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Research Article

COMPARISON OF PATIENT WARMING SYSTEM WITH INTEGRATED AIR-ACTIVATED HEAT PACKS VERSUS FORCED-AIR WARMING DEVICE. RANDOMIZED CONTROLLED CLINICAL TRIAL TO EVALUATE FEASIBILITY AND SAFETY

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ABSTRACT

Background: Up to 20% of patients experience unintended perioperative hypothermia (UPH) defined as a core temperature below 36°C (2). The peripheral compartment is usually 2-4 °C cooler than the central compartment (3). This temperature gradient is maintained by central regulation in the hypothalamus of peripheral arteriovenous shunts in the fingers and toes. General Anesthesia reduces the threshold for centrally modulated vasoconstriction by 2°C.Thermoregulatory vasoconstriction decreases subcutaneous oxygen tension.
Reduced levels of oxygen in tissues results in an increase in surgical site infections as well as other complications, all of which results in postoperative morbidity and mortality with an increased length of hospitalization.

Methods: Forty-eight patients undergoing abdominal, gynecological, breast and head and neck surgery were randomly assigned to two groups. The control group used a Forced Air Warming Device (FAWD), (3M™ Bair Hugger™ warming unit, 3M, Maplewood, MN) and the study group using a pajama-type garment with gloves and socks containing air-activated heating packs (HEATMAX INC. Dalton, GA). The patients' anesthetic care was standardized. Core temperature measurements were made in the admissions area, at 15 minute intervals during general anesthesia and in the Post Anesthesia Care Unit (PACU). Additional measurements were recorded of ambient operating room temperature, temperature one meter from the patient's head, dorsal hand temperature in admissions area, at the start of general anesthesia and 60 minutes thereafter. Core temperature was measured on admission to the PACU and at 15 minute intervals until patient was normothermic.

Results: Mean (±SE) intraoperative core temperature at 120 minutes, 35.27 °C (± 0.45) in study group and 36.09 °C in control group. (± 0.13), (P-Value 0.0656). Mean (±SE) intraoperative core temperature at 150 minutes, 35.33 °C (± 0.18) in the study group and 36.26 °C in control group. (± 0.21), (P-Value 0.0007) see Table 2. The mean (±SE) PACU admission core temperature was 36.5 °C (± 0.11) in the study group and 36.79 °C in the control group. (± 0.09), (P-Value 0.04). All patients from both groups were normothermic on admission to the PACU.

Conclusions: This study was designed primarily as a proof of concept study to show that an integrated heat-pack garment was effective in maintaining normothermia during the perioperative period as compared to a FAWD. The findings were that there was no statistical significance between the two groups for before or after surgery and for the first 120 minutes of anesthesia. Thereafter the Control group had significantly higher temperatures although there were more participants in the control group after 120 minutes (Table2). All of the patients in both groups were normothermic on admission to the PACU, conforming with the NICE guidelines. No patient felt cold or experienced clinical or ECG manifestations of shivering in the PACU.

INTRODUCTION

Humans are homeothermic and require a constant core body temperature (37 °C with a range of 0.6 °C) for optimal metabolic function. The Operating Room (OR) is usually kept below 23°C. In the absence of a warming device a patient will rapidly lose core temperature whilst under general anesthesia (1). A low ambient OR temperature is the norm. Surgeons and assistants wear gowns, gloves and masks which make them hot in a Normothermic environment. Forced Air Warming Devices may further increase the local temperature at the operating table.

Up to 20% of patients experience unintended perioperative hypothermia (UPH) defined as a core temperature below 36°C (2). The peripheral compartment is usually 2-4 °C cooler than the central compartment (3). This temperature gradient is maintained by central regulation in the hypothalamus of peripheral arteriovenous shunts in the fingers and toes. General Anesthesia reduces the vasoconstriction threshold to well below core temperature (4-9) and resets the threshold for

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peripheral vasoconstriction and maintenance of core temperature by 2 °C. As a result of this, there is redistribution of core temperature to the periphery; according to the Second Law of Thermodynamics. In addition, anesthesia modulated loss of sympathetic tone with its peripheral vasodilatory effect, results in heat loss from the central compartment to the periphery (10). It is not uncommon for a healthy patient under general anesthesia, to undergo a decrease in core temperature of 0.5-1.5°C within the first hour of anesthesia (10).

