Original Article

Passive Warming using a Heat-Band versus a Resistive Heating Blanket for the Prevention of Inadvertent Perioperative Hypothermia during Laparotomy for Gynaecological Surgery

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Abstract

Background: Inadvertent perioperative hypothermia (IPH) is a common problem, despite advancements in a variety of warming systems. The use of a resistive heating blanket (RHB) is a common but costly approach to patient warming. We have introduced the use of a heat-band in our centre as a cost-effective alternative to the RHB for patient warming. The efficacy of the heat-band in preventing IPH during laparotomy for gynaecological surgeries was compared with that of the RHB.

Methods: Thirty-two patients undergoing surgeries under combined general-epidural anaesthesia, with an expected duration of surgery of 2–4 h, were randomised to receive either the heat-band or RHB. The core body temperatures of the two groups were compared at several perioperative times, in addition to the incidence of post-anaesthesia shivering, time to extubation and intraoperative blood loss.

Results: The core body temperatures were comparable between the two groups in the pre-operative period, immediately after the induction of anaesthesia and skin incision, 1 h after the incision, at the time of complete skin closing, at extubation, upon arrival to the recovery room and 1 h post-operatively. There were no significant between-group differences in the incidence of post-anaesthesia shivering, time to extubation and intra-operative blood loss.

Conclusion: The heat-band is as effective as the RHB in preventing IPH and its complications in gynaecological laparotomies.

Keywords: hypothermia, accidental, perioperative period, laparotomy

Introduction

Inadvertent perioperative hypothermia (IPH), defined as a core body temperature of < 35.5°C, is a common complication during anaesthesia and surgery. It causes several adverse events, including shivering, delayed recovery from anaesthesia, morbid myocardial outcomes, surgical wound infection and coagulopathy, thereby increasing the need for transfusions (1–4). Consequently, it is standard practice to monitor the patient's body temperature and adopt strategies to prevent heat loss in the perioperative period.

In our centre, the resistive heating blanket (RHB) (Geratherm® Blanket Patient Warming Systems, Geschwenda, Germany) is widely used as a warming device (Figure 1). A low voltage current heats the blanket at a selected temperature of between 30 °C and 42 °C. As the heat is transferred

Figure 1: Resistive heating blanket (Geratherm® Blanket Patient Warming Systems, Geschwenda, Germany). Source: http://www.geratherm.de/en/temperature-management-2. April 15, 2014.

primarily to the patient by conduction, the device requires direct skin contact to work effectively, and incorrect placement of the blanket can lead to poor heat transfer. The blanket is available in segments, allowing a large fraction of the body surface area (BSA) to be warmed during the surgery. However, the array of wires attached to the blanket can pose some practical difficulties. Furthermore, the dependence of the device on electricity means that it is subject to electrical failures and relatively high running costs. In addition, RHBs cost several thousands of euros and thus may not be affordable in less-affluent centres.

In an attempt to find a cost-effective alternative to the RHB warming device, our centre has introduced the use of a new passive warmer called a heat-band (Figure 2). Based on our experience of using the heat-band in recent years, it is economical, yet effective. A complete set of heat-bands costs €212 as compared to the current purchase cost of the RHB (Geratherm® Blanket Patient Warming Systems, Geschwenda, Germany) of €7, 320. Since it was first introduced in 2010, the heat-band has won several innovation awards at both local and national levels. However, there have been no clinical trials evaluating its efficacy to date.

The heat-band is a resistive insulator with a fibre matrix designed to entrap air. This air is still and forms an insulating barrier that prevents convective heat loss and associated hypothermia. The heat-band contains three layers of insulating material: an innermost layer of soft cotton, a middle layer of polyester and an outer layer of synthetic polyurethane leather. The band can be wrapped around different parts of the body, including the limbs and torso. Each band has straps that can be securely fastened to eliminate accidental opening or dislodging of the band when worn by the patient. At our centre, the standard practice is to apply the heat-band immediately after the induction of anaesthesia and to remove it at the end of the surgery prior to transporting the patient to the post-anaesthesia care unit (PACU). As the heat-band does not require electricity to operate, there is no risk of burning a patient, it is not subject to electrical failures, there are no wires attached, and it is lightweight. As the heat-band is reusable, it must be cleaned after each use to reduce the risk of cross-contamination. Decontamination of the heat-band can be achieved by washing it in a non-biological detergent on a cool water cycle of a washing machine. This is a sufficient decontamination method for non-critical items, such as the heat-band. Prior to the cleaning process, all parts of the band are unfastened to ensure unrestricted contact with the washing solution.

