Comparing two different methods for wrapping cold and wet patients - A human crossover field study

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Forord

Arbeidet med denne masteroppgaven har vært fullt av høye fjell og dype daler. Jeg har lært, blitt utfordret, forstått, gledet meg og kjent på mestringsfølelse, men også fortvilt, stanget hodet i veggen, vært forvirret, og angret på hele prosjektet. Nå når denne reisen skal oppsummeres, sitter jeg igjen med takknemlighet over ny kunnskap som jeg håper å kunne gjøre nytte av ved en senere anledning. Med denne oppgaven har jeg fått en unik mulighet til å bidra til å utvikle et fagfelt jeg brenner for, og som jeg håper å kunne fortsette å delta i utviklingen av i fremtiden.

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Innholdsfortegnelse

Summary

Accidental hypothermia increases mortality and morbidity in trauma patients. Various methods for wrapping hypothermic patients are used worldwide. The aim of this study was to compare two different methods for wrapping hypothermic patients with the goal to reduce evaporative heat loss. Eight volunteers randomly participated in two different scenarios were they either kept the wet clothing or got the wet clothing removed before being wrapped in a vapor barrier, a dry insulation layer, and a windproof thermal rescue bag. Each participant conducted both scenarios. Skin temperature were measured, and a questionnaire was recorded for a subjective evaluation of comfort, thermal sensation, and shivering. The study showed significant differences between the two groups.

List of abbreviations

°C – Temperature Celsius

RTC – Randomized controlled trial

SJTREM – Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine

T core – Body core temperature

T skin – Skin temperature

Introduction

One of the first to recognize the dangers of being wet and hypothermic was Dr. Benjamin Rush, a surgeon-general of military hospitals. He first described this condition during the American Revolutionary War, and within that time period, he eventually prohibited wet clothing for injured soldiers in order to avoid more serious complications [1]. The early application of adequate insulation to reduce cold exposure and maintain heat balance is a key feature and an integrated part of prehospital primary care, particularly to stop post-injury hypothermia in rural areas with prolonged evacuation times [2, 3]. Many different methods and products are used worldwide for insulating and wrapping wet and hypothermic patients, but few studies describe the actual effects of these methods. Some prehospital guidelines on protection against cold recommend the removal of wet clothing prior to insulation. Others recommend the use of a vapor barrier between the patient and the insulation in order to reduce evaporative heat loss [3, 4].

Approaching the time to decide the theme for my master thesis, I received a request to compare two different methods for wrapping cold and wet patients. The person requesting wanted to make a guideline for treating hypothermic patients. The goal was to end up with one preferred method. Literature searches showed that some studies recommend wet clothing removal or the addition of a vapor barrier. These searches found no comparison of these two methods, and no conclusion as to which is the most effective [5, 6].

Existing recommendations and guidelines for the prehospital setting are mostly based on tradition and local experience [5, 6]. The lack of scientific approaches makes this study is important. Prehospital personnel should know if removing wet clothing is most effective, or if it is better to leave the wet clothing underneath a vapor barrier. It is also of clinical importance to know if the effect is significant enough to prioritize wet clothing removal even in difficult conditions. In the field, however, the ability to remove wet clothing might be impeded due to harsh environmental conditions or the patient's condition and injuries.

What is MountainLab, and what role does it play in this project?

MountainLab is a concept developed by dedicated prehospital personnel interested in a wide range of research as well as mountain life and outdoor activities. This unique concept is rooted in Mountain Medicine Research Group at the University of Bergen. The idea is to create an annual meeting point for those interested in conducting prehospital field research. Different research teams can meet and conducts their projects at the same location during a given period of time, sharing knowledge and resources. The common denominator is that research goals require field studies. The relevant topics can be from many different fields, such as anaesthesiology, traumatology, toxicology, general medicine, cardiology, etc.

The concept of MountainLab has three main goals:

- Research, product development and innovation.
  MountainLab will be an arena where high quality research is conducted.
- Networking, sharing ideas and experience.
  Doing research together leads to networking, good conversations and exchanging of ideas.
- Inter-operating and coordination.
  There are major logistical and professional benefits from coordinating different projects.

While MountainLab is getting well established in the academic community, the concept is still developing annually. From the start there has been a waiting list of people wanting to join the different projects. MountainLab has been in the unique position that recruiting participants and assistants has never been a problem. This is quite promising for future projects, and for recruiting new researchers with innovative ideas.

The scientific production from MountainLab so far:

2014: *The Impact of Environmental Factors in Pre-Hospital Thermistor-based Tympanic Temperature Measurement: A pilot field study,* published in Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine in September 2015.

2015: *Mountain rescue cardiopulmonary resuscitation: a comparison between manual and mechanical chest compressions during manikin cardio resuscitation,* published in Emergency Medicine Journal in March 2017.

2016: *Comparison of three different active warming methods for preventing hypothermia – a cross over study in humans,* not yet published.

2017: This study - *Comparing two different methods for wrapping cold and wet patients - a human crossover field study,* not yet published.

My role in MountainLab was until 2016 to function as a contact person, assistant, handyman, organizer and apprentice. I am grateful that this group of highly skilled researchers trusted me with the opportunity to do my master thesis in their research group.

Definitions

This compilation is focusing on the theoretical foundation for this project, and elaborating and discussing the choice of study design, methods and analysis. The result chapter is a brief summary of the main findings, including the main figure shown in the article. The discussion chapter has a slightly different angle than in the article.

The article follows the submission guidelines from Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine (SJTREM). SJTREM does not practice a formal word limit. However, they recommend authors to be as brief as possible without omitting essential details when writing their manuscript. For this reason, the article is as concise as possible, and I have chosen to emphasize this over the university's guidance document requesting approximately 5000 words. A comprehensive authors guide can be found in appendix 1.

The aim and outcome measures of this study

The aim of this study is to compare the effect of the removal of wet clothing versus keeping the wet clothing prior to vapor barrier and insulation. The outcome measures are skin temperature (T skin) and a subjective evaluation of comfort, thermal sensation, and shivering.

Theoretical foundation

Maintenance of a normal body core temperature (T core) is achieved from a balance between heat production and heat loss. The most important mechanisms of heat loss include radiation, evaporation, conduction, and convection, with the latter accounting for minimal heat loss. Radiation is the transfer of radiant energy, and it contributes to 55-65% of heat loss. This is the route of heat loss in fully exposed patients. Evaporation is the conversion of a liquid into vapor and usually accounts for 20-30% of total body heat loss, approximately 20-25% of which occurs from the skin surface, and the other 2-9% from the lungs. Conduction is the transfer of heat by direct contact between masses and accounts for up to 15% of the total heat loss. Water can increase the conductive losses by 25 times being one of the fastest ways to lose body heat. Convection is defined as the transfer of heat due to the flow of liquids or gases over a surface. Heat loss by convection is normally minimal, but it can be severely increased in windy conditions (12-15%) [7-9]. The proportion of heat loss due to radiation, evaporation, conduction and convection may vary to a large extent between different settings.

Accidental hypothermia and thermal comfort

There are two different main types of hypothermia, therapeutic and accidental hypothermia. Therapeutic hypothermia is clinically induced and is application of targeted temperature management. This has various applications, such as in different surgeries, or as a neuroprotector in post-resuscitation cardiac arrest [10, 11]. Therapeutic hypothermia will not be discussed further in this assignment.

Accidental hypothermia is an involuntary drop in T core to <35°C, and is a condition associated with increased morbidity and mortality in trauma patients [12, 13]. The negative impact of accidental hypothermia is well documented [14]. Maintenance of body temperature is important for both trauma victims comfort and homeostasis, with hypothermia associated with poor outcomes in several studies [7, 14].

Hypothermia has profound systemic effects, and initially hypothermia involves a sympathetic response. This causes vasoconstriction, tachycardia, and increased myocardial oxygen consumption. In mild hypothermia, patients have intense shivering and cold white skin. Moderate hypothermia may cause mental status changes, such as amnesia, confusion, and apathy, in addition to slurred speech, reduced shivering, hyporeflexia, and loss of fine motor skills. Most severely hypothermic patients is not shivering, and may present with hallucinations, cold edematous skin, areflexia, oliguria, fixed dilated pupils, hypotension, bradycardia, and pulmonary edema [9].

The experience of thermal discomfort, shivering and feeling cold can occur at any body temperature. The sensation of being cold can occur independent of T core, and this is normal from time to time in everyday life. There are individual differences to this cold sensation, and some feels cold more easily than others. However, a T core below 36.5°C is associated with thermal discomfort in most patients [15].