There are multiple adverse effects of mild hypothermia. These include morbid cardiac outcomes, increases in surgical blood loss and a tripling of surgical site infections (SSI's)(11-18)

The National Institute for Health and Care (NICE) Guidelines, Hypothermia: prevention and management in adults having surgery, has focused institutional efforts on preventing hypothermic complications during and after surgery (19).

The current methods of patient warming have several disadvantages. Non-disposable cotton blankets may function as carriers of Methicillin Resistant Staphylococcus Aureus and other hospital acquired infection. Linens require laundering and processing and sometimes this process is out-serviced. This involves energy expenditure (transport, laundry services) before the product reaches the clinical setting. Blankets are usually warmed in a warming cabinet, again requiring an external energy source before use. In addition, Cotton blankets are poorly insulative and rapidly lose heat after being removed from the warming cabinet (20). Cotton as a crop is also non-eco-friendly crop using which requires pesticides and scarce water resources (21).

Forced Air Warming Devices (FAWD) are cumbersome and noisy and increase the ambient temperature in the immediate vicinity of the operative site (22). They are non-recyclable, non-eco-friendly, require an external energy source, maintenance and spare parts. Many of these factors exclude the use of a FAWD from a Third World scenario. Based on a quick Google Search, 40-80% of sophisticated medical devices become rapidly obsolete in a low technology environment due to lack of technicians, parts and even the correct voltage power supply. In addition, a simple thing such as an instruction manual written in English or German, for example, can be unintelligible thereby preventing the use of the device.

Other electric devices such as resistive polymer devices and heated circulating fluid devices also have the disadvantages of a power supply and a separate controller unit requiring maintenance and spare parts. They are often reusable and therefore require disinfection between uses with the risk of them acting as carriers of nosocomial infection.

Forced Air Warming Devices as well as resistive warming and circulating fluid devices all require the input of the hospital staff in the pre-operative, intraoperative and post-operative phases of surgery. In all cases, the patient is immobilized; attached to an 'umbilical' and a power supply. A cotton hospital gown, open at the rear 'Johnny-Coat' is often worn underneath and cotton blankets are frequently laid over the device to secure it. A FAWD, pre-surgical version of the device (3M™ Bair Hugger™ warming unit, 3M, Maplewood, MN) is designed in a similar pattern to the ubiquitous 'Johnny-Coat', fastened at the back. This gives inadequate coverage for the patient when he or she ambulates and the heat source is lost as soon as the unit is detached from the power supply for the patient to be able to ambulate.

The primary author is a Plastic Surgeon in Private Practice for more than 30 years. During that time, both as a physician and as a patient, he has been struck by the design defects of the standard Johnny-Coat. This cotton garment fails in on both counts in covering and insulating the patient. It has mid upper-arm sleeves, extends to the knees, ties at the back and has a full-length opening at the back. It is made of cotton and from a male view-point, looks like a dress! There is nothing about it which would intuitively add to a patient's sense of well-being in terms of comfort or appearance.

In order to simplify and improve the '*warming and clothing algorithm'*, a single-use, eco-friendly, recyclable garment was developed which has an integrated self-contained warming source consisting of air-activated heating packs (HEATMAX INC. Dalton, GA). The garment mimics a pair of pajamas with gloves and socks. 'Dressing 'is a skill learned in childhood and generally requires no assistance. It is a basic activity of daily living along with holding a knife and fork. If a garment is designed in such a way that it is to all intense and purposes, *a pair of pajamas with gloves and socks* then the vast majority of-patients will be able to grasp how to apply the device without assistance. In this way, the patient will not be stressed by being placed in unfamiliar and inadequate flimsy clothing and will be kept warm in the relatively low ambient temperatures present throughout the hospital environment. Even outside the Operating Room, a comfortable ambient room temperature for a fully clothed person can be uncomfortably cold for a patient dressed in the standard hospital gown. The image of the patient walking down the hallway in a short - sleeved above knee gown with exposed back and buttocks, is depressingly familiar in Health Care Institutions throughout the world. It is a paradox that in poorer countries where patients may wear their own clothes in the hospital, that they may be at less risk of hypothermia and hospital based infection than in the sophisticated Health Care Systems in the 'developed' world.