This study compared the effectiveness of the heat-band with the RHB in a randomised, controlled trial of patients undergoing a laparotomy for gynaecological surgery under combined epidural-general anaesthesia (GA).

Materials and Methods

Study design

This was a randomised controlled trial conducted in the OR of Hospital Universiti Sains Malaysia (HUSM).

Study population

Thirty-two patients undergoing elective gynaecological laparotomies between January 2013 and October 2014 at HUSM were recruited after obtaining written informed consent. The inclusion criteria were aged 18–65 years, American Society of Anaesthesiologists (ASA) class I–II and scheduled for elective gynaecological laparotomy under combined epidural-GA, with an expected duration of surgery of at least 2 h (upper limit of 4 h). Patients with a pre-operative temperature >37.5° C or <36.0° C, a recent history of fever or infection (within three days before surgery),

Figure 2: Heat-band.

a previous history of malignant hyperthermia, thyroid disorders and pregnancy were excluded. The patients were then randomised to one of two temperature-management groups: passive warming with the heat-band or active warming with the RHB (control group).

Randomisation and allocation concealment

Randomisation and allocation concealment were done by an independent person who was not involved in the study. The randomisation scheme was generated via the website Randomization. com (http://www.randomization.com) using the method of randomly permuted block randomisation, with random block sizes. The randomisation details were given to the investigators in sequentially numbered, opaque and sealed envelopes marked according to the randomisation scheme.

Blinding

The patients were blinded to the type of temperature-management strategy they received intra-operatively. Blinding of the patients was achieved by applying the warming devices only after they had lost consciousness following the induction of GA, and the devices were removed immediately after extubation.

Due to their physical form, it was neither possible nor practical to cover the warming devices. Hence, the investigators in the OR could not be blinded to the warming devices, which were covered by the surgical drapes after their application. Although the investigators were aware of the allocated arms, the individuals who collected the data and assessed the outcome remained blinded to the allocation. The data collectors were unaware of the allocation because they were only allowed to enter the OR after the applied warming devices had been covered by the surgical drapes. The assessment of shivering during recovery was done by PACU nurses who were also unaware of the allocation, as the devices were removed in the OR prior to transporting the patients to the PACU. Finally, the individual who performed the statistical analysis was blinded by simply labelling the groups with non-identifying terms (A = heat-band and B = RHB).

Sample size calculation

The sample size of this study was calculated using PS Power and Sample Size Calculations, Version 3.0, January 2009. In a previous study, the core body temperature showed a normal distribution, with a standard deviation (SD) of 0.4° C (5). To detect a clinically significant difference

in the core body temperature of 0.5° C, which was considered clinically relevant, a minimum sample size of 14 in each group (or 28 in total) was needed to be able to reject the null hypothesis, with 90% power and an alpha of 0.05. Thirty-two patients (n=16 in both the heat-band and RHB groups) to allow for a dropout rate of 10%.

Study protocol

The study protocol was reviewed and approved by the Research and Ethics Committee, School of Medical Sciences, Universiti Sains Malaysia (Figure 3).

The patients first underwent a thorough pre-operative assessment on the day prior to the surgery and were pre-medicated with oral midazolam (7.5 mg) at night and just prior to the call to the OR. When they were transported to the OR, they wore a hospital gown and were covered with a single cotton blanket.