T core measurements is normally used to stage and guide the management of hypothermic patients. In the prehospital phase, however, the measurement of T core at the incident site may be impossible or unreliable [16, 17]. Most prehospital services is not equipped to measure T core in non-intubated patients. A classification based on the Swiss staging system of accidental hypothermia, provides useful guidance in a prehospital situation were temperature measurements is not available to indicate the severity of hypothermia. This system relies on a situational awareness that hypothermia might be present, and an assessment of clinical findings, such as level of consciousness and the presence of vital signs [16, 18].

Table 1: The Swiss system for staging of accidental hypothermia

Stage	Clinical Findings	T core (°C) if available
Hypothermia I (mild)	Clearly concious, shivering (1)	35 - 32°C
Hypothermia II (moderate)	Impaired consciousness, may or may not be shivering	< 32 - 28°C
Hypothermia III (severe)	Unconcious, vital signs present	< 28°C - 24°C
Hypothermia IV (severe)	Apparent death, vital signs absent	< 24°C (2)
Hypothermia V (dead)	Death from irreversible hypothermia	Variable

1. Consciousness and shivering may be impaired by other factors (e.g. comorbid illness or drugs) independent of T core
2. Alternative causes to cardiac arrest should be considered if T core is > 28°C.

Incidence

Hypothermic patients can be found in any environment, in both urban and rural environments. The danger of being hypothermic is dependent on the presence of existing comorbidities, the patients' injury severity score and the degree of hypothermia [9].

There is sparse knowledge about the incidence of accidental hypothermia. From experience we have seen that in the prehospital setting, T core is not measured in the majority of cold patients. Intubated patients are an exception due to esophageal thermometers. A large retrospective investigation of the trauma registry in Germany, documented patients between 2002 and 2012. They gained data from 111,791 patients, and the goal was to describe the epidemiology of accidental hypothermia in polytraumatized patients [19]. The study compared multiple-injured patients with or without hypothermia, and included more than fifteen thousand patients. They concluded that documentation of T core remains challenging as the number of recorded hypothermic patients appears to be too small. Potential cases for inclusion in this study was 39.555, but temperature data was available only in 38.5% of the patients.

Their findings show that temperature was below 36.0°C in approximately 30% of the recorded patients. Temperatures below 34.0°C had close to 33% overall mortality rate. In addition to the temperature itself, risk factors for increased mortality include the severity of the injury, wet clothing, low transport unit temperature, use of anaesthesia, and prolonged surgery [19]. The clinical outcome worsened as temperature declined.

A randomized trial including 100 patients with minor trauma found temperature < 36°C in 80% of the patients, and temperature <35°C in 27%. The study also identified that mean T core decreased further during transport to hospital [20].

A prospective observational study including 732 patients, identified the incidence and significance of accidental hypothermia in major trauma cases. The study demonstrated that in seriously injured patients, accidental hypothermia was associated with a threefold increase in mortality, independent of measured risk factors. They concluded that the safest clinical approach would be to aim for a temperature >35°C in patients with multiple injuries [21].

Preventing, treating and insulating

How to best prevent and treat hypothermia in the prehospital setting is not yet known, and scientific documented and feasible methods have been limited [20, 22]. In the Norwegian National Trauma Plan it is emphasized that prevention of hypothermia is important [23]. The plan strongly recommends that the air ambulance service should have a national procedure and equipment for preventing and treating accidental hypothermia, but no specific recommendations are listed.

Shivering and active movement are very efficient mechanisms of heat production, and are effective rewarming strategies for patients who are fully conscious and able to move. Patients who are awake and alert should not be prevented from mobilizing if this will help the rescue [18].

Lack of adequate insulation and impaired heat production during transport allows continued cooling, and insulation from cold, wet and wind as soon as possible is essential [18]. If the patient is wet, heat loss will be significantly increased because of evaporation and collapse of trapped air in the insulating materials [3]. If air temperature drops below 26–30 °C the body needs insulation provided by clothing to maintain homeostasis and thermal comfort. The thermal requirements of clothing are dictated by the ambient conditions and the activity level of the individual. In cold weather, it is necessary to store heat within clothing to remain in thermal comfort [24]. The thermal properties of different materials are determined by their ability to reduce heat exchange. Under dry conditions, the insulating capacity is proportional to the trapped air volume in the material, while the effect of wet materials will significantly increase the evaporative and conductive heat loss [6, 24].

The term *clo* is a relative measure of the ability of insulation to keep an individual warm. One clo is defined as the amount of clothing required by a resting person to stay comfortable at ambient conditions where temperature is 21°C, relative humidity is less than

50 percent, and air movement does not exceed 0.1 m/s. This is roughly the insulation value of typical indoor clothing, like a business suit. Lowest clo value (0) is that of a nude person, and highest practical clo value is 4, and is found in Eskimo clothing (fur pants, coat, hood, gloves, etc.). Winter clothing typically has an average clo value of >1, and typical summer clothing of 0.6 [24, 25].

Method and analysis

Effect – Terms and definitions

Time effect/periodic effect – What happens during the course of the experiment, which is equal for all test subjects (fatigue, weather and wind, etc.), spontaneous change over time.

Treatment effect – What separates the groups at the end of the experiment and is caused by the intervention (ideally wash out will remove this before the next attempt).

Crossover effect – Not starting completely from baseline, there has been a change from the first round of experiments which cannot be removed before the next round (difference in temperature, learning, etc.).

Study design – What to do and why?

The research question in this study limited the choice of study design and method. The «golden standard», double blinded randomized controlled trial (RCT), was not suitable for this particular research question. We aimed to compare two different interventions with insufficient preexisting data available, and chose to conduct a field study designed as a randomized crossover longitudinal clinical trial. Analysis at one time point, which is the idea of a cross-sectional study, was used for baseline measures.

Randomized controlled trials (RCT) reduce bias associated with imbalance in known and unknown confounding variables, and are the gold standard for evaluating the impact of an intervention [26]. On the other hand, RCTs may require significant resources (both time and money), recruiting volunteers may cause selection bias, and it can be ethically challenging. In RCTs the group effect is not significant and the group effect coefficient is close to 0 [27].

The **crossover** design is a type of RCT where each participant serves as his or her own control, and the order in which a test subject receives the interventions is randomized. This design provides for efficient use of the test subjects and significantly reduces between-subject variability, but it requires adjusting for individual effect in the statistical analysis [27, 28]. In the power of the statistical test carried out to confirm the existence of a treatment effect, lays another advantage of crossover trials. It allows the detection of smaller effect sizes with reduced sample sizes than parallel-group trials to meet the same criteria in terms of type I and type II error risks [29].

A crossover design might cause a crossover effect. To avoid this the two trial periods must be separated by a washout phase that is sufficiently long to rule out any crossover effect. In other words, the effect of the first experiment must have disappeared completely before starting the second period [27, 29].

Measuring data repeatedly at different time points, is known as **longitudinal** research and involves repeated observations of the same variables (e.g., skin temperature) over short or long periods of time. This allows an understanding of the degree and direction of change over time [30].

The main purpose of a study design is to separate periodic effects from treatment effects. This is achieved by calculating the treatment effects separately in two randomized groups. The differences between treatment effects can be assessed by means of a standard t-test for independent samples using the intra-individual differences between the outcomes in both periods as the raw data. The existence of crossover effects must be ruled out for this method to be valid [29].

What is ANCOVA, and why was it used to analyze our data?

Analysis of covariance (**ANCOVA**) is a general linear model which blends analysis of variance (ANOVA) and regression. ANCOVA evaluates whether the means of a dependent variable are equal across levels of a categorical independent variable, often called a treatment or intervention, while statistically controlling for covariates. In statistics, a covariate represents a source of variation that has not been controlled in the experiment and is believed to affect the dependent variable. The aim of an ANCOVA is to adjust for the influence such uncontrolled within-group error variance has on the outcome variable. This is in order to increase statistical power and to ensure an accurate measurement of the true relationship between independent and dependent variables. Statistical power in this case, is the probability a significant difference is found between groups when one exists [31].

While using a crossover design for the study, we used an ANCOVA for analysis because the crossover effect was assumed to be 0. The first choice would be a linear mixed effects model, but that would require 265 estimations ((1 intercept + 65 time effects + 1 group effect + 65 interactions) * 2 (coefficient, standard error) + 1 SD (random effect) = 265 estimations). In addition, the linear mixed effects model proved to be very sensitive to a number of parameters that were difficult to control with the small number of participants (for instance, the covariance structure between the time points). After eliminating the time effect, we did an ANCOVA with random effect for each time point instead. In the ANCOVA for each time point we did not have to estimate the time effect and the interaction, but had a group effect in each model (each time point).

