

Comparison of Two Different Temperature Maintenance Strategies during Open Abdominal Surgery

Upper Body Forced-air Warming versus Whole Body Water Garment

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Background: A new system has been developed that circulates warm water through a whole body garment worn by the patient during surgery. In this study the authors compared two different strategies for the maintenance of intraoperative normothermia. One strategy used a new water garment warming system that permitted active warming of both the upper and lower extremities and the back. The other strategy used a single (upper body) forced-air warming system.

Methods: In this prospective, randomized study, 53 adult patients were enrolled in one of two intraoperative temperature management groups during open abdominal surgery with general anesthesia. The water-garment group (n = 25) received warming with a body temperature (rectal) set point of 36.8°C. The forced-air-warmer group (n = 28) received routine warming therapy using upper body forced-air warming system (set on high). The ambient temperature in the operating room was maintained constant at approximately 20°C. Rectal, distal esophageal, tympanic, forearm, and fingertip temperatures were recorded perioperatively and during 2 h after surgery. Extubated patients in both groups were assessed postoperatively for shivering, use of additional warming devices, and subjective thermal comfort.

Results: The mean rectal and esophageal temperatures at incision, 1 h after incision, at skin closure, and immediately postoperatively were significantly higher (0.4–0.6°C) in the group that received water-garment warming when compared with the group that received upper body forced-air warming. The calculated 95% confidence intervals for the above differences in core temperatures were 0.7–0.1, 0.8–0.2, 0.8–0.2, and 0.9–0.1, retrospectively. In addition, 14 and 7% of patients in the control upper body forced-air group remained hypothermic (< 35.5°C) 1 and 2 h after surgery, respectively. No core temperature less than 35.5°C was observed perioperatively in any of the patients from the water-garment group. A similar frequency of the thermal stress events (shivering, use of additional warming devices, subjective thermal discomfort) was observed after extubation in both groups during the 2 h after surgery.

Conclusions: The investigated water warming system, by virtue of its ability to deliver heat to a greater percentage of the body, results in better maintenance of intraoperative normothermia that does forced-air warming applied only to the upper extremities, as is common practice.

MILD perioperative hypothermia has been associated with morbidity.¹⁻⁶ It is therefore appropriate to keep surgical patients normothermic (*i.e.*, at least 36°C) unless hypothermia is specifically indicated. Cutaneous heat loss and heat redistribution are the most critical factors influencing hypothermia, and active warming is required in major surgery. Forced-air warming is in common use, but its effectiveness can be impaired when the available body surface area for warming is reduced and the current systems do not permit the use of two separate blankets (*e.g.*, upper and lower body) without obtaining two separate forced-air units. An upper body forced-air warmer also cannot be applied until after central lines in the upper part of the body are placed. Moreover, current technology does not allow for the precise adjustment of the warming temperature in relation to the body temperature of the patient. The currently used circulating water-warming devices, including water mattresses, are ineffective in maintaining normothermia intraoperatively.⁷ A new system has been developed that circulates warm water through a garment, which is worn by the patient during surgery, measures body temperature, and warms the patient to an adjustable set-point temperature using a microprocessor-controlled algorithm. The garment, which covers the anterior and posterior surfaces of the body, including limbs, overcomes some of the practical difficulties of the previous systems and does not obscure the neck during the postinduction line placement in the upper part of the body.

In the current trial we compared the perioperative temperature maintenance strategy using the new water garment with our current warming methods (upper body forced-air warmer) to determine whether the new system provides more consistent maintenance of normothermia in patients undergoing major abdominal surgery with general anesthesia. The comparison of the water-garment warmer with placebo or adding a third arm (placebo arm) to this study was ruled out based on the ethical consideration that lack of any intraoperative warming represents substandard anesthesia care and may be potentially harmful for the study patients. Therefore, the widely used practice of thermal care consisting of single-unit upper body forced-air warming (in conjunction with warming of all intravenous fluids) was used as comparison in this trial.

