construct and criterion validity, where criterion validity refers to a measure´s association with one or more outcome criteria.

The most common single item judgement scales are Visual Analouge Scales (VAS), Numerical Rating Scales (NRS) and Verbal Rating Scales (VRS). A VAS consists of a visual line, usually 100 mm long, where the ends of that line are labeled with descriptions for the extremes of the studied modality. The respondent places a mark on the line representing his or her level of experienced intensity in relation to the described extremes. Instead of a visual line, a NRS consists of a range of numbers, usually 0 – 10, and a VRS consists of a list of words or phrases, describing various degrees of the studied modality (17). In clinical practice such scales are commonly used for the assessment of pain, where they have been shown to be both valid and reliable (17, 18). However, they are also used for the assessment of other modalities such as thermal sensation and (dis)comfort (12 - 16).

The international standard BS EN ISO 10551:2001 outlays general principles for construction of subjective judgement scales for assessment of the influence of the thermal environment (19). There are however, to the authors' knowledge, no previous studies on reliability and

validity of psychometric methods for assessment of the influence of the thermal environment in more extreme ambient conditions.

In accordance with the basic principles stated in the international standard (19) and with some modifications to increase usefulness in a prehospital rescue scenario we have designed a NRS, the Cold Discomfort Scale (CDS), for assessment of the thermal state of patients in a cold environment (20, 21). The objective of this study was to evaluate this NRS regarding reliability, defined as test-retest stability and criterion validity defined as the ability to detect changes in cold discomfort due to cumulative cold stress.

Methods

Design, settings and subjects

The study was conducted in October and November 2011 at the Thermal Environment Laboratory, Lund University, Sweden. Thirteen male and nine female volunteered for participation (Table 1). They were cardiopulmonary healthy and had no regular medication or history of local cold injuries. None of them were habitual smoker or abused narcotics. Written informed consent was obtained from all subjects. Ethical approval was obtained from the Regional Ethical Review Board in Umea.

The study protocol was designed as a test-retest where subjects were exposed in -20 °C for 60 minutes to evaluate reliability and validity of the Cold Discomfort Scale. All subjects thus conducted two identical trials on two separate occasions, at about the same time of day, approximately one week apart. During the twenty-four hour period prior to the trials subjects avoided smoking or drinking alcohol, had a minimum of six hours of rest during the night and were also instructed to avoid physical exertions. The diet was not modified but they all had regular meals.

Monitoring

Cold discomfort was monitored using the Cold Discomfort Scale (CDS), a numerical rating scale, where the subjects assess the thermal state of their whole body, not specific body parts, providing integer values from 0 to 10, where 0 indicates not being cold at all and 10 indicates unbearable cold. Subjects were asked the following qestion:

On a scale from 0 to 10, where 0 means not being cold at all and 10 means unbearably cold: How cold do you feel right now?

To assure that there was no risk of local cold injuries, finger and toe temperature was continuously monitored using thermistors (Rhopoint Components Ltd, UK, accuracy ±0.2 °C, time constant 10 s) taped to the left ring finger and the left index toe.

Ambient air temperature was continuously monitored using three sensors (PT 100, Pico Technology Ltd, UK, accuracy ± 0.03 °C) positioned in level with the supine subject, adjacent to the ankles, the mid trunk and the head.

Protocol

Subjects dressed in light, two-piece thermal underwear, a fleece cap, two pair of gloves and two pair of woollen socks and an outer foot cover. Insulation of hands and feet were reinforced to avoid the risk of local cold injuries. At first, subjects sat quitely at an ambient temperature of about 21 °C for fifteen minutes of baseline data collection. They then entered the climatic chamber (2.4 x 2.4 x 2.4 m), set to -20°C, and lay down in a supine position on a foam mattress. One of the medical doctors responsible for the study (P.L or O.H) accompanied the subject in the cold chamber during the whole trial, and every five minutes subjects were asked to express their thermal state according to the CDS. After 60 minutes of cold exposure the trial was completed and subjects exited the cold chamber. Clothing and monitoring equipment were removed and the subjects then had a warm shower until restoration of thermal comfort.

Data analysis

As the Cold Discomfort Scale comprises ordinal data non parametric statistics were used. Reliability of the Cold Discomfort Scale was analyzed for test-retest stability, using weighted (quadratic difference) kappa coefficient (22), comparing median CDS ratings between the two trials, including all the measurements made every five minutes and also, separately for every single measurement. StatXact 9 software (Cytel inc., Cambridge, MA, USA) was used for the analysis.

Pre-study calculations indicated a minimal sample size of 18 to detect a difference in CDS ratings of 2 or more (IQR; 2) presupposed 80% statistical power at an α-level of 0.05. Criterion validity was analyzed by comparing median CDS ratings over a moving 30 minutes interval (5-35 minutes; 10-40 minutes; 15-45 minutes.etc) using Wilcoxon Signed Ranks test. Statistical significance was defined as $p < 0.05$ and, in analysis of criterion validity, after correction for multiple comparisons according to Bonferroni as $p < 0.008$. SPSS 18.0 software (SPSS inc., Chicago, IL, USA) was used for the analysis.