Student's t-test for pair-wise comparisons was used to find the time point for when the groups returned to baseline temperature. The t-test can be used for dependent variables to determine if two sets of data are significantly different from each other [31].

Multiple testing was not considered because the tests are highly dependent on each other and the adjustment is difficult to dimension. A significance level of 0.005 was calculated, and that showed a significant difference 10 minutes after wrapping (see Figure 1 in the article).

Literature search

In order to do thorough preparations to know if there were existing relevant research, I got help from a librarian at the University of Bergen. A structured literature search for relevant background material was conducted June 22nd 2017, including the following key words:

- ("Hypothermia"[Mesh]) AND "Emergency Medical Services»[Mesh] resulted in 317 articles
- ((((hypothermia) AND (prehospital OR emergencies OR emergency)) AND (bedding OR linens OR wrapping OR clothing OR gown))) NOT (("Hypothermia"[Mesh]) AND "Emergency Medical Services»[Mesh]) resulted in 39 articles

Ethical considerations

Any information regarding the participants is confidential, and the information has only been used as agreed upon before the start of the experiment. All data were anonymized.

There were some discomfort for the participants. They got cold, but the core temperature remained constant during the entire study. The participants were informed of the risk of shivering and cold discomfort, and they signed consent forms prior to the study.

The study was approved by the Regional Ethics Committee for Medical and Health Research, 2017/150/REK nord.

Results

The experiment resulted in 7280 collected measurements during the study day. (8 participants * 7 measuring points * 2 scenarios * 65 minutes (30 minutes cooling period + 5 minutes intervention + 30 minutes passive rewarming) = 7280 measurements). Despite the large number of measurements and the complexity of the study, no single measurement or series showed any errors, and all could be included in the analysis.

Environmental conditions during the study day are shown in Table 2 and in Figure 1 in the article. Regarding humidity throughout the day, there were considerably more stable conditions inside the snow cave than outside.

Mean (± SD)	**Temperature (°C)**	**Humidity (%RH)**
Outside the snow cave	-2.9 (± 0.9)	73.2 (± 7.3)
Inside the snow cave	3.1 (± 1.2)	79.9 (± 2.8)
Resting area	22.3 (± 1.2)	29.8 (± 2.0)

Table 2. Environmental conditions during the study day, presented as means with corresponding standard deviations (SD).

The exposure when the wet clothes were cut, and the participants got wrapped in insulating material, was less than 2.5minutes for all the participants.

As shown in Figure 1 there were significant differences in the two groups 2 minutes after the subjects were wrapped. The difference stabilized after approximately 10 minutes, but there was a clear positive effect of removing the wet clothing.

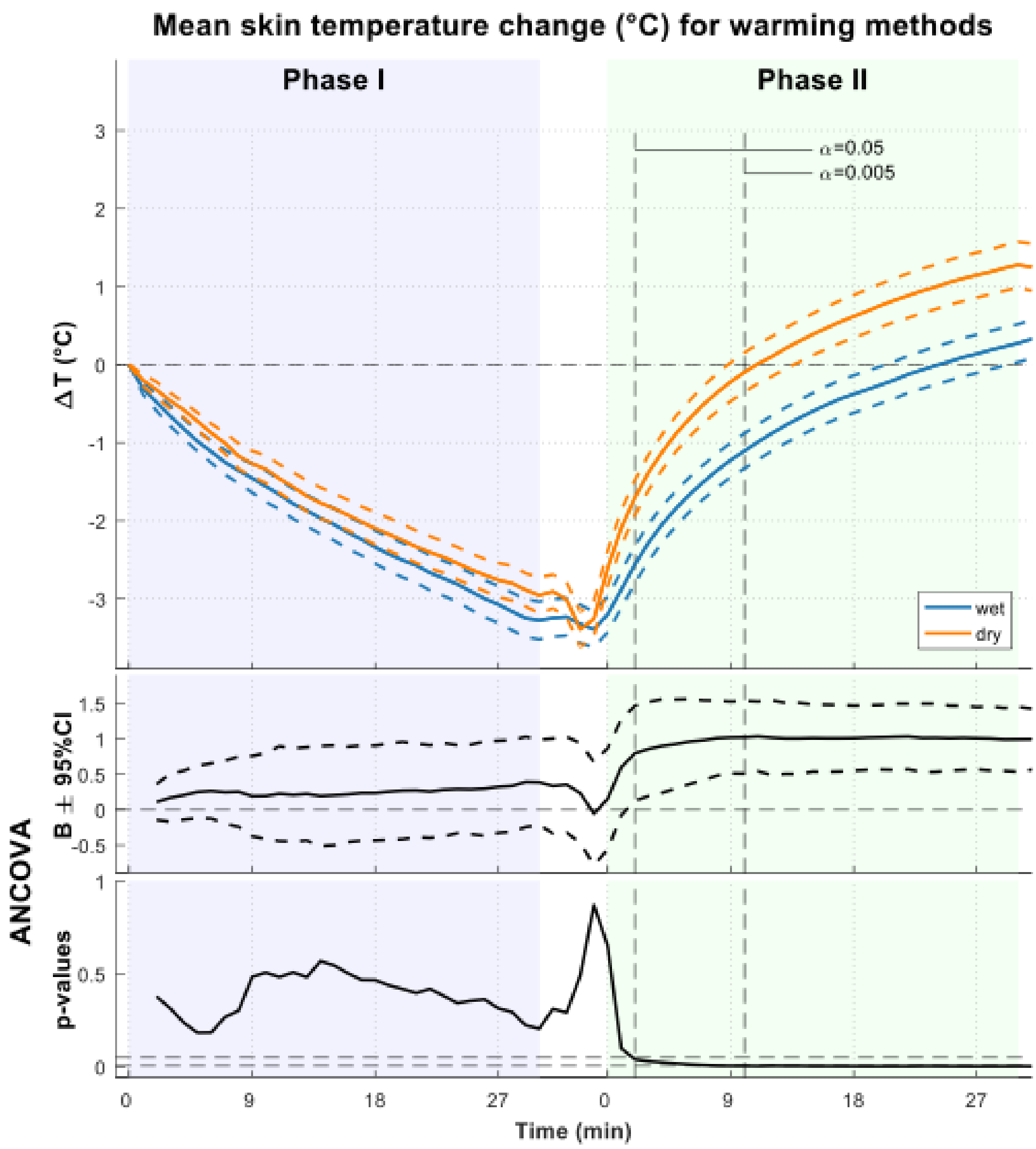

Figure 1 Mean T skin change for both groups with 95% CI and the result of the ANCOVA analysis. Coefficient B shows the mean temperature difference between the groups adjusted for baseline.

Regarding the answers from the questionnaires (Figure 3 in the article) there was a significant difference in skin feeling between the two groups. The dry group felt warmer and had a dry skin feeling after wrapping, while the wet group felt slightly wet during the whole experiment. These results were not significant, but a trend indicated that the dry group was slightly warmer and felt more comfortable than the wet group.

Discussion

In the absence of wind, an external temperature of about +27°C is needed to maintain a normal T core using only basal metabolism when a person in undressed [15, 32, 33]. This means that in a most parts of the world, all four seasons, we need to protect our patients against heat loss.

Hypothermia increases mortality and morbidity in the traumatized patient. Wet patients are exposed to extensive heat loss due to evaporation. Two different wrapping methods for the hypothermic patient are in daily use in Norway. Some services remove the wet clothing, and others are wrapping the patient in a vapor barrier leaving the wet clothing on the patient.

A systematic approach is needed to reduce morbidity and mortality due to hypothermia, and structured protocols and suitable equipment should be in place to optimize prehospital triage, transport and treatment. Lack of adequate insulation during transport allows continued cooling, and thereby increases the risk of complications, e.g., cardiac arrest. Insulation from cold, wet, and wind as soon as possible is essential, but the optimal prehospital transport and rewarming strategies are so far unknown [18, 34].

A Swedish thermal manikin study demonstrated that wet clothing removal or the addition of a vapor barrier effectively reduced evaporative heat loss. They concluded that these two options might be of great importance in prehospital rescue scenarios in cold environments with limited insulation available, such as in mass-casualty situations or during protracted evacuations in harsh conditions [4].

Initial measures should be taken to insulate the patient from the surface, remove wet clothing if possible, and supplying a vapor barrier and an adequate wind- and water proof insulation [35].