Once in the OR, an electrocardiogram, electronic blood pressure monitor and pulse oxymeter were applied to record the patient's heart beat, non-invasive blood pressure and oxygen saturation level, respectively. An 18G intravenous (IV) catheter, pre-loaded with 10 mL/kg of warmed normal saline, was inserted and the saline administered via slow infusion running through a fluid warmer. Prior to the
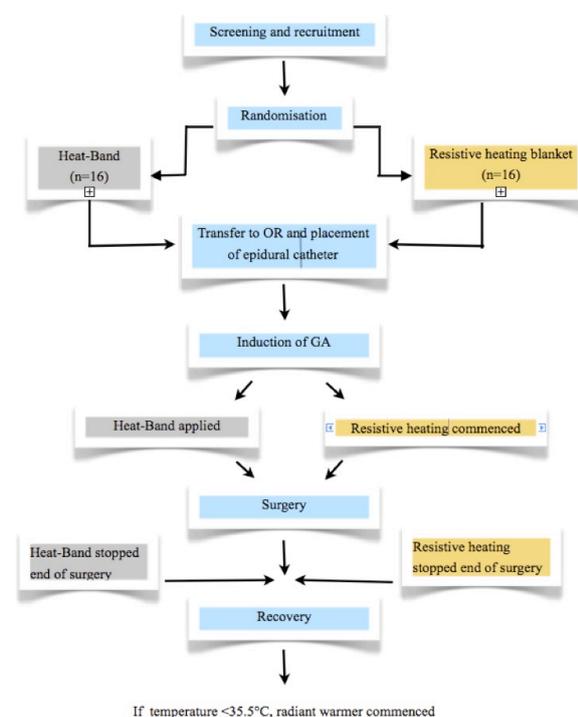

Figure 3: Study protocol.

induction of GA, an epidural catheter was inserted at any interspace between T8 and L1 using a standard technique, with the patient in a sitting position. Two millilitres of 2% lignocaine without adrenaline was given as a test dose. The patient was then placed in a supine position.

Each patient was pre-oxygenated for 3 minutes prior to intubation. GA was induced with 2 µg/kg of IV fentanyl and 2 mg/kg of IV propofol. Paralysis was induced with IV rocuronium (0.6 mg/kg) to facilitate intubation. Mechanical ventilation was achieved using a closed anaesthesia system to maintain an end-tidal carbon dioxide partial pressure of 40±5 mmHg. Anaesthesia was subsequently maintained with 2% sevoflurane in oxygen:air of 1:1.

The experimental group received warming using passive insulation with the heat-band. Each patient was wrapped in the heat-band immediately after the induction of GA, and the warming was continued intra-operatively until the patient was transferred from the OR table to a stretcher at the end of the surgery, at which time it was removed. The band encircled both the upper and lower extremities and upper chest.

The RHB (Geratherm® Blanket Patient Warming Systems, Geschwenda, Germany) group received the warming therapy immediately after the induction of GA, and it was continued until the end of the surgery. The temperature output unit of the warming blanket was set to a medium temperature (38 °C). The warming blanket covered the anterior aspects of both arms and chest and both lower extremities up to the upper thigh, as recommended by the manufacturer.

Intra-operative analgesia was provided by a loading dose of 10 mL of 0.25% plain bupivacaine via an epidural catheter in divided doses. One hour after the last bolus dose, a continuous infusion of 0.1% plain bupivacaine and 2 µg/mL of fentanyl at a rate of 6–12 mL/h was started. Subsequent anaesthetic, haemodynamic and fluid management were at the discretion of the attending anaesthetist.

Other measures to prevent IPH were standardised in both groups. They included the use of a fluid warmer (Animec AM-2S), pre-warmed surgical irrigation fluid in a warming cabinet (Olympic Warmette) set to 37 °C, heat and moisture exchange (HME) filters in the breathing circuits, low-flow anaesthesia (fresh gas flow of 0.5–1 L/min) and an ambient temperature of 20±0.5 °C in the OR. No effort was made to control the ambient temperature in the recovery room.

In the event that a patient developed hypothermia (defined as a core body temperature of < 35.5° C) during the surgery, the OR was warmed to 22° C as a 'rescue' to assist with rewarming of the patient. Cases of hypothermia in the recovery room were considered as device failure. In these cases, the patients were switched to a radiant warmer, but they were included in the final analysis of the results. Significant shivering, defined as a shivering score of ≥ 3 (Table 1), was treated with IV pethidine stat (25 mg), repeated as necessary.

Assessment

Assessment of the core body temperature

The core body temperature was measured using an infrared tympanic membrane thermometer (Welch Allyn ThermoScan Pro 4000 Thermometer). The average of two measurements from the same ear in each patient was taken, after ensuring no wax or tympanic damage was present. The core body temperature was recorded at the following times: 0 = pre-operatively; 1 = OR baseline; 2 = incision; 3 = 1 h after the incision; 4 = closing; 5 = at extubation; 6 = arrival at recovery; and 7 = 1 h post-operatively.