MATERIALS AND METHODS

The study was registered with the National Institute of Health ClinicalTrials.gov PRS: NCT02905708, with the approval of the Norwalk Hospital Institutional Review Board and with prior written informed consent, we studied 48 participants undergoing elective surgery. Inclusion criteria: all ethnicities and insurance status, ages 18-80, BMI less than or equal to 37.0 and ASA physical status Grades I and II. The participants were placed in a randomized prospective fashion into one of two groups. Arm 1: Control (FAWD) and Arm 2: Test Garment.

The following systems were studied

Arm 1: Lower-BodyFAWD garment attached to a BairHugger® model 200(3M™ Bair Hugger™ Therapy, 3 M, Eden Prairie, MN, USA). This forced-air warming system consists of a power unit utilizing an electrical heater and

fan to generate an air flow that is delivered downstream to an upper body blanket;

Arm 2: Integrated Garment with Air-Activated heating packs (HEATMAXInc., Dalton, GA, USA)

General endotracheal anesthesia with neuro-muscular depolarizing agents were used in 46 of 48 patients. Intravenous fluids were infused at ambient temperature.

In the post-anesthetic care unit and post-surgical ambulatory area all the patients used one of the two warming devices until discharge or transfer to the ward.

Patients were divided randomly into two groups. In the first group of 24 patients, the patient was placed in a FAWD gown in the pre-surgical area (3M™ Bair Hugger™ warming unit). During surgery, the legs were covered by a lower-body FAWD garment attached to a Bair Hugger® model 200 (3M™ Bair Hugger™ Therapy, 3M, MN) which was set on high (air temperature=43°C). In the recovery room, the patient had a full body FAWD applied up to the shoulders.

In the second group of 24 patients, the patient dressed themselves in the integrated heat-pack garment with gloves and socks, at the time they disrobed on admission. The heat packs were automatically activated on removing the garment from its sealed vacuum pack. The patients remained in the garment for the entire peri-operative period until they were ready for discharge. If they were an inpatient they stayed in the garment for transfer to the ward. Temperature and vital signs monitoring, for the purpose of this study, ceased with discharge or transfer to the ward.

Core temperature was recorded predominantly with an esophageal thermometer (46 out of 48). In all patients, Preoperative Core Temperature was measured in the preoperative holding area and the PACU with a Temporal Artery Thermometer, Part #: TAT-5000 (Exergen Corporation, Watertown, MA, USA). Temperature measurements in the OR were initiated after the patient was anesthetized and after placement of the temperature recording device and thereafter automatically recorded at 15 minute intervals until the conclusion of surgery. During recovery, temperature measurements were initiated on admission to the Post-Anesthesia Care Unit (PACU) and continued at 15 minute intervals until the subject was Normothermic. Shivering was evaluated on admission to the PACU at15-minute intervals thereafter. Shivering was classified as absent, mild (when only detected by electrocardiographic artifacts), or severe (when clinically obvious). The time between the first and the last manifestation of tremor was considered the total duration of shivering.

OR temperatures and Dorsal Hand Skin Temperature was measured using a RYOBI Non-Contact InfraRed Thermometer IR002 (One World Technologies, INC, Anderson, SC, USA).

Dorsal hand skin temperature (T) was measured in the pre-surgical holding area (DH AMBI), at the start of general anesthesia on the operating table in the operating room (DHGA0) and again 60 minutes later (DHGA60). In addition, the ambient temperature of the operating room was measured at the start of surgery as well as ambient temperature one meter from the patient's head after induction of general anesthesia (after placement of the FAWD if the patient belonged to that treatment arm).

RESULTS

Participant flow is summarized in Fig 1. Flow diagram of control group using FAWD compared with study group using integrated heat pack garment. The diagram shows a single center trial with parallel randomized groups.