Using a snow cave as a cold chamber

A similar crossover study done by Thomassen and colleagues was designed to compare the metabolic and thermal responses of healthy humans exposed to three different experimental wrapping methods [6]. The experiment was performed in a cold climatic chamber in an accredited laboratory at SINTEF Technology and Society (Department of Health Research, Trondheim, Norway). Using a laboratory for the tests gave them the possibility to control and standardize the environmental conditions (temperature, humidity and wind) during all experiments. In our study, we used a self-made snow cave as a cold chamber, and there were some uncertainties in whether we would achieve stabile enough conditions to get reasonable data. A literature search on 'field studies', 'cold chamber' and 'climatic laboratory' didn't result in any advice to what could be expected. By conducting the study in a snow cave, we removed the wind impact and limited the temperature fluctuation, but we can never control the environment 100% unless using a laboratory.

Our connections at SINTEF started out as fairly inquisitive to our project, but as it turned out, we managed to get a lot more stable conditions than anticipated (see Table 2 above, or Figure 1 in the article, for environmental conditions during the study day).

Considering the economical aspects, the study at the research laboratory at SINTEF cost approximately ten times more than our field study, having the same number of participants, and a similar aim and design.

Even though a research laboratory may have more options and possibilities, especially regarding standardization and equipment, doing research in the field could in some cases be considered an applicable alternative.

Exposure time

We reduced the exposure time to a minimum by using a pre-rehearsed technique for cutting the clothes and wrapping the participants. For all the participants the exposure time was less than 2.5 minutes. The relatively short duration of both cold exposure and the subsequent insulation intervention might be of importance. In this study the benefit of removing wet clothes outweighs the disadvantage of the exposure.

For untrained personnel, in windy conditions and difficult situations, the exposure time could be substantially longer. If the cold exposure were to be e.g., 6-8 minutes, the temperature drop is likely to be greater. It is uncertain how low a temperature drop that can be allowed before this method is not preferable. We strongly recommend personnel to rehearse the chosen technique for cutting and wrapping to keep the exposure time as short as possible.

Could increased shivering immediately after removing the wet clothing explain the higher mean skin temperature (T skin) throughout the course of the experiment?

Shivering is a challenge in research on hypothermia. The ideal research setting would be to medically suppress the shivering response in order to control this individual factor in the participants. This, however, needs a careful approach and thorough planning for a safe and controlled experiment.

Shivering can increase heat production up to five times in a resting patient, and is said to be a very efficient mechanism of heat production and rewarming strategy [18]. A Norwegian study performed an evaluation of three different prehospital wrapping methods.

The goal was to evaluate the metabolic responses in humans with wet clothing. A significant difference was found between the three methods over time. One group had significantly higher metabolic heat production by shivering, and this was the same group who had the lowest T skin throughout the experiment. The mean T core was the same in all three groups [6].

In our study neither group reported shivering after wrapping (see Figure 2 in the article). It is not likely that the short period of exposure and increased shivering (max. 2 minutes, 18 seconds) can explain the significant difference in T skin in the 30 minutes long passive rewarming phase (see Figure 1 in the article). The participants subjective evaluation of thermal sensation corresponds to the temperature measurements (see Figure 2 in the article).

Conclusion

The benefit of removing wet clothes seems to outweigh the disadvantage of the exposure, and appears to be preferable to keeping the wet clothing underneath a vapor barrier.

This study can increase how healthcare professionals are reflecting on prevention and treatment of accidental hypothermia, and how they chose to wrap and insulate their hypothermic patients.

A snow cave can in some cases and for some research questions be used as an alternative to a cold chamber in an accredited laboratory.

Prehospital personnel should rehearse cutting and wrapping techniques so they are prepared for situations where exposure time might be a critical factor for the patient.

Shivering is an effective source of heat production and might affect the participants differently. This can be a limiting factor for research on hypothermia.

Further studies are recommended to increase knowledge that can be used in clinical guidelines in prehospital care. Future research should focus on harsher weather conditions and how that affects the patient during the exposure phase.

The results of this study may provide recommendations for a considerable part of the professional and volunteer health and rescue services around the world.

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Article: Comparing two different methods for wrapping cold and wet patients - A human crossover field study

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Abstract

Background

Accidental hypothermia increases mortality and morbidity in trauma patients. Various methods for wrapping hypothermic patients are used worldwide. The aim of this study was to compare the removal of wet clothing versus keeping the wet clothing prior to vapor barrier and insulation to reduce evaporative heat loss. The outcome measures are skin temperature and a subjective evaluation of comfort, thermal sensation, and shivering.

Methods

Eight volunteers were dressed in wet clothing and placed in a supine position in a snow cave. After an initial phase of cold exposure, the participants randomly either kept the wet clothing (wet group) or got the wet clothing removed (dry group). Both groups were wrapped in a vapor barrier, a dry insulation layer, and a windproof thermal rescue bag before a passive rewarming phase. Conducting both scenarios, each participant served as his or her own control. Skin temperature was measured every 60 seconds, and a questionnaire was recorded every 9 minutes for a subjective evaluation of comfort, thermal sensation, and shivering. Changes in skin temperatures were assessed by ANCOVA. A paired t-test was used to identify significant differences between the two groups. The subjective ratings were assessed by graphical and descriptive methods. P-values less than 0.05 were considered significant.

Results

Skin temperature was significantly higher in the dry group 2 minutes after wrapping. The dry group shows a significant change in skin feeling immediately after the wet clothing was removed. Regarding thermal sensation and shivering/sweating there is a trend indicating that the dry group is slightly warmer and feeling more comfortable than the wet group.

Conclusion

This study demonstrated that removing of wet clothing appears to be preferable to keeping the wet clothing underneath a vapor barrier.

Approval

The project was approved by the Regional Ethics Committee for Medical and Health Research.

Keywords

Accidental hypothermia, emergency medicine, insulation, prehospital, vapor barrier, emergency medical service,

Background

Accidental hypothermia is an involuntary drop in body core temperature (T core) to < 35°C [1], and has been shown to be an independent risk factor for increased morbidity and mortality in trauma patients, unrelated to the severity of the injury [2-5]. Hypothermia can be aggravated due to a combination of exhaustion, clothing, bleeding, entrapment, cold intravenous fluids and/or sedative drugs in the field [6]. From the time of rescue until arrival at the hospital, mean T core have been known to decrease further. Prolonged transportation time and delayed professional care, may increase the risk of hypothermia [7].

Exposure to cold temperature is an uncomfortable, subjective experience [8]. Thermal discomfort contributes to fear, pain, and an overall sense of dissatisfaction. Even mild hypothermia is associated with several complications. The physiological consequences are related to its initial impairment of coagulation, platelets dysfunction and lactic acidosis [9, 10]. Damage control resuscitation focuses on the treatment of acidosis, coagulopathy and hypothermia, also known as the “lethal triad”. While treatment guidelines already exist for acidosis and bleeding, there is no evidence-based systematic approach for preventing and managing hypothermia in trauma patients in the prehospital setting [3, 5, 11].

The incidence of accidental hypothermia is difficult to estimate. A study using a specially designed questionnaire, had the aim to estimate the prevalence of accidental hypothermia in Poland. They found that the actual incidence of accidental hypothermia in Polish emergency departments may exceed up to four times the official data. They suggest this may be a result of the lack of unified guidelines, and that the data concerning the morbidity and mortality rates do not appear to fully represent the problem [12].

A randomized trial including 100 patients with minor trauma, found T core < 36°C in 80% of the patients, and T core < 35°C in 27%. From time of rescue until arrival at the hospital, mean T core decreased further [7].

A retrospective investigation of the trauma register in Germany documented patients between 2002 and 2012. The goal was to describe the epidemiology of accidental hypothermia in polytraumatized patients. The study included more than fifteen thousand multiple-injured patients, and temperature was below 36.0°C in approximately 30% of the patients. Temperatures below 34,0°C had close to 33% mortality rate [13].

In the prehospital care of a cold and wet patient, early application of adequate insulation is of utmost importance to reduce cold stress, limit body core cooling, and prevent deterioration of the patient’s condition. Recommendations and guidelines for handling the hypothermic patient in the prehospital setting, are mostly based on tradition and local experience, not on scientific evidence [6, 14]. Prehospital guidelines on protection against cold recommend the removal of wet clothing prior to insulation, or the use of a vapor barrier between the wet patient and the insulation to reduce evaporative heat loss [4, 10, 15]. Structured protocols should be in place to optimize prehospital care, transport and treatment, and recommendations should focus on a small set of universally available options [4].