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Material and Methods

Study Protocol

The institutional review board at Vanderbilt University approved the study protocol. In this prospective and randomized study, 60 adult patients (age > 18 yr), American Society of Anesthesiologists class II-IV, were initially enrolled after obtaining written informed consent and were randomized to one of two temperature-management groups. To assure that a similar number of patients in both groups were of comparable complexity, the randomization procedure was performed separately for patients requiring insertion of a pulmonary artery catheter and for those who did not require pulmonary catheter insertion. Each patient underwent a detailed preoperative evaluation that included history, physical examination, 12-lead electrocardiogram, chest radiograph, and biochemistry screening tests (see below). Exclusion criteria for the study included pregnancy, current fever (core temperature > 38°C), recent septic condition (within 3 days before the study), burn injury or multiple traumatic injuries, abdominal procedures involving rectal manipulation, and surgery in lithotomy position. Subjects underwent open abdominal procedures with general anesthesia lasting more than 120 min (from the time of incision). This minimum length of surgical procedures was selected because of the assumption that longer surgical time will be associated with more thermal stress in a cold operating room (OR) and will therefore present more challenge for the investigated warming devices.

The investigated system (Allon, MTRE, Advanced Technologies, Or-Akiva, Israel) used in this study is a device approved by the Food and Drug Administration that circulates warm water through a special whole body garment worn by the patient during surgery, and uses a computer to adjust the circulating water temperature to control the patient's temperature. The three-element system uses a temperature sensor, heat pump, and the specially manufactured suit (garment) applied with Velcro, through which the warm water is circulated. The garment is modular in design, allowing for exposure of various body parts or areas as required during specific surgical procedures, leaving the rest of the body covered. The garment is designed as a two-dimensional body wrap, assuming a three-dimensional shape when wrapped around the patient (fig. 1). These components are interconnected through a microprocessor, which adjusts circulating water temperature within precise limits. The maximal water temperature entering into the garment (upper cutoff limit) is 41°C. The temperature in the garment is not constant but during normal condition oscillates between 34 and 38.5°C while attempting to maintain normothermia. The body temperature (from up to three different temperature sensors) is constantly displayed. The water garment allows for the greater body

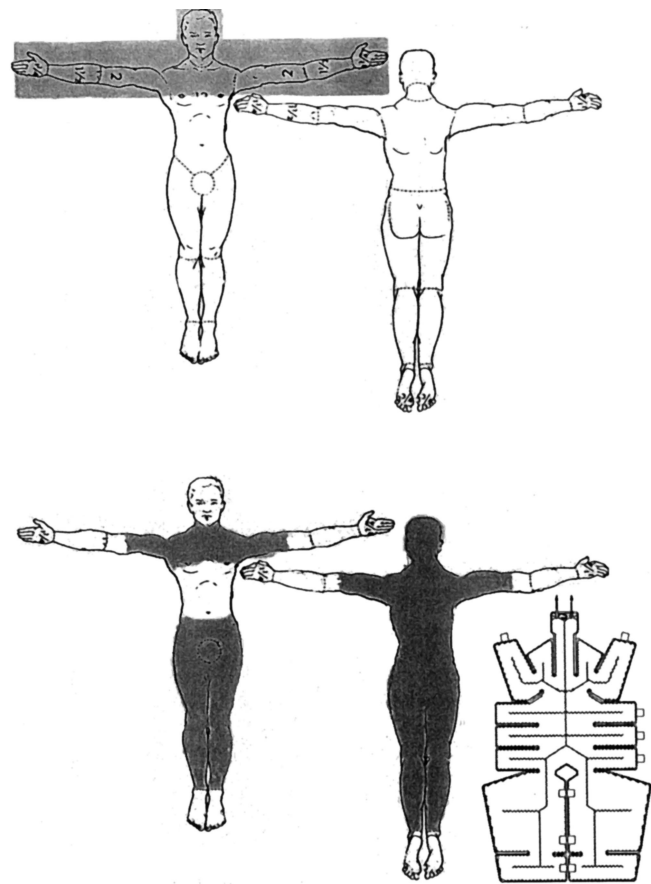


Fig. 1. Comparison of the magnitude of the covered body surface (shaded areas) covered by the forced-air warmer (top) and water-garment warmer (bottom, with the diagram of the garment included).

area to be covered (and warmed) compared with the forced-air system. In settings of open abdominal surgery, with the single water garment we have been able to cover large parts of both lower and upper extremities, upper anterior, lateral portions of the chest, and the entire back of the patient, which accounts for approximately 70–80% of the total body surface. On the other hand, the single, upper body blanket used in the commonly used forced-air warmer systems is able to cover only 20–40% of the total body surface.