The naopharyngeal temperature was also continuously monitored intra-operatively. However, the nasopharyngeal temperature probe cannot be applied in the pre- and post-operative periods because it is poorly tolerated by awake patients. Thus, only intermittently measured tympanic thermometer recordings were used in the between-group comparisons.

Table 1: The five-point classification scale of shivering

Grading status of shivering	
Grade 0	No shivering
Grade 1	One or more of: Piloerection, peripheral vasoconstriction, peripheral cyanosis with, but without visible muscle activity
Grade 2	Visible muscle activity confined to one muscle group
Grade 3	Visible muscle activity in more than one muscle group
Grade 4	Gross muscle activity involving the whole body

Assessment of post-anaesthesia shivering (PAS)

The occurrence of PAS among the patients was assessed every 5 minutes from the time of the patient's arrival in the PACU for 1 h. The shivering intensity was noted and graded using a 5-point classification scale of shivering (Table 1).

Assessment of the time to extubation

The time to extubation was measured (in minutes) from the time of application of the surgical dressings after skin closure to the time of extubation of the trachea.

Assessment of intra-operative blood loss

The intra-operative blood loss was assessed by measuring the amount of blood collected in suction bottles and estimating the level of blood in and around the operative field.

Data collection

Demographic details, such as the patient's age, weight, height, and ASA status, were collected. Anaesthetic and surgical data, including the type of surgical procedure, duration of the anaesthesia (i.e. the time from pre-oxygenation to extubation), duration of the surgery (i.e. the time from the first skin incision to the application of the dressing), volume of IV fluid and surgical irrigation fluid and the total amount of drugs (fentanyl, propofol, bupivacaine, vasopressors, and inotropes) used were also recorded. Using a wall-mounted digital thermometer, the ambient OR temperature was recorded every 30 minutes throughout the surgery. Incidences of adverse effects associated with both the heat-band and the RHB were recorded.

Primary outcome

The primary outcome was the core body temperature at different perioperative times: pre-operative period, immediately after the induction of anaesthesia (OR baseline) and the skin incision, 1 h after the incision, at the time of complete skin closing, at extubation, upon arrival to the recovery room and 1 h post-operatively.

Secondary outcomes

The secondary outcomes were complications of hypothermia (i.e. the incidence of PAS and its intensity), in addition to the time to extubation and amount of intra-operative blood loss.

Statistical analysis

Statistical analysis was carried out using SPSS, version 22.0. The between-group demographic, anaesthetic and surgical data were compared using an independent t-test, a Chi-square test or Fisher's exact test, where appropriate. The results were expressed as means (SD) or frequencies (percentages), as appropriate. An independent t test was used to compare the mean core body temperature, mean extubation time, and mean estimated blood loss between the groups. The proportion of patients who had PAS in the two groups was compared using a Chi-square test. The level of significance was determined as $P < 0.05$.

Results

Demographic data

Thirty-two patients were enrolled in the study, with 16 in the heat-band group and 16 in the RHB group. There were no dropouts, and no device failures or adverse effects of the warmers occurred in either group. The patients were well balanced in terms of demographic, anaesthetic and surgical details (Table 2) and underwent similar surgical procedures (Table 3).

Primary outcome

The pre-operative core body temperature was comparable between the two groups (Table 4 and Figure 4). Immediately after the induction of anaesthesia, the core body temperature decreased similarly in both groups. The core body temperature continued to decrease comparably at the time of the skin incision over the next hour. Subsequently, the downward trend in the core body temperature stabilised in both groups. At the time of complete skin closing and extubation, the core body temperature was comparable between the two groups. The core body temperature was also comparable in both groups upon arrival to the PACU and 1 h after the surgery at the time of discharge.

Secondary outcomes

Incidence and intensity of PAS

The incidence of PAS in the heat-band group was 18.8% (n = 3), whereas the incidence was 25% (n = 4) in the RHB group. There was no significant difference in the overall incidence of PAS between the two groups (Table 5).

There was also no significant between-group difference in the intensity of shivering. Grade 1 shivering was observed in 12.5% (n = 2) of patients in both groups, and grade 2 shivering was observed in 6.25% (n = 1) and 12.5% (n = 2) of patients in the heat-band and RHB group, respectively (Figure 5). None of the patients in either group had grade 3 or 4 shivering.

