

Safety and Efficacy of CarbonCool Half-Body Vest for HAZMAT Decontamination Crews Wearing Personal Protective Equipment: A Pilot Study

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Keywords: cooling vest; PPE; reusable vest

Abbreviations:

DBP: diastolic blood pressure
HAZMAT: hazardous materials
HR: heart rate
HRI: heat-related illnesses
PPE: personal protective equipment
SBP: systolic blood pressure

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Abstract

Background: Personal protective equipment (PPE) are essential for medical personnel responding to hazardous materials (HAZMAT) incidents. However, their impermeable design causes increased physiological strain and reduced thermoregulation, limiting work times and causing heat-related illnesses (HRI). Use of wearable cooling devices slow heat accumulation and have been shown to reduce thermal and cardiovascular strain in such situations.

Methods: This was a prospective clinical evaluation to determine the tolerability and effectiveness of the CarbonCool cooling system – a half-body cooling vest – in participants undergoing a HAZMAT decontamination recertification. Physiological measurements (heart rate [HR], weight, temperature, and blood pressure) and participant feedback were obtained. The main outcome of interest was participants' tolerability of the cooling vest.

Results: A total of 23 healthy participants were recruited, with 10 randomized to the intervention group and 13 in the control group. Mean age in the control and intervention group was 35.5 years old (SD = 7.8) and 30.0 years old (SD = 6.2), respectively. Qualitative feedback obtained from participants regarding safety, mobility, and cooling efficacy was largely positive. Difference of before–after temperature and HR was 0.3°C (SD = 0.8) and 11.5bpm (SD = 13.6) in the control group compared to 0.0°C (SD = 0.5) and 0.0bpm (SD = 6.4) for the intervention group.

Conclusion: This clinical evaluation showed that the CarbonCool cooling vest is safe and tolerable in participants wearing PPE. Further trials with sample size powered to detect physiological outcomes are needed to assess the effect of the cooling vest on a subject's endurance to heat stress.

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Introduction

Incidents involving the release of hazardous materials (HAZMAT) often occur unexpectedly, threatening both individual and public health. One such example would be the 2011 Fukushima Daiichi Nuclear Power Plant (Japan) incident which contributed to 600 disaster-related deaths and an increased radiation risk to 20,000 nuclear plant workers.¹ Another incident involving nerve gas poisoning in the Tokyo, Japan subway resulted in 11 deaths and more than 5,000 people requiring emergency medical evaluation.² Furthermore, the lack of adequate decontamination and personal protective equipment (PPE) protocol led to 23% of staff at the responding hospital experiencing secondary exposure to Sarin.³ Personal protective equipment play an essential role in HAZMAT incidents, minimizing the risk of secondary infection of patients and emergency medical responders.

As full-body garments, PPE are designed to be impermeable, and with high insulation capabilities, in order to provide the necessary protection from fire, chemical, biological, radiological, nuclear, and explosive (CBRNE) hazards.⁴ However, this also leads to increased physiological strain, reduced thermoregulation ability, and decreased heat transfer to the environment,^{5,6} thereby exacerbating heat stress and limiting work times.^{7–9} Heat stress is a known occupational health hazard¹⁰ that leads to reduced work capacity and

productivity,^{11,12} reduced cognitive performance,^{13–15} and an increased risk of accidents and occupational injuries.^{15,16}

In addition to heat stress, PPE users are also at increased risk of suffering from heat-related illnesses (HRIs). The adverse effects of HRIs have been demonstrated in numerous studies across professions utilizing PPE, such as health care personnel of Ebola treatment centers,⁹ construction workers in Hong Kong,¹⁷ mine rescue workers,¹⁸ and fire fighters.⁸ Up to 74.8% of firefighters were found to have experienced HRI symptoms, with 5.0% experiencing such symptoms 20 times or more in a year.⁸ Myocardial infarctions are the leading cause of fire fighter deaths in the United States and are attributed to the additional strain on the cardiovascular system caused by high thermal loads.¹⁹ Illnesses can rapidly progress to heat exhaustion, collapse, and even death from heat stroke,²⁰ thus necessitating proper assessment and management of HRIs. Health care workers are particularly at risk due to their lack of acclimatization.