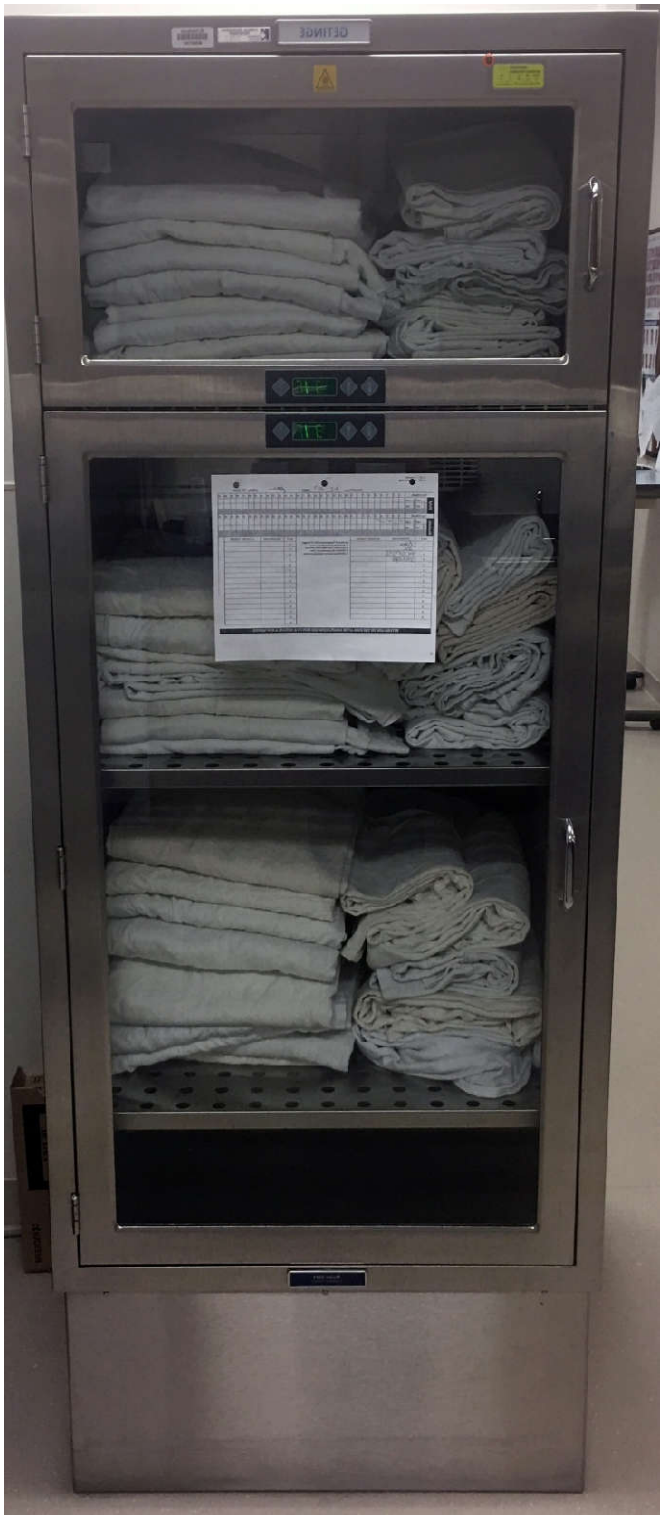

Figure 1 Cotton blanket warming cabinet in PACU. (color photograph)

Figure 2 Patient in study garment in Ambi.(color photograph)

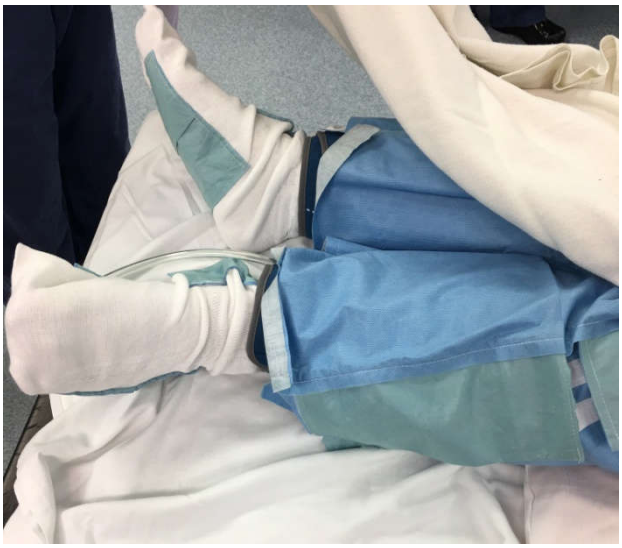

Figure 3 Leggings and socks with ICD's in place. (color photograph)

Figure 4 Glove with pulse oximeter in place in OR. (color photograph)

We compared demographics and baseline characteristics of the participants in the 2 groups using 2-tailed *t* tests or χ^2 tests.