Methods

Study design, aim and outcome measures

This is a field study designed as a crossover clinical trial. The aim was to compare the removal of wet clothing versus keeping the wet clothing, prior to vapor barrier and insulation. The outcome measures were skin temperature (T skin) and a subjective evaluation of comfort, thermal sensation, and shivering.

Participants

Test subjects were recruited among health care workers and medical students. Inclusion criteria were >18 years of age, non-nicotine using healthy individuals. All subjects abstained from physical exercise and alcohol 24 hours prior to the study.

Study setting

Location

The study took place in a snow cave (4.9m x 2.7m x 1.7m) in Hemsedal village, 660 meter above sea level, in March 2017. Ambient temperature and humidity in the snow cave, the resting area and outside was recorded every minute throughout the study day.

Clothing

Cotton T-shirts, long sleeved shirts, and trousers were prepared by leaving the clothing in a sealed plastic bag containing 700 ml water over night in a warm bathroom. Dry fleece hats and mittens were used for insulation of head and hands, and the participants wore similar dry cotton socks and sneakers.

Preparation

The participants were divided into two groups, and the groups alternated between resting and participating in the experiment. The participants arrived at the preparation room before the test wearing only underwear, and they got assigned a personal assistant for the whole study period. Assistants helped the participants to get fitted with skin thermistors and dressed, and baseline measurements were made. The participants then walked outside for 100 meters from the preparation room to a sheltered snow cave, and were placed in a supine position on a 14-mm sleeping mat (Mammut Bamse Extreme, Mammut Sports Group, Seon, Switzerland) on the snowy ground.

Experiment

After a 30 minutes initial cooling phase, the participants either got the wet clothing removed (dry group, DG), or kept the wet clothing on (wet group, WG). The participants stayed still in a supine position while assistants cut the clothing. The cutting was pre-rehearsed and was timed to be exactly alike each time. Starting from the sternal notch, the cutting was conducted medially over the torso to the pants line. Then, both sleeves were cut from the wrist to the shoulder and neck. The trousers were cut from the waistband medially down both lower extremities to the ankle. Using a log roll technique, the wet clothing were removed from underneath the participants. Both the dry group and the wet group were wrapped in a vapor barrier (Bubble wrap, TAP Telion-Air-Pac GmbH, Braunschweig, Germany), a dry insulation layer (cotton, plaited ambulance blankets), and a windproof thermal rescue bag (Fjellduken Thermo Hunter, Jerven AS, Odda, Norway).

Between each scenario the participants were to recover for a minimum of 120 minutes in room temperature (temp. 22.27 ± 1.18°C) to avoid crossover effects, and they were encouraged to rest and be thermally comfortable during this period. Each participant served as his or her own control, and after the resting period the opposite scenario was conducted. This means that heats 1 and 3, and heats 2 and 4 contained the same participants (Figure 1). A detailed time sheet for each scenario is presented in Table 1.

Table 1. Detailed time sheet for each scenario

Total time	**Time**	**Action**
- 30 min.	30 min.	Resting period
Start	Start	Participants met in the preparation room wearing only underwear.
5 min.	5 min.	Monitoring equipment was placed by assistants.
7 min.	2 min.	Assistants helped participants dress in equal, wet clothing
10 min.	3 min.	Both assistants and participants went outside, walked 100 meters and entered the snow cave. Participants laid down simultaneously.
40 min.	30 min.	Cooling period. T skin every 60 seconds, and cold discomfort was recorded every 9 minutes by assistants.
45 min. (1) or	5 min. (1) or	Assistants cut clothing simultaneously and wrapped participants in insulating layer using equal, pre-rehearsed technique.
45 min. (2)	5 min. (2)	Assistants wrapped participants in insulating layer using equal, pre-rehearsed technique.
1 hour 15 min.	30 min.	Passive rewarming. T skin every 60 seconds, and cold discomfort was recorded every 9 minutes by assistants.
3 hours 15 min.	120 min.	Back to preparation room. Assistants helped remove monitoring equipment and dress in dry clothes. Rest and recovery.

Instrumentation and measurements

Skin temperatures was measured using thermistors (YSI-400 Yellow Springs Instrument, USA, accuracy ± 0.15°C) connected to a datalogger (Smart Reader Plus 8 ACR Systems

INC., USA). Skin thermistors were places on seven predefined locations (head, arms, hands, feet, legs, thighs and trunk). Mean T skin was calculated using the Hardy and Dubois formula.

Local and overall thermal sensation, thermal comfort and degree of shivering/sweating were measured using a modified and validated questionnaire developed by Nielsen et al. 1993 [16].

Interruption criteria

The participants could withdraw from the study without any explanation at any point.
The test was to be terminated if one or more of the skin thermistors recorded temperatures of 10°C or less for more than 20 minutes.

Power calculations

Assuming changes observed in Henriksson 2015 [10], power analysis indicated that a minimum of 6 participants were needed (in a crossover design) for a temperature difference of 1.2 degrees and a standard deviation of 0.8, a power of 0.8 and a significance level of 0.05 using a paired t-test. Taking into account drop out, e.g., due to technical issues, 8 participants were included. A block randomization for block size 4 was used, i.e., each test run was randomized separately.

Statistical analysis

Changes in T skin were assessed by ANCOVA adjusted for baseline temperature and for random effect due to participants being their own control. An ANCOVA was calculated for each measuring time point after baseline. Elapsed time until return to baseline temperature was estimated, and a paired t-test was used to identify significant differences between the two groups. The subjective ratings of thermal comfort, thermal sensation, and degree of shivering were assessed by graphical and descriptive methods.

P-values less than 0.05 were considered significant. All computation and graphical illustration has been done in Matlab 9.0 (Natick, MA) and IBM® SPSS® Statistics Version 25 (IBM Corporation, Armonk, NY, United States).

Ethical considerations

The project was approved by the Regional Ethics Committee for Medical and Health Research (2017/150/REK nord).

Results

A total of 8 volunteers were included, and written informed consents were obtained. The participants characteristics were as follows: median age 28.5 (range 21-47 years); height 180.0 cm (range 168-188 cm); and body mass index (BMI) 23.0 (range 17.7-33.2). 5 were male and 3 were female. During the experiment we used 7 measuring points on each of the 8 participants. Measuring each minute during the 2 different scenarios resulted in 7280 measurements during the study day. No single measurement or series showed any errors, and all could be included. The study protocol was executed as planned, and no participants withdrew from the experiments.

Environmental conditions during the study day are shown in Figure 1. Regarding relative humidity (RH) throughout the day, there were considerably more stable conditions inside the snow cave than outside.

The exposure time was less than 2.5minutes (min. 2 minutes 0 seconds, and max. 2 minutes 18 seconds) for all the participants.

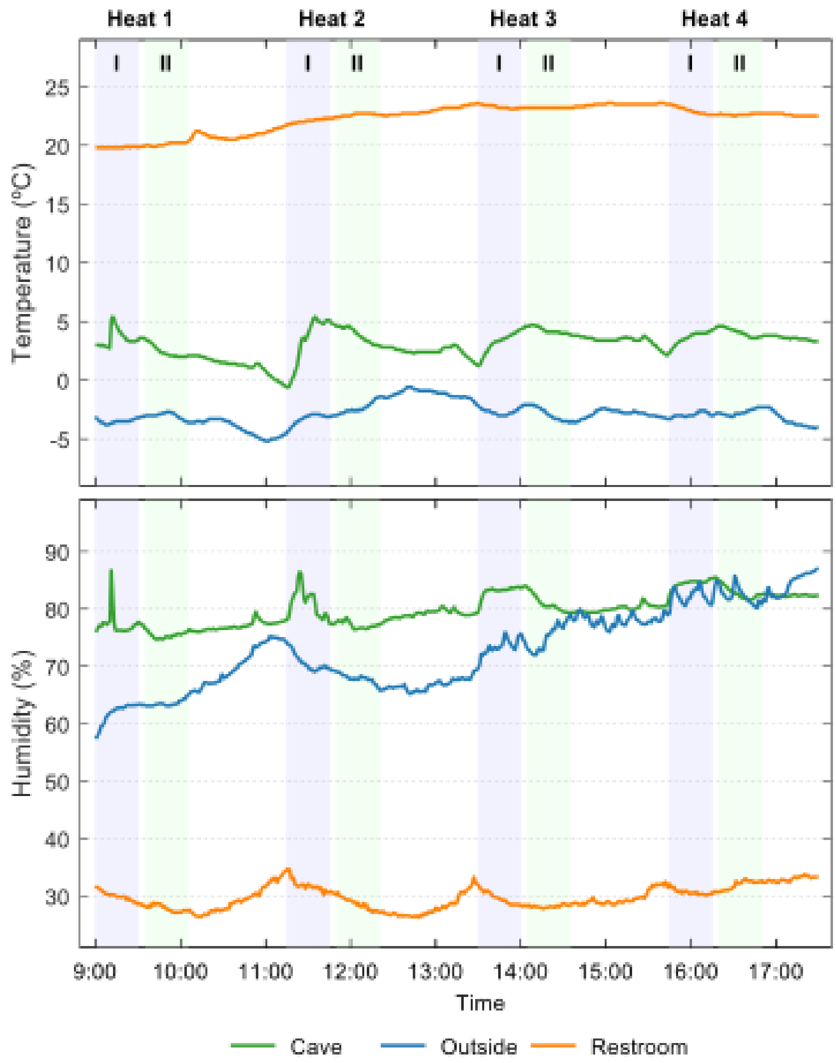

Figure 1. Environmental conditions during the study day. Heats 1 and 3, and heats 2 and 4, contained the same participants.