Table 2: Demographic, anaesthetic and surgical details of patients in the two groups. Values are expressed in mean (SD) or frequency (percentage)

	Heat-Band (n = 16)	Resistive Heating (n = 16)
Age (years)	43.1 (12.5)	46.4 (8.8)
Weight (kg)	65.2 (9.5)	73.8 (11.5)
Height (cm)	155.3 (5.6)	156.8 (4.8)
BMI (kg/m2)	26.6 (5.0)	30.1 (5.3)
ASA I/II	8/8 (50%/50%)	7/9 (44%/56%)
Anaesthesia ready time (min)	23 (13)	20 (10)
Duration of anaesthesia (min)	205 (61)	185 (49)
Duration of surgery (min)	179 (57)	156 (45)
Total fentanyl dose (ug)	128 (45)	117 (22)
Total propofol dose (mg)	113 (24)	115 (24)
Total bupivacaine dose (mg)	38 (18)	37 (22)
Total ephedrine dose (mg)	14 (13)	11 (11)
Volume of fluids infused (mL)		
Crystalloid	1866 (726)	1563 (479)
Colloid	219 (315)	250 (258)
Packed red blood cells	56 (225)	113 (201)
Volume of irrigation fluids (mL)	2150 (570)	1763 (432)
Ambient OR temperature (°C)	19.7 (0.6)	19.8 (0.5)

Table 3: Type of gynaecologic procedures in the two groups. Values are expressed as frequency (percentage)

Type of procedures	Heat-Band (n = 16)	Resistive Heating (n = 16)
Myomectomy	0	2 (12.5%)
Cystectomy	4 (25%)	3 (18.75%)
Myomectomy and Cystectomy	2 (12.5%)	0 (0%)
TAHBSO*	6 (37.5%)	8 (50%)
TAHBSO* and omentectomy	0	1 (6.25%)
Simple hysterectomy	1 (6.25%)	0
Extrafascial hysterectomy	0	1 (6.25%)
Wertheim's hysterectomy	2 (12.5%)	1 (6.25%)
Salpingectomy	1 (6.25%)	0

*Total abdominal hysterectomy and bilateral salpingo-oopherectomy.

Time to extubation

The time to extubation, defined as the time from the application of surgical dressings after skin closure to the time of extubation of trachea, measured in minutes, was comparable between the two groups (Table 6).

Intraoperative blood loss

There was no significant difference between the two groups in estimated blood loss intraoperatively (Table 6).

Table 4: Perioperative core body temperature in degree celcius (°) in the two groups. Values are expressed as mean (SD)

	Heat-Band (n = 16)	Resistive Heating (n = 16)	t value	P value	95% Confidence Interval of the Difference
Pre-operative period	37.0 (0.2)	37.0 (0.1) °C	0.13	0.469	(-0.09, 0.10)
OR baseline	36.7 (0.4) °C	36.4 (0.4) °C	1.76	0.500	(-0.04, 0.50)
Skin incision	36.4 (0.4) °C	36.2 (0.4) °C	1.28	0.580	(-0.11, 0.47)
1 h after incision	36.1 (0.4) °C	36.0 (0.4) °C	0.67	0.696	(-0.20, 0.40)
Closing	36.1 (0.4) °C	36.1 (0.4) °C	0.26	0.943	(-0.26, 0.33)
At extubation	36.2 (0.5) °C	36.1 (0.4) °C	0.42	0.815	(-0.24, 0.37)
Upon arrival to recovery	36.3 (0.5) °C	36.2 (0.4) °C	0.37	0.742	(-0.25, 0.36)
1 h postoperatively	36.7 (0.3) °C	36.6 (0.3) °C	1.45	0.948	(-0.06, 0.38)

Table 5: Incidence of PAS in the two groups. Values are expressed as frequency (percentage)