The treatment group received warming using the water-garment warmer with a temperature set point of 36.8°C. Patients were placed in the garment, which was prefilled with the warm water (36.8°C), before induction of anesthesia, and the warming was continued intraoperatively until the transfer from the OR table to the stretchers at the end of surgery when the garment was removed. The group that received an upper body forced-air warmer received warming therapy using a convective air-warming system consisting of the Bair-Hugger Warming Unit Model 505 and the Bair-Hugger upper body warming blanket Model 522 (Augustine Medical, Eden Prairie, MN). The warming blanket was positioned on the patient, and warming was started after induction of

anesthesia and monitor placement and was continued until the end of surgery. The forced-air warming unit temperature output was set on high (43°C). All intravenous fluids were warmed to 37°C with a controlled fluid warmer (Hemokinetitherm, Dupaco Inc., Arcadia, CA) in both groups. The ambient OR temperature was kept constant at the lowest possible setting for 30 min before and throughout the surgery. OR temperature was continuously measured (and recorded every 5 min) by a mercury thermometer positioned at the level of the patient and not further than 50 cm from the body. The reported mean ambient temperature represents the average of all recorded temperature measurements during the operation (for ambient OR temperature) or postoperatively (for ambient recovery temperature). No effort was made to control ambient temperature postoperatively. For patients receiving convective air warming, the warming temperature was reduced for patients with core temperature greater than 37°C (to the settings of medium, 36°C). Patients whose rectal or esophageal temperatures decreased to less than 34.5°C had the room warmed to 24°C (or approximately 75°F) as a "rescue" to assist with patient rewarming.

For general anesthesia, standard premedication (midazolam and fentanyl) and induction techniques (*i.e.*, thiopental or propofol; succinylcholine or vecuronium; fentanyl or lidocaine and esmolol as clinically indicated) were performed. Anesthesia was maintained with isoflurane, nondepolarizing muscle relaxants (vecuronium or pancuronium), and fentanyl (repeated bolus doses, as directed by cardiovascular stability, at the discretion of attending anesthesiologist). No additional benzodiazepines, scopolamine, or nitrous oxide was administered during the intraoperative period in either group of patients. All patients were monitored intraoperatively using standard American Society of Anesthesiologists monitors. After induction, a radial artery catheter was placed for continuous monitoring of the arterial blood pressure and blood sampling. In the majority of the patients who were not monitored using the pulmonary artery catheter, an esophageal Doppler monitor (Deltex Medical Inc., Irving, TX) was placed into the esophagus, and the cardiac index was continuously displayed and recorded throughout the intraoperative period.

A rectal thermistor probe (Series 4000, Yellow Springs Instrument Lab, Yellow Springs, OH; accuracy $\pm 0.2^\circ\text{C}$, 5-cm insertion depth), esophageal probe (Mon-a-therm esophageal stethoscope, 18 French with temperature sensor; thermistor 400 Series, Mallinckrodt Corp., St. Louis, MO), and forearm and fingertip skin temperature probes were placed on the patient after induction of anesthesia. Rectal and skin temperatures were continuously recorded in both experimental groups using the temperature-monitoring module of the investigated water-warming system during the surgical procedure and for 2 h postoperatively. Esophageal temperatures were

continuously monitored intraoperatively on the Hewlett Packard monitoring module of the anesthesia machine. In addition, tympanic membrane temperatures were recorded preoperatively and immediately on arrival from the OR to the recovery room using a commercially available infrared probe (FirstTemp Genius, Sherwood Medical, St. Louis, MO). On arrival in the postanesthesia care unit (PACU) or surgical intensive care unit (SICU), all extubated patients were periodically assessed (every 15 min for 1 h and every 30 min thereafter) by the nursing staff (blinded as to the type of warming used perioperatively) for shivering, requirement for use of additional warming devices (warm blankets, radiant heat devices, convective air warmer), and subjective thermal comfort using standard scales. Additional warming devices were applied in the PACU-SICU in patients when they exhibited shivering, when their body temperature was less than 36°C, or when they complained about being cold (thermal comfort scale < 5). The type of additional warming devices was left to the discretion of staff in the PACU-SICU. Vital signs were also recorded, including rectal temperature, heart rate, blood pressure, oxygen saturation, and respiratory rate (every 15 min for 1 h and every 30 min thereafter).