Skin Temperature (T skin)

Mean T skin change for both the wet group and the dry group with 95% confidence interval (CI) and the result of the ANCOVA analysis is presented in Figure 2. Coefficient B shows the mean temperature difference between the groups adjusted for baseline. The difference seems to stabilize after approximately 10 minutes. The dry group returned to baseline temperature after a mean of 12.5min (SD 8.3, 16.7) while the wet group needed 28.1min (SD 18.8, 37.4), p=0.003. According to ANCOVA there was a significant effect 2 minutes after the subjects were wrapped ($p<0.05$). A p-value of 0.005 shows a significant effect 10 minutes after wrapping.

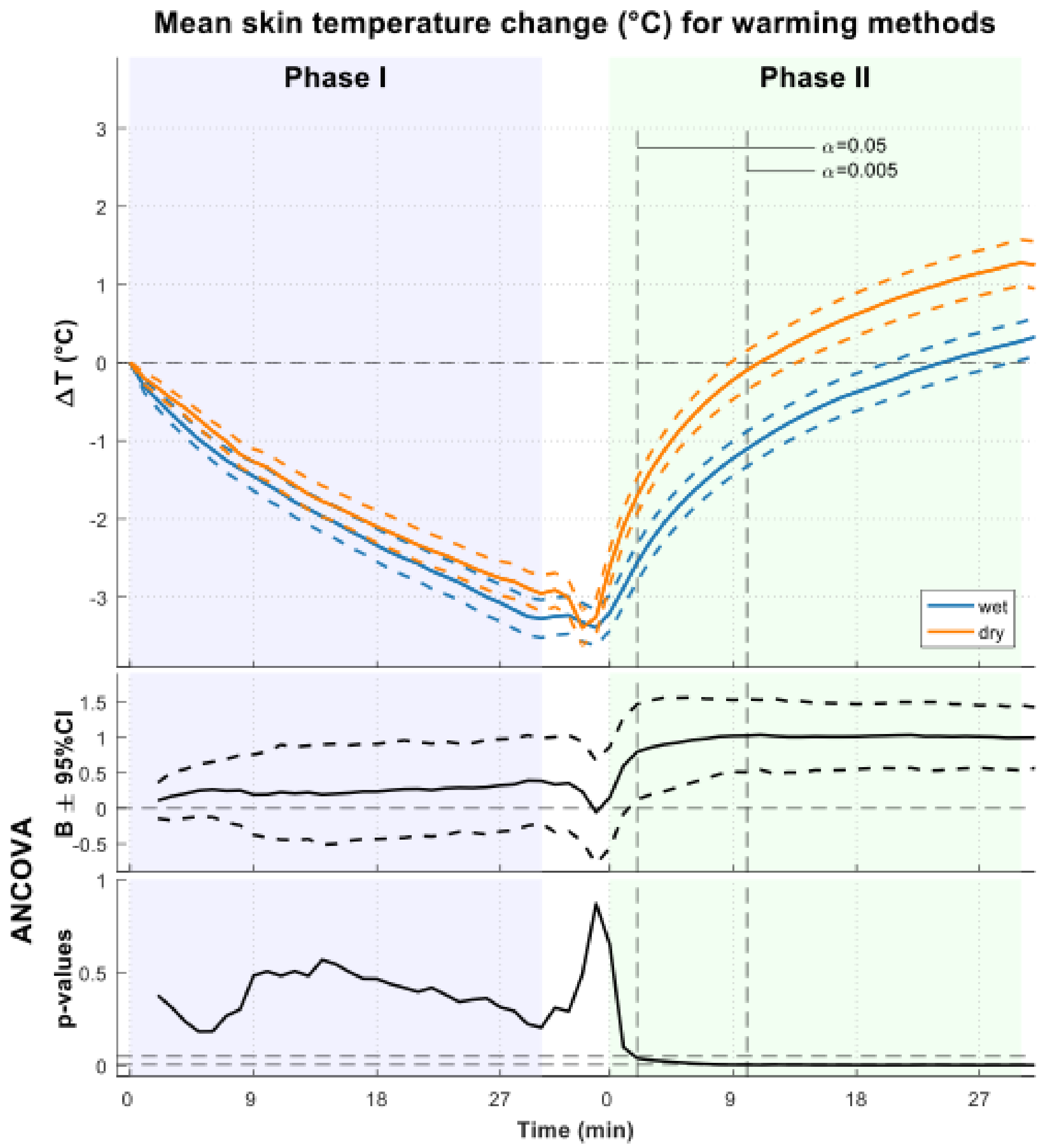

Figure 2. Mean T skin change for both groups with 95% CI and the result of the ANCOVA analysis. Coefficient B shows the mean temperature difference between the groups adjusted for baseline.

Thermal comfort and degree of shivering

The dry group shows a significant change in skin feeling immediately after the wet clothing was removed (Figure 3). Before and after the intervention the answers are stable. The wet group shows no such change, and the answers are stable from start to finish.

Regarding thermal sensation and shivering/sweating the data is not significant, and the reason might be the small sample. However, there is a trend indicating that the dry group is slightly warmer and feeling more comfortable than the wet group. Subjective evaluations were obtained every 9 minutes during the experiment.

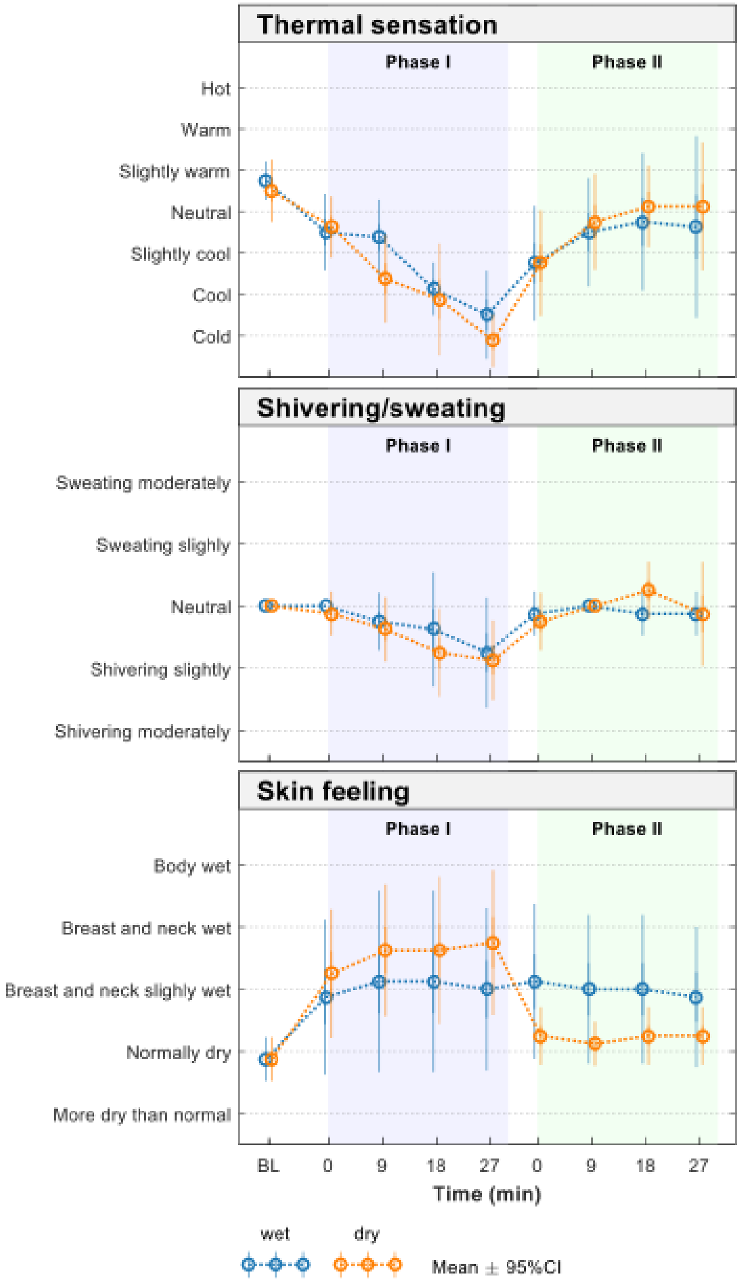

Figure 3. Mean ± 95% CI for thermal sensation, degree of shivering/sweating, and skin feeling.