Core temperatures were recorded in the Admissions Area and in 15-minute intervals during general anesthesia. We assessed the association of these temperatures with the study group (type of warming device used) during the surgery using generalized estimating equations with repeated observations. We modeled these correlations using an independent structure. To assess the difference over time, we included a 2-way interaction term of time interval x group. We compared (LS Means) temperatures of the two study groups at each interval. Covariates included BMI and ambient temperature of the OR. All analyses were conducted using SAS, version 9.4 (SAS Institute Inc.). $P < .05$ was considered significant.

Statistical Analysis

Our analytical sample included 48 participants evenly divided between the control and study groups. Table 1 shows the demographics and baseline characteristics. There were no significant differences between the two groups with the exception of body mass index (BMI). Participants in the study group were slightly heavier than those in the control group (p=0.05).

Multivariate models examined the difference in body temperature over time, controlling for age and BMI. For the first 2 hours of surgery, there were no differences between the two groups (Table 2 and Graph 1). Fewer participants in the study group had surgery times longer than 2 hours, and the control group's temperatures were higher during the remaining surgery time.

Tables 3a and 3b summarize Control and Study Group Procedure Information. Table 4 and Graph 2 show

temperatures by group and time in the PACU. Average temperatures for both groups were above 36^{0}C.

The Dorsal Hand Temperature was warmer in the study group in Ambi and in the OR at GA 0 and GA 60, but the numbers failed to achieve statistical significance.

In the PACU all patients in both arms were normothermic (core temperature greater than 36°C), see Table 4 and Graph 2.

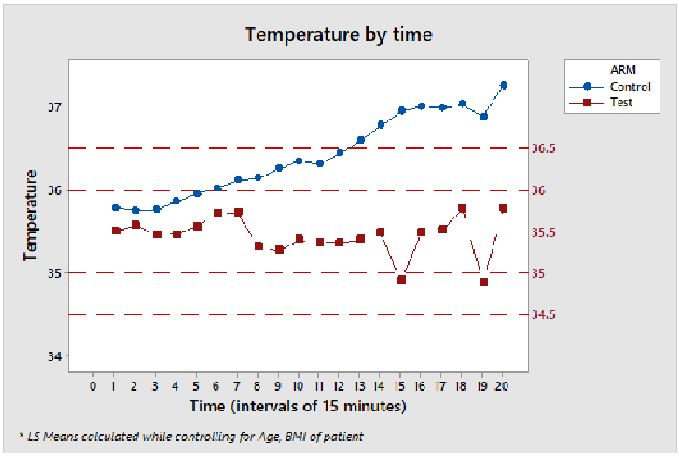

Figure 1 Graph Temperature by time.

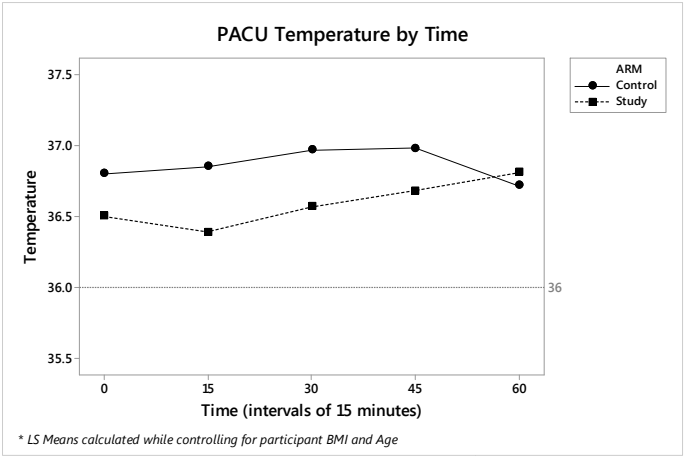

Figure 2 Graph PACU temperature by time.