Results

Totally, 44 trials were conducted, each of the 22 subjects conducting two trials each. The average ambient air temperature for all trials was ± °C (mean ± SD) and the average wind speed was 0.2 ± 0.0 m/s (mean ± SD). Skin temperature of the left index finger and left second toe never went below + 8 °C for any of the subjects.

Median CDS ratings increased from 0 (interquartile range, IQR; 0 - 0) during baseline to 7 (IQR; 5 - 7) at the end of the first trial (test) and from 0 (IQR; 0 – 0) to 6 (IQR; 5 - 7) during the second trial (retest) (Figure 1).

Reliability analyzed for test-retest stability, using weighted kappa coefficient, were 0.84, including all the measurements made every five minutes and were from 0.48 to 0.86 separated for every single measurement (Table 2).

Criterion validity analyzed by comparing median CDS ratings (n = 22) over a moving 30 minutes interval revealed that CDS ratings were significantly increased during each 30 minutes interval (5-35 minutes; 10-40 minutes;15-45 minutes etc) (Table 3).

Discussion

Overview

In a laboratory setting the test-retest stability of median CDS ratings over the 60 minutes of cold exposure was 0.84 (very good agreement) when all the measurements made every five minutes were included and 0.48 – 0.86 (moderate to very good agreement) when separated for every single measurement (22). The Cold Discomfort Scale was significantly sensitive to detect a difference in cumulative cold stress over a moving 30 minutes interval throughout the whole 60 minutes of cold exposure.

Reliability

It is always difficult to achieve identical conditions in a test-retest design when measuring subjective parameters. Even if all arrangements are made the same, the subject might react differently to the same cold exposure at two different occasions. There might also be a habituation which can either increase or decrease the sensitivity to the exposure. CDS ratings were generally somewhat higher in the first trial compared to the second trial, and this difference might be a result of a decreased sensitivity to the cold exposure from beeing more

experienced and therefore less anxious about being exposed to the cold the second time compared to the first time. However, test-retest stability was still very good when all the measurements every five minutes were included and moderate to very good when separated for every single measurement.

Validity

Criterion validity was defined as the minimum time for which a clinically significant cumulative cold stress in - 20°C wind still conditions would be desirable to detect. The results revealed that CDS ratings were statistically significantly increased for each 30 minutes interval (5-35 minutes; 10-50 minutes; 15-45 minutes etc) and thus the cold discomfort scale was valid for detecting a change based on the defined cumulative cold stress. However, during the last 20 minutes it seems like CDS ratings are not increasing as much as during the first 40 minutes. This might be an indication of a limitation to detect differences in cumulative cold stress when cold exposure is protracted due to habituation to ambient conditions.

Practical implications

As part of primary medical care it is important to have accurate measures to evaluate the thermoregulatory state of the patient, both upon arrival of the rescue team and during treatment and evacuation. In the field however, especially in harsh ambient conditions, reliable measures of body core temperature, skin temperature or shivering thermogenesis is often hard to achieve (9). In a prehospital rescue scenario, subjective judgement scales might thus be an important alternative tool for assessment of the thermal state of patients in a cold environment.

Assessment of the thermal state of the patient might be an early predictor of cold stress and therefore may be used to evaluate the risk of developing hypothermia. It is also important not to underestimate evaluation of the patient's subjective experience of medical care. Much resources and a lot of effort are invested to optimize medical treatment including pain relief but patients thermal comfort is easily forgotten. Therefore, reliable and valid subjective judgement scales for assessment of the thermal state of patients in a cold environment is important for improving prehospital medical care.

The international standard BS EN ISO 10551:2001 outlays general principles for construction of subjective judgement scales for assessment of the influence of the thermal environment (19). These general principles recommend symmetrical 7 to 9-degree rating scales comprising a central indifference point and two times 3 or 4 degrees of increasing intensity for both hot

and cold. Because subjective judgement scales used in prehospital as well as hospital medical care most commonly ranges from 0 to 10, for example when assessing pain intensity using the Visual Analouge Scale (VAS), we considered a similar range of the CDS would be more easily understood by patients and also very important, more familiar to the rescue personel. If judgement scales with different ranges are used, that could be confusing. Furthermore, since we are only interested in cold exposure, we think it is better to simplify the scale to be assymetrical, describing only cold. In the litterature (19, 23) there is a distinction between perception/ thermal sensation and affective assessment/ (dis)comfort where the former describes perception of afferent perpiheral and central stimuli and the latter describes the state of mind that expresses (dis)satisfaction with the surrounding environment. The CDS does not differentiate between perception and affective assessment of the thermal environment. This design enables rescue personel to give short, pithy instructions to patients when obtaining data instead of explaining the different definitions of perception versus affective assessment. Making these modifications to international standard instructions we think that the CDS has advantages in practical use in a prehospital rescue scenario.