Discussion

Skin temperature (T skin)

The main finding shows that the dry group had a higher mean T skin change than the wet group. There were significant differences in the two groups 2 minutes after the participants were wrapped. The difference seems to stabilize after approximately 10 minutes. In addition, the dry group returned to baseline temperature in less than half the time the wet group needed (12.5min vs. 28.1min), and there was a clear positive effect of removing the wet clothing.

Studies show that both removal of wet clothing and adding a vapor barrier substantially decreases evaporative heat loss from a casualty [2, 4, 10, 15, 17]. A Swedish manikin study found that the removal of wet clothing or the addition of a vapor barrier resulted in a reduction in total heat loss of 19-42% (calculated in Watts/m_2 body surface area) [15]. The same research group showed in a later study that wet clothing removal or the addition of a vapor barrier significantly increased T skin rewarming. They concluded that in a sustained cold environment with limited shelter available, such as in protracted evacuations or mass casualty situations in harsh conditions, wet clothing removal or the use of a vapor barrier is recommended to limit the need for shivering thermogenesis and improve the patient's condition on admission to the emergency department [10, 18].

A different study conclude that appropriate measures to avoid cold exposure include moving the patients into a shelter if possible, removing of wet clothing, insulating the patient from the ground, and containing endogenous heat production with an adequate wind- and waterproof outfit/cover [6].

Some studies point out that although removing wet clothing may increase patient comfort, it may result in increased rapid cooling during the exposure. They consider the wet clothing removal unnecessary in a cold or windy environment if a vapor barrier is used [4, 10, 18]. Our findings show that it might be preferable to remove wet clothing regardless of the weather conditions. The exposure during wrapping does not appear to have any significant effect. The temperature of the wet group drops a little more in phase 1 than in the dry group, but this seems to be a coincidence due to a small sample while the exposure was not very strong (no wind, snow or rain). In addition, we may have too rough time measurements to catch the minimum point. We would assume that the effect is slightly overestimated, and would be a bit weaker in reality.

For all the participants the exposure time was less than 2.5 minutes, and when dry group had a significantly higher increase in mean temperature change only 2 minutes after wrapping, the benefit of removing wet clothes seems to outweigh the disadvantage of the exposure. However, the relatively short duration of both cold exposure and the subsequent insulation intervention should be considered. By using a pre-rehearsed technique for cutting and wrapping we reduced the exposure time to a minimum. In a real life scenario, the exposure might be substantially longer.

Thermal comfort and degree of shivering

Thermal comfort seems to improve patients' psychological and physiological status, and warmth seems to contribute to experiences of comfort and safety [19]. In this study the dry group felt warmer and had a dry skin feeling after wrapping, while the wet group felt that the breast and neck area was slightly wet during the whole experiment. The results are not significant, likely because of the small sample, but there is a trend indicating that the dry group is slightly warmer and feeling more comfortable than the wet group. During the initial 30-minute cold exposure in our study, heat loss from the skin and the subsequent vasoconstriction rendered a significant decline in mean T skin, and this cold stimulus triggered shivering in our participants.

Cold is an unpleasant sensation for patients, and thermal discomfort contributes to increased pain, fear and anxiety, an overall sense of dissatisfaction, and a fear of dying [9, 20-22]. A field study with the aim to investigate injured and ill patients' experiences of cold exposure, found that cooling of the back and chest were the leading influences of the overall sensation of discomfort from cold [20].

A qualitative study focusing on the experience of being cold, found that initially the pain was the main problem for the patients and not the feeling of being cold. However, thermal discomfort from cold increased with time and became the patients' primary problem independent of the severity of their injuries, and shivering was described as the worst experience of all [21].

Clinical implications and future research

These results show a significant difference in T skin between the dry group and the wet group, and may serve as a recommendation to remove wet clothing if possible. This finding may be important for how the professional and the volunteer health and rescue services around the world train and equip their personnel.

Further studies are needed to increase knowledge that can be a base for clinical implications in prehospital care. Future research should focus on real life scenarios collecting data from hypothermic patients. In harsher weather conditions an exposure might affect patients more than in our study.

We recommend rehearsing cutting of clothes and wrapping in vapor barrier and insulation to keep the exposure time to a minimum.

Strengths/Limitations

The study enrolled healthy volunteers with a normal temperature, and the results may not be predictive for all real life scenarios. The age, injuries, and physical condition of the patient might affect heat loss and thermoregulation capabilities, as well as practical aspects of possible insulation interventions. Thermal comfort can also be different in real life scenarios. Injured or sick patients may have a worse experience of thermal discomfort in a decreased temperature compared to young and healthy study participants. Despite this, we believe the results are transferable to a clinical setting because the experiment was set in controlled conditions without influences of fear and pain that can influence the vasoconstriction and the feeling of chill/cold.

Despite standardization, a field study may be biased by changes in temperature and wind. By conducting the study in a snow cave, we removed the wind impact and limited the temperature fluctuation, but we can never control the environment 100% unless using a laboratory. Additionally, accidental hypothermia can happen in any environment, and the sheltered snow cave will only reflect a limited number of real-life situations.

The participants were not blinded, and this may have influenced the subjective scorings. However, we do not think this caused any systematic bias since they were not informed of the temperature measurements or recordings before or during the tests. Neither did they have any knowledge on the assumed effects of the different treatment methods. Although there were a limited number of participants in this study, the crossover design enabled comparative evaluation of the interventions. However, a systematic bias cannot be excluded.

Conclusion

The benefit of removing wet clothes seems to outweigh the disadvantage of the exposure, and appears to be preferable to keeping the wet clothing underneath a vapor barrier.

List of abbreviations

95% CI – 95% confidence interval

°C – Degrees Celsius

RH – Relative humidity

T core – Body core temperature

T skin – Skin Temperature

Declarations

Ethics approval and consent to participate

The project was approved by the Regional Ethics Committee for Medical and Health Research, 2017/150/REK nord. All data is anonymous, and participants gave written consent prior to the study.

Consent for publication

Not applicable.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Not applicable (for the master thesis assignment and the university).

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Appendix 1: Guide to authors

Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine does not place a formal limit on the number of words, references or figures/tables in its articles. However, our editors do expect submissions to be concise. When writing your manuscript, be as brief as possible without omitting essential details.

Quick points:

- Use double line spacing
- Include page numbering
- Do not use page breaks in your manuscript

The title page should:

- present a title that includes, if appropriate, the study design.
- list the full names, institutional addresses and email addresses for all authors
- indicate the corresponding author

Abstract

The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study was performed, and how statistical tests were used
- **Results:** the main findings
- **Conclusions:** brief summary and potential implications

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study was necessary or its contribution to the field.

Methods

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions and comparisons. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses
- the type of statistical analysis used, including a power calculation if appropriate

Results

This should include the findings of the study including, if appropriate, results of statistical analysis which must be included either in the text or as tables and figures.

Discussion

This section should discuss the implications of the findings in context of existing research and highlight limitations of the study.

Conclusions

This should state clearly the main conclusions and provide an explanation of the importance and relevance of the study reported.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided.

Declarations

All manuscripts must contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and material
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements

Preparing figures

- Multi-panel figures (those with parts a, b, c, d etc.) should be submitted as a single composite file that contains all parts of the figure.
- Figures should be numbered in the order they are first mentioned in the text, and uploaded in this order.
- Figures should be uploaded in the correct orientation.

- Figure titles (max 15 words) and legends (max 300 words)

Preparing tables

- Tables should be numbered and cited in the text in sequence using Arabic numerals (i.e. Table 1, Table 2 etc.).
- Tables less than one A4 or Letter page in length can be placed in the appropriate location within the manuscript.
- Table titles (max 15 words) should be included above the table, and legends (max 300 words) should be included underneath the table.
- Color and shading may not be used. Parts of the table can be highlighted using superscript, numbering, lettering, symbols or bold text, the meaning of which should be explained in a table legend.
- Commas should not be used to indicate numerical values.