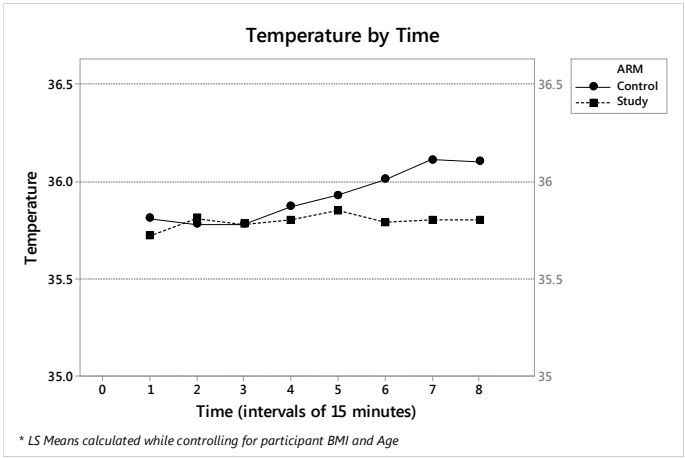

Table 1 Demographics and Baseline Characteristics

	Control (n=24)	Study (n=24)	P-Value
Age, mean (SD)	53.3 (14.5)	47.5 (12.5)	0.14
BMI, mean (SD)	25.9 (5.1)	28.4 (3.7)	**0.05**
Gender, n (%)			0.38
Female	15 (62.5)	9 (37.5)	
Male	12 (50.0)	12 (50.0)	
Ethnicity, n (%)			0.73
African American/Black	5 (20.8)	4 (17.4)	
White	15 (62.5)	13 (56.5)	
Other	4 (16.7)	6 (26.1)	
ASA Status, n(%)			0.27
1	3 (12.5)	6 (25.0)	
2	21 (87.5)	18 (75.0)	
Procedure Type, n(%)			0.07
Abdominal Only	11 (45.8)	15 (62.5)	
Chest, Chest&Abdominal, Head, Neck	3 (12.5)	6 (25.0)	
Lithotomy	10 (41.7)	3 (12.5)	
Admission Temperature (C), mean (SD)	36.7 (0.2)	36.6 (0.2)	0.36
Dorsal Hand Temperature (C), mean (SD)	28.4 (3.9)	28.9 (2.7)	0.65
Operating Room Temperature (C), 1 Meter from Patient, mean (SD)	20.6 (3.4)	21.6 (5.9)	0.5
Admission Systolic Blood Pressure	134.2 (20.8)	132.5 (20.9)	0.78
Admission Diastolic Blood Pressure	81.3 (11.2)	81.1 (9.2)	0.94
Discharge Systolic Blood Pressure	128.1 (18.1)	126.2 (16.3)	0.70
Discharge Diastolic Blood Pressure	77.0 (12.0)	76.3 (10.7)	0.85
General Anesthesia Minutes, mean (SD)	235.7 (98.5)	197.7 (101.3)	0.19
Surgery Minutes, mean (SD)	179.3 (91.5)	146.0 (93.1)	0.22

Table 2 Least-square mean temperatures at each time point, adjusted for participant BMI

	Control		Study		
Minutes	n	Estimate (SE)	n	Estimate (SE)	P-Value
15	18	35.79 (0.12)	23	35.45 (0.21)	0.1696
30	24	35.75 (0.1)	23	35.55 (0.2)	0.3807
45	24	35.76 (0.1)	24	35.44 (0.26)	0.2629
60	24	35.84 (0.1)	23	35.43 (0.28)	0.1788
75	21	35.92 (0.11)	19	35.53 (0.26)	0.1544
90	20	35.98 (0.11)	15	35.72 (0.15)	0.1754
105	19	36.07 (0.13)	14	35.74 (0.17)	0.1488
120	18	36.09 (0.13)	15	35.27 (0.45)	0.0656
135	16	36.19 (0.16)	9	35.18 (0.28)	0.0007
150	14	36.26 (0.21)	8	35.33 (0.18)	0.0007
165	13	36.32 (0.19)	6	35.32 (0.24)	0.0013
180	13	36.38 (0.2)	6	35.32 (0.26)	0.0011
195	11	36.58 (0.2)	6	35.4 (0.31)	0.0019
210	10	36.76 (0.19)	4	35.48 (0.33)	0.0007
225	7	36.93 (0.24)	4	34.92 (0.2)	<.0001
240	7	36.99 (0.26)	4	35.5 (0.31)	0.0006
255	7	37.02 (0.24)	3	35.52 (0.41)	0.0035
270	7	37.02 (0.24)	2	35.8 (0.74)	0.1389
285	3	36.89 (0.32)	1	34.9 (0.04)	<.0001
300	2	37.28 (0.14)	2	35.8 (0.74)	0.0476