While mild heat stress may not lead to significant adverse effects, development of hyperthermia often progresses insidiously and may remain undetected initially.²¹ Furthermore, multiple factors such as environment, activity, and individual variation contribute towards one's risk of occupational heat exposure, making it immensely difficult to accurately predict the risk of HRI.¹⁰ Monitoring the extent of heat stress is not logistically nor financially feasible, and efforts should be concentrated on methods to minimize occupational heat stress and discomfort instead.

Wearable cooling devices allow for personal microclimate cooling and are another method aimed at reducing the adverse effects of heat stress from PPE use. Previous studies have explored the use of both passive²² (ie, chilled garments and ice packs) and active cooling devices (usually involving a pump circulating chilled coolant).^{9,23} While active cooling devices are able to attain a higher rate of cooling, this comes with many drawbacks, including the need for external powering and their greater weight. An ideal cooling device for PPE users should be lightweight, easy to don/doff, and not hinder the individual's mobility.

This was an observational, clinical implementational study to determine the effectiveness of the CarbonCool cooling system (Global Healthcare SG; Singapore) – a half-body cooling vest – in participants undergoing a HAZMAT decontamination recertification exercise. Physiological measurements such as heart rate (HR), weight, temperature, and blood pressure were obtained. Specific feedback on the experience by participants was also reported.

This study hypothesizes that the cooling vest would help to reduce heat stress, as assessed through physiological measurements and qualitative surveys. The main outcome of interest is safety and tolerability – whether participants have to abort the use of the cooling vest due to discomfort or cold injuries.

Methods

Study Design and Methods

This was a prospective, single-center, observational and feasibility study. The study was conducted on two separate occasions during the Hospital Decontamination Recertification Exercise for HAZMAT (Singapore General Hospital; Singapore) in 2016 and 2018. Six cooling vests were provided on the first occasion and four suits on the second occasion. These were allocated to participants who were thus designated as the intervention group, while the remaining participants were allocated into the control group. Due to practical considerations, there was no blinding of participants to the allocated intervention or control. The data analyst was blinded to treatment allocation.

As a pilot study, the aim was to assess the safety and efficacy of the CarbonCool half-body vest.

The institute's Central Institutional Review Board granted exemption for this research project (CIRB 2018/3189).

Setting

This study was conducted at Singapore General Hospital, Singapore in an outdoor setting. Singapore is a highly urbanized, small tropical island, with a land area of approximately 276.1 square miles and population density of 20,065 persons per square mile.²⁴ Temperatures in Singapore range from an average of 23.3°C to 31.7°C (73.9°F–98.8°F) daily, with high humidity and rainfall throughout the year.²⁵

Selection of Participants

A total of 12 male and 11 female participants from Singapore General Hospital took part in this trial. Participants were all healthy staff (without comorbidities) who had undergone training as decontamination staff for mass HAZMAT incidents with yearly recertification. There were 13 participants in the control group and 10 participants in the intervention group.

Interventions

Written informed consent was obtained from subjects prior to the start of trial procedures. No additional training was conducted prior to the actual trial as participants were already trained in both the exercise and the donning of PPE. All participants were required to wear standard PPE necessary for hospital decontamination station crew during HAZMAT operations and training. Participants in the intervention group wore the CarbonCool vest over a T-shirt, followed by the standard PPE (CLD500 suit; Paul Boyé Technologies; Labarthe-sur-Lèze, France), which is a Level B suit consisting of a full face-piece with an airway purifying respirator and chemical resistance clothing.²⁶ Participants in the control group wore only a T-shirt and standard PPE. All participants were subject to the same amount of physical activity during the training exercise and donned the PPE for a total of 55 minutes.

CarbonCool Cooling System

The CarbonCool cooling system consists of a free-size half-body sleeveless vest made of neoprene and thermoplastic polyurethane and can hold up to 12 MPad (Global Healthcare SG; Singapore); MPad encases a graphite water solution found to be 15-times more thermally conductive than ice and is responsible for the cooling properties of the vest.

The MPad is located within the external material at the abdominal, shoulder, as well as upper and lower back area regions. The cooling vest was fitted over a T-shirt, with Velcro straps used to secure the vest snugly around the user. Each CarbonCool vest weighs less than four kilograms and is manufactured to be suitable for up to one hour of use. The MPad was kept in a freezer for at least 24 hours prior to use in the study, then was subsequently placed in the pad holders of the vest.