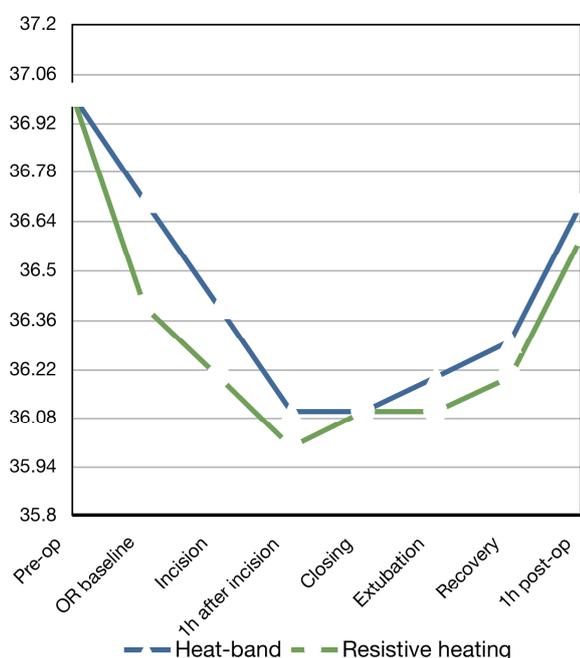| Shivering	Heat-Band (n = 16)	Resistive Heating (n = 16)	Chi-Square (df)	P value
Yes	3 (18.8%)	4 (25%)	0.18 (1)	0.669
No	13 (81.2%)	12 (75%)		

Figure 4: Perioperative core body temperature in degree celcius (°C) in the two groups at different timepoints. Values are expressed in mean.
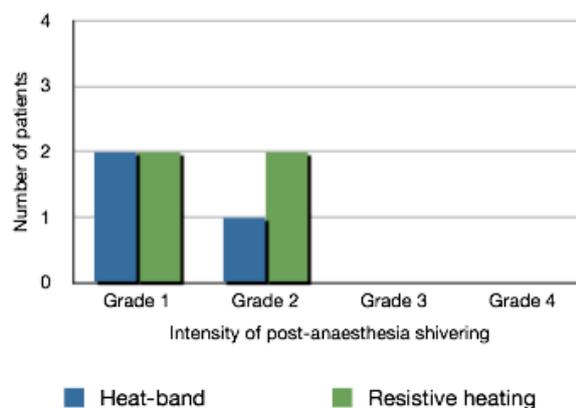

Figure 5: Intensity of PAS in the two groups according to the five-point classification scale of shivering (see Table 1). Values are represented as frequency.

Table 6: Time to extubation (in min) and intraoperative blood loss (ml) in the two groups.

	Heat-Band (n = 16)	Resistive Heating (n = 16)	t value	P value	95% Confidence Interval of the Difference
Time to extubation (min)[a]	9 (4)	11 (5)	-1.11	0.780	(-6.54, 2.02)
Intraoperative blood loss (ml) [b]	551 (401)	525 (347)	0.15	0.330	(-327.83, 379.83)

[a] = mean (standard deviation)
[b] = frequency (percentage)

Discussion

The results showed that the body temperature achieved via passive warming with the heat-band was comparable to that obtained via active warming using the RHB. Furthermore, there were no differences in hypothermia-related complications (i.e. the incidence of PAS, recovery from anaesthesia and intra-operative blood loss) between the groups. This finding is interesting, as the heat-band, unlike its comparator, is not equipped with an external heat supply source. This trial was conducted under conditions that presented a challenge for any warming devices: open abdominal surgeries, use of combined epidural-GA and surgery duration of over 2 h. A number of factors may explain the discord between the findings of this study and those of earlier work, which demonstrated a lack of effectiveness of various passive warming devices (6–10).

First, the design of the heat-band, which is worn as a wrap-around garment, meant that a greater BSA was covered during the surgery. In the over-body design of the RHB, the area of skin contact is largely limited to the patient's front. The effectiveness of all surface-warming systems is proportional to the BSA covered (6). In the setting of open abdominal surgery, using the heat-band, we could cover large parts of both the lower and upper extremities, in addition to the upper anterior and lateral portions of the chest and upper back, which account for approximately 70% of the total BSA, without interfering with the surgical access. On the other hand, the RHB covered only 35% of the total BSA (Figure 6).

Despite the different amount of BSA covered, the two warming devices were equally effective, as evidenced by the comparable core body temperature throughout the perioperative period. The RHB, an active warming device, provides a continuous supply of external heat, which can be
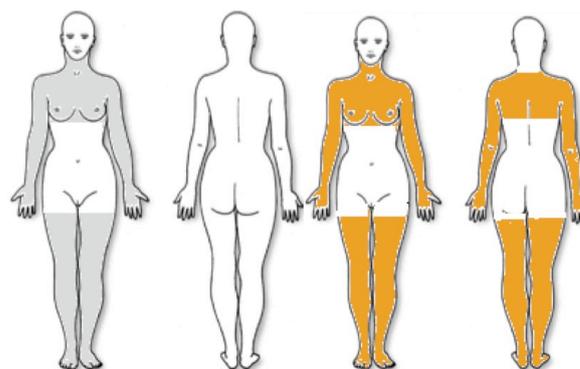