Table 3a CONTROL Group Procedure Information

Participant	Procedure type	Procedure
3	ABDOMINAL	LAP CHOLECYSTECTOMY
7	ABDOMINAL	LAPARASCOPIC SALPINGO-OPHORECTOMY
21	ABDOMINAL	LAP APPENDECTOMY & CECECTOMY
22	ABDOMINAL	LAP SIG COLECTOMY
23	ABDOMINAL	DIAGNOSTIC LAP
37	ABDOMINAL	LAP VENTRAL HERNIA
39	ABDOMINAL	LAP CHOLECYSTECTOMY, OPEN UMBILICAL HERNIA REPAIR
46	ABDOMINAL	LAP GASTRIC ANTRECTOMY
47	ABDOMINAL	LAP NISSEN W/ PARAESOPHAGEAL HERNIA REPAIR
49	ABDOMINAL	LAP INGUNIAL HERNIA REPAIR BILATERAL
52	ABDOMINAL	LAP CHOLECYSTECTOMY

36	CHEST/ABDOMEN	BIL REDUCTION MAMMO/ABDOMINOPLASTY, LIPO FLANKS/UPPER ABDOMEN
11	HEAD&NECK	FACELIFT
15	HEAD&NECK	FACELIFT
16	LITHOTOMY	LAP SIG COLECTOMY
24	LITHOTOMY	LAP HYSTERECTOMY
27	LITHOTOMY	LAP HYSTERECTOMY
29	LITHOTOMY	LAP HYSTERECTOMY, SACRO-COLPOPEXY, PVS
35	LITHOTOMY	PUBOVAGINAL SLING, REPAIR CYSTOCELE AND RECTOCELE, VAG HYST
38	LITHOTOMY	LAP MYOMECTOMY
41	LITHOTOMY	LAP SIGMOID COLECTOMY, COLOSTOMY
43	LITHOTOMY	LAP SIGMOID COLECTOMY
44	LITHOTOMY	LAP ASSISTED SIGMOID COLECTOMY
48	LITHOTOMY	LAP ASSISTED SIGMOID COLECTOMY

Table 3b STUDY Group Procedure Information

Participant	Procedure type	Procedure
1	ABDOMINAL	LAP HYSTERECTOMY
2	ABDOMINAL	LAP ING &UMB HERNIA
5	ABDOMINAL	VENTRAL HERNIA MULTIPLE
8	ABDOMINAL	LAP VENTRAL HERNIA
12	ABDOMINAL	LAP CHOLECYSTECTOMY
13	ABDOMINAL	ING HERNIA
14	ABDOMINAL	INGUINAL HERNIA
17	ABDOMINAL	UMB HERNIA ING HERNIA
18	ABDOMINAL	VENTRAL HERNIA
19	ABDOMINAL	VENTRAL HERNIA
25	ABDOMINAL	LAP COLECTOMY
30	ABDOMINAL	LAP CHOLECYSTECTOMY
34	ABDOMINAL	LAP INJUINAL HERNIA
42	ABDOMINAL	REPAIR INGUNIAL HERNIA
50	ABDOMINAL	REPAIR, VENTRAL HERNIA
6	CHEST	BIL BREAST REDUCTION
31	CHEST	BIL BREAST RED
9	HEAD&NECK	FACELIFT
10	HEAD&NECK	FACELIFT
20	HEAD&NECK	FACELIFT
33	HEAD&NECK	NECK/JAWLINE LIFT, SUBMENTAL PLATYSMAPLASTY, LIPO JOWLS
26	LITHOTOMY	LAPOVARIAN CYSTECTOMY
28	LITHOTOMY	CYSTOSCOPY, STENT PLACEMENT, LAP SIGMOID
51	LITHOTOMY	LAP SIGMOID RESECTION

Table 4 Mean temperatures in PACU at each time point

	Control		Study		
Minutes	**n**	**Mean (SE)**	**n**	**Mean (SE)**	**P-Value**
0	23	36.79 (0.09)	24	36.50 (0.11)	0.04
15	7	36.86 (0.19)	18	36.37 (0.08)	<0.01
30	7	36.96 (0.14)	13	36.55 (0.13)	<0.01
45	7	36.98 (0.14)	11	36.65 (0.18)	0.21
60	13	36.66 (0.07)	11	36.81 (0.14)	0.34

Table 5 OR ambient temperature and dorsal hand temperature by time.