Physiological Measurements

For each participant, weight, body temperature, heart rate (HR), and both systolic blood pressure (SBP) and diastolic blood pressure (DBP) were recorded before donning the PPE and CarbonCool vest and again after the training exercise concluded. Heart rate and blood pressure readings were obtained using the Propaq CS monitor (Welch Allyn, Inc.; Skaneateles Falls, New York USA). Temperature was measured using Covidien tympanic thermometer (Covidien LLC; Mansfield, Massachusetts USA).

		Control Group	Intervention Group	P Value
		(n = 13)	(n = 10)	
	Age in years (Mean, SD)	35.5 (7.8)	30 (6.2)	.071
	Gender (Female) (n, %)	7 (53.8)	4 (40)	.68
	Gender (Male) (n, %)	6 (46.2)	6 (60)	
Before Decontamination Exercise	Weight, Kg (Mean, SD)	67.7 (11.2)	66.9 (10.9)	.863
	Temperature, °C (Mean, SD)	37 (0.6)	37.2 (0.6)	.432
	Heart Rate, bpm (Mean, SD)	79 (11.6)	89.8 (12.3)	.046
	Systolic Blood Pressure, mmHg (Mean, SD)	121.5 (18.2)	128.6 (12)	.275
	Diastolic Blood Pressure, mmHg (Mean, SD)	71.5 (10.7)	71.8 (15.2)	.964
After Decontamination Exercise	Weight, Kg (Mean, SD)	67 (10.8)	66.7 (10.8)	.946
	Temperature, °C (Mean, SD)	37.3 (0.6)	37.1 (0.2)	.406
	Heart Rate, bpm (Mean, SD)	90.5 (12.9)	89.8 (14.3)	.91
	Systolic Blood Pressure, mmHg (Mean, SD)	123.6 (18.4)	126.1 (11.6)	.697
	Diastolic Blood Pressure, mmHg (Mean, SD)	70.3 (9.3)	72.9 (11.7)	.573
Difference Between Before-After Decontamination Exercise	Weight, Kg (Mean, SD)	-0.2 (0.2)	-0.2 (0.2)	.577
	Temperature, °C (Mean, SD)	0.3 (0.8)	0 (0.5)	.221
	Heart Rate, bpm (Mean, SD)	11.5 (13.6)	0 (6.4)	.015
	Systolic Blood Pressure, mmHg (Mean, SD)	2.1 (9.3)	-2.5 (10.2)	.282
	Diastolic Blood Pressure, mmHg (Mean, SD)	-1.2 (8.8)	1.1 (10.9)	.588

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Table 1. Demographics and Physiological Measurements in Control and Intervention Groups*Variables and Outcome Measures*

Primary outcomes are safety, comfort, and mobility of participants while wearing the cooling vest. This was assessed via qualitative surveys conducted after the exercise for participants in the intervention group. Secondary outcomes are physiological measurements such as HR, blood pressure, temperature, and weight. Heart rate and blood pressure were recorded and body temperature was measured using a tympanic thermometer.

Statistical Analysis

Descriptive statistics for basic demographics and outcome variables were calculated, with two-sample t-test for continuous variables and Fisher's Exact test for gender. Linear regression was used to study the effect of intervention on difference in before-after in physiological measurements, adjusting for age and gender. Data were analyzed using R (R Foundation for Statistical Computing; Vienna, Austria).

Results*Population Flow*

This study recruited 23 participants, 13 of whom were in the control group while 10 were in the intervention group. Measurements obtained from all patients in both groups were analyzed in their assigned groups. There were no crossovers between groups or drop-outs from either group.

Baseline Characteristics

Table 1 shows the basic demographics and vital signs of the control and intervention groups, both before and after donning the PPE. The mean age in the control group was slightly higher at 35.5 years old with SD = 7.8 as compared to the intervention group at 30.0 years old with SD = 6.2. Females made up 53.8%

and 40.0% of the participants in the control and intervention groups, respectively.