Limitations and further research

Subjective judgement scales as a tool for assessment of the thermal state of the patient is of course limited to conscious patients, not suffering from any major distracting injury. To the authors' knowledge this is the first study evaluating reliability and criterion validity of a subjective judgement scale for assessment of the thermal state of patients in an extreme cold environment. Considering the small study population, limited time period for cold exposure and limited ambient conditions further studies to confirm these results may be required.

Conclusion

In a prehospital rescue scenario subjective judgement scales might be a valuable measure for assessment of the thermal state of concious patients. The results of this study indicated that the CDS is both reliable and valid for such purpose.

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Table 1. Subject characteristics.

Gender (m/f)	13/9
Age (years)	23.3 (4.4)
Weight (kg)	72.7 (15.3)
Height (cm)	178.9 (9.6)
BMI	22.5 (2.9)

Values are mean (± SD) or number of subjects.

Table 2. Test-retest stability CDS ratings at 5 minute intervals.

Time (min)	Test * (n=22)	Re-test * (n=22)	Weighted kappa coefficient ** (n=22)
5	2 (1.25 - 3)	1 (1 - 2)	0.56 (0.25 - 0.86)
10	3 (2 - 3)	2 (1 - 2)	0.48 (0.20 - 0.77)
15	3.50 (3 - 4)	2 (1.25 - 3.75)	0.56 (0.31 - 0.81)
20	4 (3.25 - 4)	3 (2 - 4)	0.60 (0.38 - 0.83)
25	5 (4 - 5)	3 (2.25 - 4.75)	0.53 (0.30 - 0.76)
30	5 (4 - 6)	4 (3 - 5)	0.68 (0.48 - 0.87)
35	6 (4 - 6)	4 (3 - 5)	0.64 (0.40 - 0.88)
40	6 (4 - 6)	4.5 (6 - 4)	0.70 (0.49 - 0.90)
45	6 (4.25 - 6)	4.5 (6 - 4)	0.72 (0.51 - 0.92)
50	6 (5 - 7)	5.5 (5 - 7)	0.76 (0.57 - 0.96)
55	6 (5.25 - 7)	6 (5 - 7)	0.86 (0.72 - 1.0)
60	6.5 (5.25 - 7)	6 (5 - 7)	0.85 (0.81 - 0.99)

Values are median (IQR)* and weighted kappa coefficient (95% CI)**.

Table 3. CDS change over a 30 minutes moving interval.

Time (min)	Test and retest (n=22)*	Test and retest (n=22)**	Wilcoxon signed rank test
5 vs. 35	2 (1 - 2.25)	5 (3.75 - 6)	$p < 0.001$
10 vs. 40	2 (2 - 3)	5.5 (4 - 6)	$p < 0.001$
15 vs. 45	3 (2 - 4)	6 (4 - 7)	$p < 0.001$
20 vs. 50	4 (2 – 4)	6 (5 - 7)	$p < 0.001$
25 vs. 55	4 (3 - 5)	6 (5 - 7)	$p < 0.001$
30 vs. 60	5 (3 - 6)	6 (5 - 7)	$p < 0.001$

Values are median (IQR).

* First time in interval, ** second time in interval.

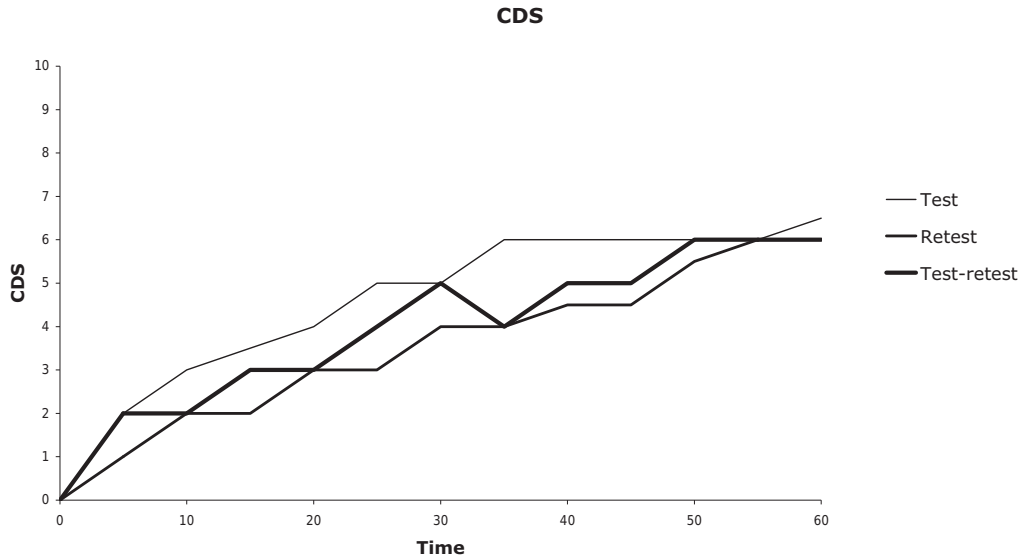

Figure 1. Median CDS ratings of test (n = 22), retest (n = 22) and merged median CDS ratings of test-retest (n = 22).