	Control	Test	P-Value
OR Ambient Temp	19.3 (1.9)	18.2 (2.7)	0.13
DH Ambi	30.7 (2.8)	31.5 (2.6)	0.34
DH GA 0	28.6 (4.2)	29.0 (2.9)	0.72
DH GA 60	28.5 (4.6)	31.2 (3.2)	0.06

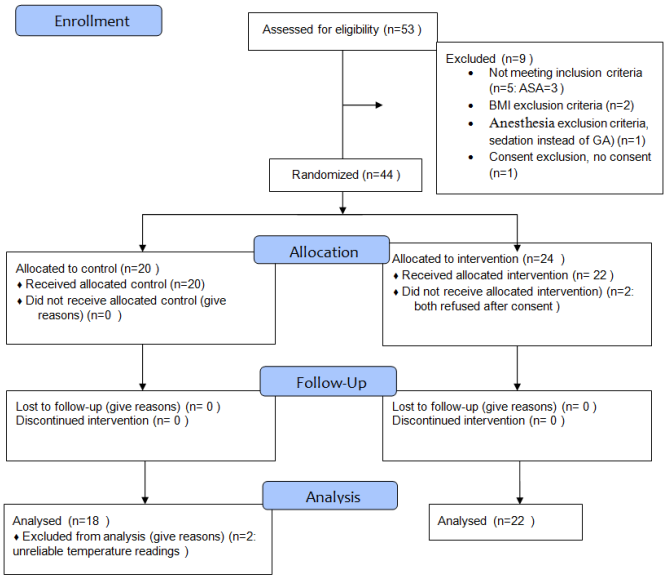

Fig 1 Flow chart of study: screening, randomization and analysis

DISCUSSION

This study was designed primarily as a 'proof of concept' study to demonstrate that the integrated heat-pack garment was effective in maintaining normothermia during the perioperative period.

There was no statistical significance between the two groups for the first 120 minutes of anesthesia. Thereafter the Control group had significantly higher temperatures although the number of participants in the Control group was higher.

All of the patients in both groups were normothermic on admission to the PACU thereby conforming with the NICE guidelines. No patient felt cold or experienced clinical or ECG manifestations of shivering in the PACU.

This initial study with a prototype garment, demonstrated that the pajama like garment with gloves and socks and integrated heat packs, is not only more user friendly but also an effective means of patient warming in the peri-operative period. The garment had other demonstrable advantages over the resistive polymer (RP) and Forced Air Warming Devices (FAWD).

1. It is a single use device unlike the RP or the FAWD device.
2. It is 'eco-friendly" All of the components are bio-degradable.
3. It requires no external power supply, controller or device.
4. There is no umbilical to immobilize the patient. The device does not require that the patient remain immobile.
5. During ambulation to the bathroom in the admissions area and during transfer to the OR (ambulatory or on a stretcher) the patient does not suffer the disadvantage of being disconnected from the heat supply.
6. Last but not least, the design of a garment which simulates normal clothing and is self-contained; adds the dual advantage of requiring
   a. little or no input form the care givers
   b. makes the patient feel warm, secure and comfortable in an alien, distressing environment.

The stress and embarrassment of having one's back and buttocks exposed as you walk around is not to be discounted. This latter advantage is a 'de-stressor' reducing adrenaline secretion and the sequelae of increased pulse rate and blood pressure.

The provision of a garment that approximates normal clothing adds to the patient satisfaction level and fits with the maxim of 'under-promise and over-deliver'. The little and the big details improve patient care delivery and reduces deleterious results in any High-Risk Organization.

In summary, this randomized study prospective study indicates that intraoperative core temperatures were the same in both study groups, for the first 120 minutes of general anesthesia and both groups were normothermic on admission to the PACU. A pajama-like garment with integrated heat packs is not only more user-friendly but has been shown to be an effective means of patient warming in the peri-operative period.

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