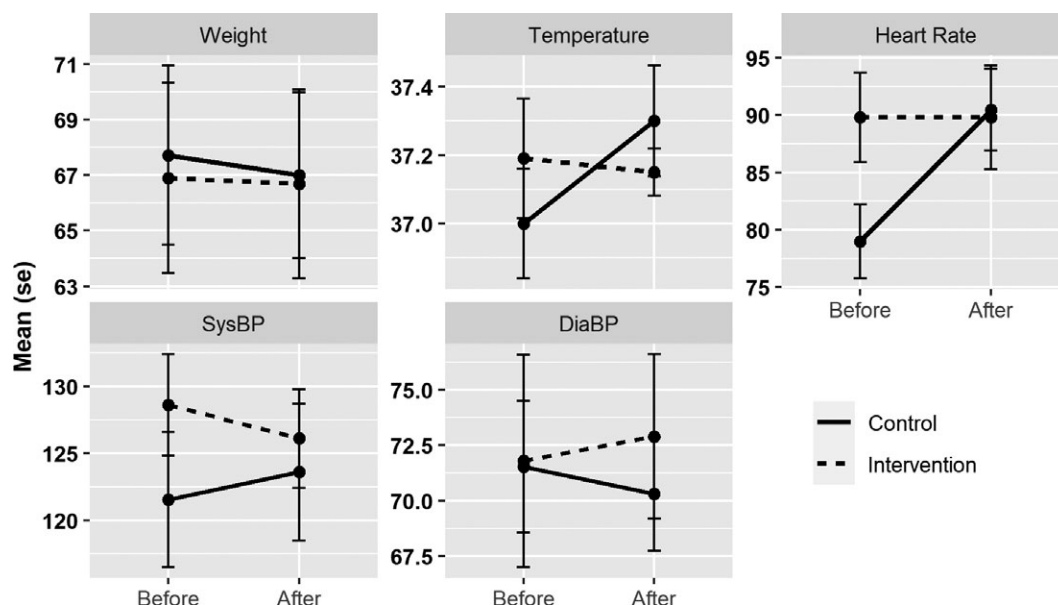
Perceptual Responses

Three main aspects of the vest (comfort, mobility, and other) were assessed. Feedback from the participants found that the cooling vest was comfortable, did not feel heavy, and gave a sensation of being cooled down. For mobility, movement was reportedly unhindered by the vest.

Participants reported positive feedback regarding the ease of wearing and removing the cooling vest. Cooling effects were also reported to have lasted for up to 45 to 55 minutes, after which the sensation of coolness started to diminish. Despite this, the vest remained comfortable.

Physiological Measurements

Trends in physiological measurement are seen in Figure 1. Participants in the intervention group showed a trend toward lower increase in body temperature and HR as compared to the control group, suggesting that the CarbonCool vest was successful in providing a cool microenvironment for PPE users. Linear regression for the effect of intervention with adjustment for age, gender, and baseline measurement was not statistically significant for all five variables. The estimated effect of the intervention for difference in before-after weight was 0.044 (95% confidence interval [CI], -0.112 to 0.199); difference in before-after temperature was -0.155 (95% CI, -0.647 to 0.338); difference in before-after HR was -7.742 (95% CI, -17.653 to 2.169); difference in before-after SBP was -0.735 (95% CI, -9.958 to 8.488); and difference in before-after DBP was 3.949 (95% CI, -3.707 to 11.605; Table 2). Difference of before-after temperature and HR were 0.3°C (32.5°F; SD = 0.8) and 11.5bpm (SD = 13.6) in



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Figure 1. Trend of Mean Physiological Measurements (with standard error bar) of Participants Before and After the Recertification Exercise.

the control group compared to 0.0°C (32.0°F; SD = 0.5) and 0.0bpm (SD = 6.4) for the intervention group (Table 1).

Discussion

This study aimed to investigate the safety and effectiveness of the CarbonCool vest for body cooling in a decontamination recertification exercise, taking into account both the physiological measurements as well as the perceptual response by participants. There is potential for use of the cooling vest across a wide range of fields for professions with mandatory PPE use, such as in HAZMAT decontamination, fire fighters, or health care personnel.

The main findings from this study were the positive perceptual responses obtained from participants in the study. The CarbonCool vest was found to provide improved comfort for PPE users while remaining lightweight and easy to don. Although a number of personal cooling devices are available,²⁷⁻²⁹ use of these equipment are limited due to constraints such as greater weight or connection to external equipment.²² An ideal body-cooling device would be one that effectively cools the individual while not adding significant additional weight and causing further physical strain.²² It is also crucial that movement not be impeded to minimize disruption to job performance. This study demonstrated the practical feasibility and ease of use of the CarbonCool vest with PPE use, with participants reporting that the vest did not feel excessively heavy and mobility being unhindered.