Fingertip blood flow was estimated in our study using the forearm minus fingertip surface temperature gradient, because there is an excellent correlation between skin temperature gradient and volume plethysmography.⁸ A skin temperature index gradient of 0°C (corresponding to a finger flow of approximately 1 ml/min) is reported to coincide with the core temperature plateau; therefore, we defined the index gradient exceeding 0°C as significant vasoconstriction.⁹

Power Analysis and Statistical Analysis of Results

The primary outcome from this study includes perioperative core temperatures in the investigated groups. The secondary outcomes include vasoconstriction index and occurrence of postoperative indicators of thermal stress. The format of this superiority trial was expressed by two hypotheses: the null hypothesis, which states that there is no difference between the upper body forced-air warmer and water-garment warmer in terms of primary outcome, and the alternate hypothesis, which states that there is a difference. A minimum sample size of 44 total subjects was calculated as needed to be enrolled and analyzed to detect a clinically relevant difference in the primary outcome of mean rectal or esophageal temperatures (temperature difference, 0.5°C between groups) according to the power analysis based on the following parameters: type II error rate ($\beta = 0.1$), type I error rate ($\alpha = 0.05$, $\delta = 0.5$, $\sigma = 0.5$). However, based on the fact that other secondary outcomes will be also measured in the study, and the possibility of some unexpected dropout from the study, the initial total

Table 1. Summary of Demographic Characteristics of the Patients

	Forced-air Warmer (N = 28)	Water Garment (N = 25)
Age (y)	52.9 ± 15	56.1 ± 11.7
Sex (M/F)	16/12	13/12
Height (cm)	170.5 ± 12.1	165.8 ± 22.6
Weight (kg)	80.7 ± 17.2	74.3 ± 13.9
Body surface area (m ²)	1.9 ± 0.2	1.8 ± 0.3
ASA class II/III/IV	9/11/8	10/11/4
Medical history		
Chronic hypertension	12	7
Coronary arteries disease	11	7
Peripheral vascular disease	3	1
Chronic obstructive pulmonary disease	0	0
End-stage renal disease	2	1
End-stage liver disease	3	4
Diabetes mellitus	9	6
Malignancy	14	14
Type of surgical procedure		
Partial liver resection	10	8
Liver transplantation	3	4
Pancreatic surgery	4	4
Exploratory laparotomy	9	6
Other	2	3
Duration of surgery (min)	299 ± 86	361 ± 141
Ambient OR temperature (°C)	20.4 ± 1.4	20.4 ± 1.5
Ambient temperature at recovery	23.1 ± 0.9	22.8 ± 0.9
Cardiac index intraoperatively (l · min ⁻¹ · m ⁻²)	3.99 ± 1.5	4.1 ± 1.3
Total fentanyl dose (μg)	850 ± 515	945 ± 475
End-tidal isoflurane (%)	0.88 ± 0.2	0.87 ± 0.2

Data presented as mean ± SD.

ASA = American Society of Anesthesiologists; OR = operating room.

number of recruited patients was increased to 60 (30 in each group).

All nonfrequency data are presented as mean ± SD. The analysis on frequency data was performed using two-sided Fisher and chi-square tests. For further assessment of the core temperature differences, 95% confidence intervals were calculated from the difference between the study groups. The parametric data were compared using a two-sided *t* test. Statistical significance of differences (null hypothesis rejected) was inferred at *P* < 0.05.

Results

From 60 patients initially enrolled in the study, seven patients were withdrawn immediately after completion of their surgical procedures. The removal was caused by the shorter-than-expected duration of the surgical procedure (< 120 min) in five patients and unplanned extension of surgery to the rectal area (two patients) that interfered with the rectal temperature sensor. The summary of the demographics of the remaining 53 patients (28 in the forced-air warmer group and 25 in the water-garment warmer group) is shown in table 1. There were