Figure 6: Comparison of the magnitude of body surface area (shaded) covered by heat-band (right) and resistive heating blanket (left).

transferred to the patient. Unlike active devices, passive devices do not have an external heat supply. Instead, they rely on preventing convective heat loss to maintain normothermia. Hence, it is expected that the heat-band, despite covering a greater BSA, reduces the core-peripheral temperature gradient to a lesser degree than does the RHB. Second, the effectiveness of the heat-band may be related to its insulating materials, which are the same as those used in outdoor clothing worn for cold-weather activities. It has been suggested that a significant improvement in the insulation values of patients in the OR is both possible and desirable, with the range of insulating materials available for outdoor activities (11). The heat-band has a triple-layer construction. Research has shown that adding additional layers of insulating material increases the efficacy of a thermal insulator (11). However, the role of the triple-layer structure in the insulating properties of the heat-band requires further detailed studies. Ideally, to determine its insulation value, the physical properties of the device should be tested under appropriate experimental conditions.

Third, the comparable core body temperature of the heat-band and RHB groups cannot be credited only to the device, as this study employed a combination of measures to prevent hypothermia. For example, the OR temperature was kept around 21° C. Patients undergoing surgery have been shown to have significantly higher core body temperatures intra-operatively at this temperature as compared to a cooler OR (12). All IV fluids given to the patients in this study were warmed using a fluid warmer (Animec AM-2S), and the irrigation fluid was also pre-warmed in a warming cabinet (Olympic Warmette) set to 37 °C. A meta-analysis showed that warmed IV and irrigation fluids resulted in a significantly higher mean core body temperature (12). The present study also used low-flow, closed breathing circuits with HME to decrease evaporative heat loss. The humidification of anaesthetic gases by HME was reported to reduce hourly evaporative heat loss by about 10–15% or 9–10 Kcal/h (13).

The present study is not the first one to demonstrate that passive warming can produce a comparable core body temperature to that obtained using active warming. In a study of 30 patients undergoing thoracic surgeries, Rathinam et al. (14), demonstrated intra-operative temperatures comparable to those obtained using forced-air warmer (FAW) and better post-operative temperatures using Mediwrap® heat retention blanket (Mediwrap™ Ltd, Essex, UK). Thermadrape™ (OR Concepts, Inc, Roanoke, TX), a metallised plastic sheet, was reported to be comparable to FAW in maintaining the core body temperature of 37 patients undergoing general surgical, orthopaedic and gynaecological surgeries (15). However, there are methodological differences between these studies and the present one. In the other studies, the passive devices were applied as a pre-warming prior to transfer to the OR, while the FAW was started later when the patient was on the operating table (14, 15). Given these methodological differences, it is difficult to compare the performance of the various devices. In the current study, the two warming devices were compared in the same type of setting, and both were applied after epidural catheter insertion and the induction of GA. Although the heat-band was not applied as a pre-warming device, the maintenance of the core body temperature of the patients in the heat-band group was comparable to that of the RHB group.

Conclusion

The present study demonstrated that a passive warming device, the heat-band, if used appropriately, was as effective as an active warming device, RHB, in preventing IPH and its associated complications. By virtue of the ability of the heat-band to prevent heat loss and conserve internal heat, the maintenance of core body temperatures was comparable to that achieved using the RHB in the perioperative period of laparotomy for gynaecological surgeries. The incidence of PAS, recovery from anaesthesia and intra-operative blood loss were also comparable to those in the RHB group. We conclude that the heat-band is a cost-effective alternative to the RHB in preventing IPH and its complications during anaesthesia and surgery of intermediate duration.

Conflicts of Interest

None.

Authors' Contribution

Conception and design, analysis and interpretation of the data: WFWM, WMNWH
Drafting of the article, collection and assembly of data: WFWM
Critical revision of the article for important intellectual content, final approval of the article, Administrative, technical, or logistic support: WMNWH, RHMZ
Provision of study materials or patients: WFWM, WMNWH, RHMZ
Statistical expertise: WMNWH
Obtaining of funding: RHMZ

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