References

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. The reference numbers must be finalized, and the reference list fully formatted before submission.

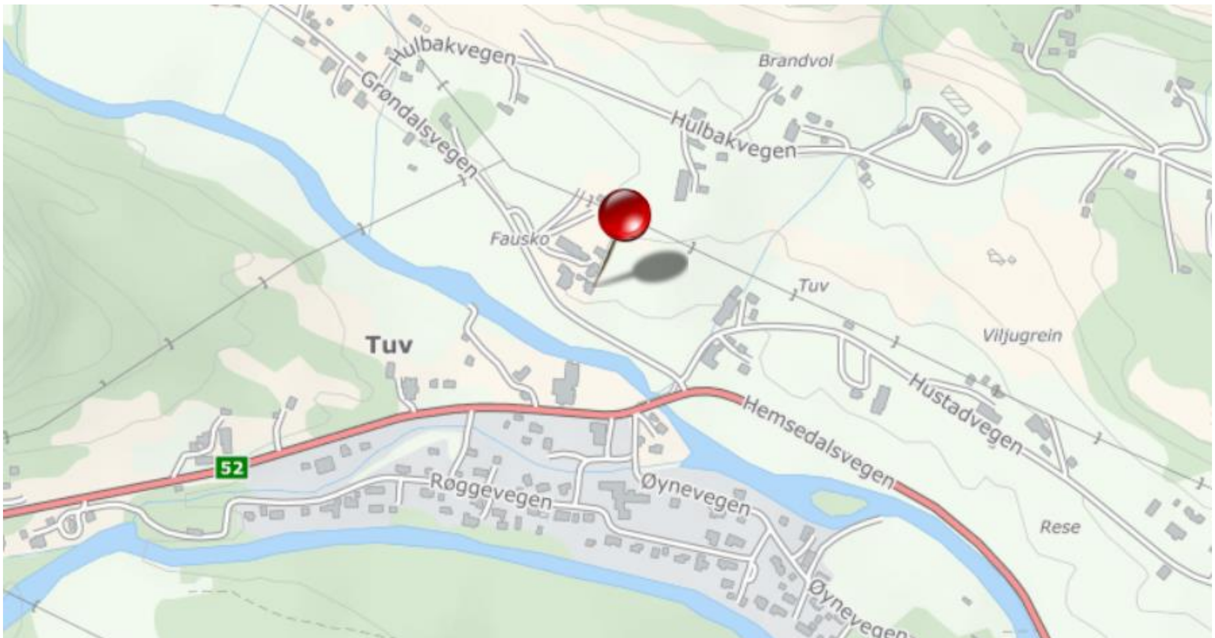
Appendix 2: Informasjon til deltakere på MountainLab 2017

Bergen 03.03.17

Velkommen som deltaker på MountainLab 2017!
Som nevnt i invitasjonen dekker vi overnatting og mat under forsøket. Dersom du har matallergier vi ikke allerede har fått vite om, må vi få beskjed snarest.

Transport til og fra Hemsedal ordner dere i utgangspunktet selv. Om noen ønsker å ta tog, kan vi være behjelpelig med å få hentet dere på Gol. Vi vil også prøve å formidle kontakt mellom de av dere som ønsker transport og dem som har mulighet til å kjøre. Vi prøver å få en endelig oversikt over dette i løpet av helgen.

Oppmøte
Informasjonsmøtet starter presis kl. 20.00 onsdag 8.mars på Fausko skysstasjon på Tuv ca. 5 minutter vest for Hemsedal sentrum. For mer informasjon se her: www.fausko.no



Innkvartering
Overnatting onsdag til torsdag er på enkelt- og dobbeltrom på Fausko skysstasjon. Dere trenger ikke å ta med sovepose. Det vil bli servert kveldsmat onsdag, frokost torsdag og smørelunsj i løpet av torsdagen. Om dere ønsker drikkevarer utover det som blir servert må dere dekke det selv.

Videre opphold i Hemsedal etter at forsøket er ferdig
Forsøket varer til torsdag ca kl. 18.00. De som ønsker å overnatte til fredag, eller hele helgen, vil kunne bo gratis på hytta til Øyvind. Dette er en enkel hytte med 10 sengeplasser, strøm og vann, og som ligger ca. 15 min. kjøring fra Fausko. Et glitrende utgangspunkt for fjellskiturer, boklesing eller kjøring i skianlegget.

Ta med

- Dunjakke eller annen tykk utejakke
- Termos til varm drikke
- Votter og lue
- Vintersko
- Vinterbukse
- Sovepose eller sengetøy dersom du skal overnatte på Øyvinds hytte
- Joggesko
- Tynne strømper
- Undertøy som kan eksponeres, pluss tørt ekstra skift
- Vi stiller med klærne som skal vætes og klippes under forsøket.

Annet
Vi trenger høyde og vekt på forsøkspersonene. Fint om du sjekker dette dersom du er i tvil om dagens status.

Noen av dere vil være forsøkspersoner mens andre blir assistenter som skal montere utstyr og gjøre målinger. Fordelingen av dette blir presentert onsdag kveld.

Vennligst ta kontakt med Linn Therese Hagen dersom du har spørsmål.

Vennlig hilsen

Øyvind Thomassen
Overlege
Akuttmedisinsk avdeling, Helse Bergen

Linn Therese Hagen
Masterstudent
Universitetet i Stavanger

Øyvind: oyvt@helse-bergen.no mobil 977 18 721
Linn Therese: lthagen@gmail.com mobil 920 58 152

HELSE BERGEN
Haukeland universitetssjukehus

Universitetet
i Stavanger

Appendix 3: Samtykke til deltakelse i forskningsprosjekt

En sammenligning mellom to ulike innpakningsmetoder for den hypoterme pasienten

Dette er et spørsmål til deg om å delta i et forskningsprosjekt for å sammenligne to ulike metoder for innpakning av hypoterme pasienter. Målet er å undersøke om tøyet til en våt og kald pasient bør klippes bort, eller om pasienten bør beholde det våte tøyet på og pakkes inn i plast (dampsperre) før innpakning i et lag av tørt, isolerende materiale.

Hva innebærer prosjektet?
Du vil bli utsatt for kulde-eksponering i to ulike scenarioer mens det måles temperatur.

Vi starter innendørs der du vil få festet 7 sensorer for måling av hudtemperatur. Deretter kles alle 8 deltakerne opp i like, vanlige, våte klær før vi går utendørs. Estimert utetemperatur vil være ±0°C (min. -5°C) og max. wind 5 m/s. Dersom det er kaldere eller mer vind, vil forsøket foregå i et skjermet område.

Du skal ligge på et liggeunderlag ute i snøen i 30 minutter. Herfra er det to ulike scenarioer i tilfeldig rekkefølge.

1. Alle klær, utenom undertøy, klippes av med tøysaks før du får på nye, tørre klær og pakkes inn i et lag isolerende materiale.

2. Du beholder de våte klærne på, pakkes inn i plast (dampsperre) før du pakkes inn i et lag isolerende materiale.

Du skal så ligge i nye 30 minutter på liggeunderlaget ute. Deretter avsluttes forsøket, og du får hvile og varme deg i et romtemperert rom. Etter ca to timer skal du gjennom det motsatte scenariet.

Forsøket avbrytes dersom en eller flere av sensorene for hudtemperatur blir værende under 10°C i mer enn 20 minutter. Graden av kuldeubehag vil også bli evaluert hvert 10. minutt.

I prosjektet vil vi innhente og registrere opplysninger om høyde og vekt. Det er en forutsetning at du er frisk og ikke røyker eller snuser for å delta i studien.

Du får ingen betaling for å delta, men du får dekket overnatting og mat under studien.

Frivillig deltakelse og mulighet for å trekke sitt samtykke
Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner. Dersom du

senere ønsker å trekke deg eller har spørsmål til prosjektet, kan du kontakte Linn Therese Hagen på tlf 92058152, eller e-post lthagen@gmail.com.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger.
Prosjektleder har ansvar for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte.

Godkjenning
Prosjektet er godkjent av Regional komite for medisinsk og helsefaglig forskningsetikk, 2017/150/REK nord

Samtykke til deltakelse i prosjektet «En sammenligning mellom to ulike innpakningsmetoder for den hypoterme pasienten».

Jeg er villig til å delta i prosjektet

....	....
Sted og dato	Deltakers signatur
	....
	Deltakers navn med trykte bokstaver