no statistically significant differences (Fisher exact test, *P* > 0.05 for frequency data; *t* test, *P* > 0.05 for continuous data) in the demographics (age, weight, height, body surface area, preoperative vital signs, preoperative core temperature, American Society of Anesthesiologists status, medical history, cigarette smoking, type of surgical procedures) and no statistically significant differences in the length of the procedure, total intraoperative fentanyl dose, average isoflurane end-tidal concentration, cardiac index, and ambient temperatures in the OR and PACU-SICU (table 1) between the two groups. The time from the entering the OR to the end of placement of all lines and positioning (anesthesia ready time) was also similar in the water-warming and forced-air warmer groups (29.4 ± 19.7 and 27.4 ± 18.5 min, respectively; *P* > 0.05 by *t* test). No statistically significant differences were observed in relation to the frequency and equivalent total doses of β-adrenergic antagonists, peripheral vasodilators, diuretics, central sympatholytic agents, narcotic analgesics, nonsteroidal antiinflammatory agents, and hypoglycemic (including insulin) medications (not shown). Neither intraoperative fluid (crystalloids) requirements (4,689 ± 2,317 vs. 6,012 ± 2,577 ml in the control vs. water-garment group) nor estimated blood loss (640 ± 848 vs. 1,036 ± 1,312 ml in the control vs. water-garment group) differed significantly (*P* > 0.05, *t* test) between experimental groups.

The individual body temperature data (rectal, esophageal, and tympanic for recovery baseline) for all patients during the perioperative period are shown as the scatter plot in figure 2. These data were statistically compared using the mean rectal and esophageal temperatures and the frequency analysis (*i.e.*, percentage of patients within the selected temperature ranges) at the given time points. Patients in the water-garment warmer group displayed statistically significantly higher (*P* < 0.05, *t* test) mean core temperatures than the upper body forced-air warmer group at incision, 1 h after incision, and at skin closing (36.4 ± 0.4, 36.5 ± 0.3, and 36.9 ± 0.3°C vs. 36 ± 0.6, 35.9 ± 0.7, and 36.4 ± 0.8°C, respectively). Tympanic temperatures at arrival to the PACU-SICU were also higher (*P* < 0.05) in the water-garment group compared with the forced-air warmer group (36.6 ± 0.4 and 36.2 ± 0.9, respectively). No statistically significant differences (*P* > 0.05) in body temperatures were observed in the water-garment and forced-air warmer groups preoperatively, at OR baseline (after induction, line placement, and positioning), and postoperatively at 1 and 2 h of recovery. The calculated 95% confidence intervals for the significant differences in core temperatures during incision, 1 h after incision, closing, and at arrival to the PACU-SICU were 0.7–0.07, 0.8–0.2, 0.8–0.2, and 0.9–0.1, respectively. Moreover, a higher percentage of patients in the upper body forced-air warmer group showed significant (*P* < 0.05, Fisher exact test) hypothermia (defined as rectal or