The intervention group demonstrated a trend toward a lower increase in body temperature and HR after the decontamination exercise, although the results were not statistically significant. Other physiological measurements such as change in weight and blood pressure showed no significant difference between the control and intervention groups.

While a number of studies on other cooling devices demonstrated efficacy through significant changes in physiological measurements,^{9,30} these were in devices that required external powering. In a study using a personal ice cooling system in PPE for HAZMAT operations under exercise stress, no significant

difference was found in temperature or HR between the intervention and control groups, yet the intervention group had an increased endurance time of almost twice the duration.²³ This suggests that physiological measurements and impact on work endurance may differ, and further studies should be carried out to determine the true effect of work endurance in the CarbonCool vest.

The results presented suggest that the cooling vest may help to reduce heat strain and also improve the subjective sensation of the individual while not compromising on mobility. Furthermore, the CarbonCool vest is reusable, thus providing an affordable alternative, especially in resource-limited regions.

Limitations

A number of limitations exist in this study. Firstly, as a pilot study, the sample size in this trial is intentionally small and therefore insufficiently powered to detect a statistically significant difference in patient-oriented clinical endpoints. Secondly, limitations imposed by ethics approval prevented the measurement of core temperature such as rectal temperature. More robust measurements could be obtained to ensure greater reliability. An example would be rectal temperature or monitoring of temperature at different time points of the activity. This would allow for a better understanding of the changes in measurements and how they are affected by the intervention.

Thirdly, the qualitative survey could be more directed with specific ratings for different components of the cooling vest. One example would be for participants to rate perceived exertion, as was done in a number of other studies on cooling vests.^{22,31,32} Performance during operational tasks was not measured, which may be impaired independently of physiological parameters. It was also not possible to blind the participants from the intervention, even with the use of sham cooling vests. Another limitation is that comparisons were made using physiological measurements obtained from a number of different individuals, thereby introducing more variability into the study. The authors intend to follow-up with a more valid crossover study subsequently.

Difference in Weight				
	Estimated Effect	95% CI (Lower)	95% CI (Upper)	P Value
Intervention	0.044	−0.112	0.199	.562
Age	−0.001	−0.013	0.011	.838
Gender, male	−0.071	−0.261	0.119	.44
Weight (before)	−0.005	−0.014	0.004	.231
Difference in Temperature				
	Estimated Effect	95% CI (Lower)	95% CI (Upper)	P Value
Intervention	−0.155	−0.647	0.338	.518
Age	0.0005	−0.037	0.036	.979
Gender, male	−0.101	−0.601	0.398	.675
Temperature (Before)	−0.916	−1.377	−0.454	.001
Difference in Heart Rate				
	Estimated Effect	95% CI (Lower)	95% CI (Upper)	P Value
Intervention	−7.742	−17.653	2.169	.118
Age	0.561	−0.134	1.256	.107
Gender, male	6.387	−2.821	15.595	.162
Before (Heart rate)	−0.139	−0.52	0.243	.455
Difference in Systolic Blood Pressure				
	Estimated Effect	95% CI (Lower)	95% CI (Upper)	P Value
Intervention	−0.735	−9.958	8.488	.869
Age	0.433	−0.215	1.081	.177
Gender, male	2.768	−7.11	12.646	.563
Systolic Blood Pressure (Before)	−0.259	−0.556	0.039	.084
Difference in Diastolic Blood Pressure				
	Estimated Effect	95% CI (Lower)	95% CI (Upper)	P Value
Intervention	3.949	−3.707	11.605	.293
Age	0.341	−0.205	0.887	.206
Gender, male	3.017	−5.059	11.093	.443
Diastolic Blood Pressure (Before)	−0.564	−0.87	−0.258	.001

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Table 2. Linear Regression Showing the Effect of Intervention on Physiological Measurements Before and After the Decontamination Exercise, Adjusted for Age, Gender, and Baseline Measurement

While small, non-randomized trials on human volunteers with surface cooling devices in experimental settings yielded mixed findings,^{30,33} these studies reflect the efficacy of the specific device used rather than the concept of using wearable cooling devices, which have been shown to have a role in reducing thermal and cardiovascular strain³⁴ in proof-of-concept studies.

Conclusion

This observational clinical implementation trial shows that the CarbonCool cooling vest is safe and tolerable in participants wearing PPE. Further trials with sample size powered to detect clinical outcomes are needed to assess the effect of the cooling vest on a subject's endurance to heat stress.

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