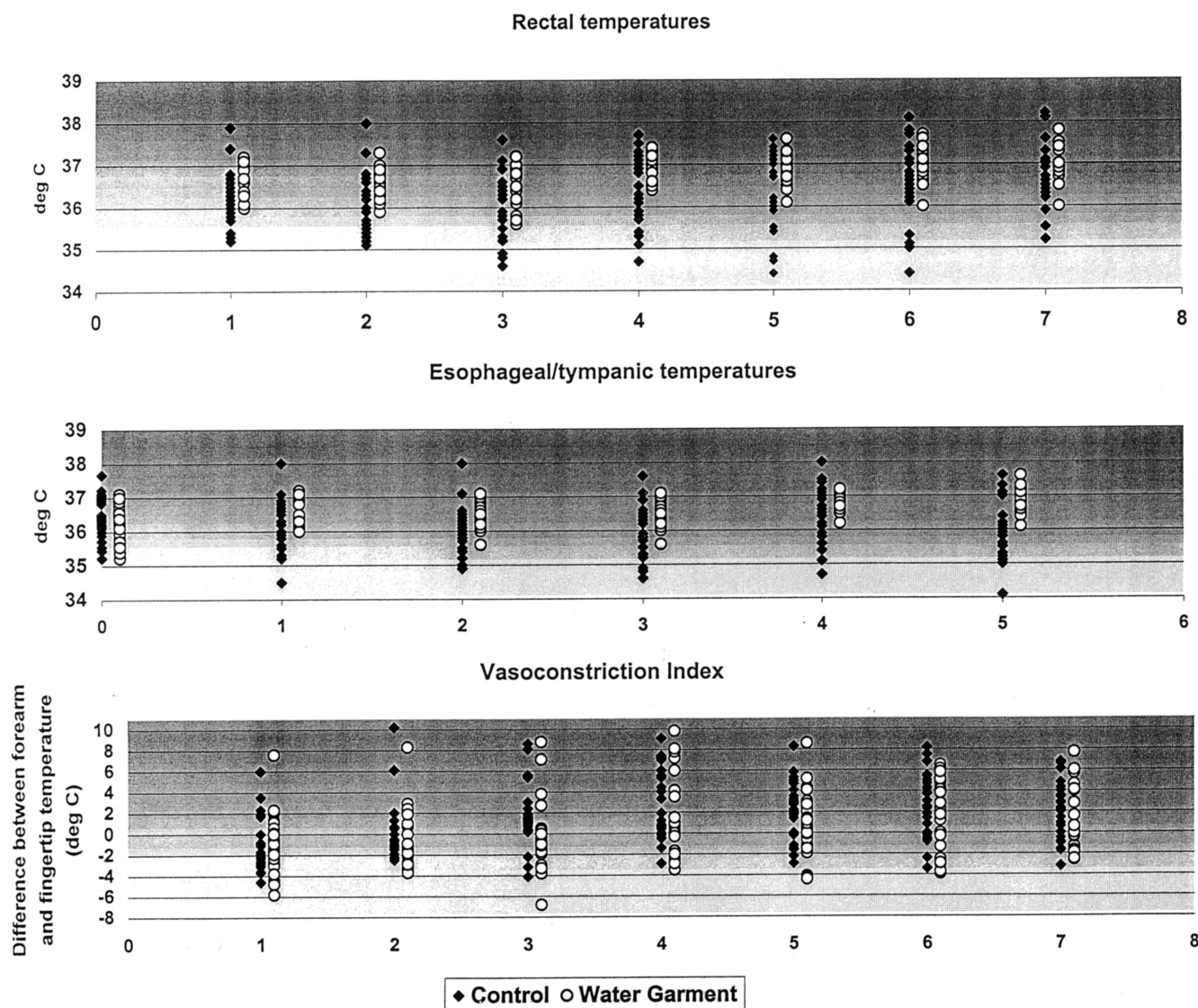


Fig. 2. Changes in the rectal temperatures (*top*), esophageal–tympenic temperatures (*middle*), and vasoconstriction index (*bottom*) during the perioperative period. Data represent individual temperature points for patients in each study group. Numbers on the horizontal axes represent different time points when the presented data were recorded: 0 = preoperative period (in holding room); 1 = operating room baseline (after induction and positioning); 2 = incision; 3 = 1 h after incision; 4 = closing; 5 = after arrival to recovery room or intensive care unit; 6 = 1 h postoperatively; 7 = 2 h postoperatively.

esophageal temperatures of $< 35.5^{\circ}\text{C}$) when compared with the water-garment group at all selected time points during the perioperative period. In particular, 22 and 24% of all patients in the upper body forced-air warmer group were hypothermic at surgical closing or at arrival to the PACU-SICU, respectively. Moreover, 14 and 7% of patients in the forced-air group remained hypothermic 1 and 2 h after surgery, respectively. No rectal or esophageal temperature less than 35.5°C was observed perioperatively in any of the patients from water-garment group. The thermal rescue measures (OR warmed to 24°C for rectal or esophageal temperatures of $< 34.5^{\circ}\text{C}$) were used for two patients in the upper body forced-air warmer group and none in the water-garment group. Four patients in the study population (two in each in-

vestigated group) presented with increased body temperature ($> 37.1^{\circ}\text{C}$ but less than 38°C) before and after induction. No patients in the water-garment group and two patients in the forced-air warmer group had body temperatures (rectal or esophageal) higher than 37.4°C during the intraoperative warming.

Statistical analysis of the mean vasoconstriction data indicates more vasoconstriction (positive values of the vasoconstriction index) in the forced-air warmer group when compared with the water-garment group at some analyzed time points during the perioperative period. However, because of the large scatter of the vasoconstriction data, the statistically significant differences between investigated groups were only demonstrated at 1 h after incision ($P < 0.05$, *t* test).

Table 2. Thermal Stress Indicators during the 2-h Postoperative Period in Extubated Patients

	Forced-air Warmer (N = 18)	Water Garment (N = 19)
Shivering	4	1
Cold thermal discomfort (subjective thermal comfort scale less than 5)	7	3
Use of additional warming devices	8	6
Presence of any above thermal stress indicators during the postoperative period	19	10

Thermal comfort scale (0–10): 0 = extremely cold and uncomfortable; 5 = normal thermal comfort (neither cold nor too warm); 10 = extremely hot and uncomfortable.

Extubated patients in both study groups were also analyzed during the postoperative period for the incidence of thermal stress indicators, defined here as the occurrence of shivering, use of additional thermal devices in the PACU-ICU, and thermal comfort less than 5 on the 1–10 scale. The occurrence of thermal stress indicators was rare in both study groups, although more frequent in the forced-air warmer group. The statistical analysis of the frequency of these events (table 2) did not reveal statistically significant ($P > 0.05$, Fisher exact test) differences between study groups for the occurrence of each thermal discomfort indicator when analyzed separately.

No complications from the use of either the water garment or the forced-air warmer (such as leaks, burns, redness, and failure of equipment or overheating) were noted in either study group.

Discussion

The results of the current study show that the water-garment warmer system we used produced higher body temperatures when compared with the single forced-air warmer. The lack of effectiveness of the previously investigated circulating water systems¹⁰ might be a result of the fact that they relied on the warm-water mattresses with the skin contact area limited largely to the patient's back. In fact, it was claimed previously that circulating water might be more effective when placed over patients rather than under them, and in that position can almost completely eliminate metabolic heat loss.¹¹ A possible explanation for the differences in the temperatures observed in the current study might be that the water garment warmer allows for the greater body area to be covered (and warmed) compared with the single forced-air system. Another explanation for the observed differences in core temperatures between two devices at incision and 1 h after incision might be that water-garment group was prewarmed (*i.e.*, patients were placed on the warm water garment before induction)

and the air-warming group was not. It is well known that prewarming patients before induction of anesthesia reduces the core-to-peripheral temperature gradient. This results in significant decrease in redistribution hypothermia. The effect of preinduction warming on core temperature was confirmed previously by other investigators.^{12,13} Moreover, the forced-air warming was only started after completion of placement of all invasive lines and positioning, which was significantly later than the start of warming with the new water garment. It is possible that, if the two systems were compared in fully equivalent settings (*i.e.*, one water warming garment and two, lower and upper body forced-air warmers, in addition to the traditional warm-water mattress), these small differences in the core temperatures will be no longer observed. In this respect, the current study did not compare the warming effectiveness of two different devices, but two different strategies of perioperative warming.

Several explanations of this relatively small difference in body temperatures between investigated systems might be offered. It was demonstrated previously that the upper body forced-air method of warming in connection with the intraoperative fluid warming has been effective in the majority of surgical cases.^{14–20} In contrast, previously published studies that have demonstrated larger differences in core temperatures used ineffective warming methods or no perioperative warming at all in the control group.

In the design and interpretation of the data, we used an approach consisting of the putative placebo trial. In this design, a putative placebo is the current most widely used method of thermal care (*e.g.*, forced-air warmer), the effect of which is of such magnitude, consistency, and demonstrated benefits (effectiveness) when compared with placebo, that it is unethical to withhold it from a subject in a clinical trial. Based on the obtained results in this study, we believe that the water garment shows similar warming effects to the active control (the putative placebo, or air warmer in this case), but also to the best outcome that might have been seen with placebo if placebo had been present.^{14–17,20}

It is important to note that several patients in the forced-air warmer group displayed both rectal and esophageal temperatures lower than 35.5°C at various times during the perioperative period, whereas virtually all patients in the water-garment group were warmer than 35.5°C at all time points perioperatively. This temperature cut point may be critical for the increased incidence of morbid cardiac events.^{6,21,22} Therefore, the point can be made that the water-garment warmer prevents patients from becoming even mildly hypothermic and maintains the body temperature above the critical temperature level.

Measured outcomes of the study included recording of the thermal discomfort, the incidence and severity of

shivering, and use of additional warming devices during the 2-h postoperative period. A significant number of the patients (30%) remained intubated postoperatively as a result of the severity and length of some surgical procedures and blood loss and massive fluid resuscitation, which resulted in the decision not to extubate patients postoperatively and transfer them directly from the OR to the SICU. Sixteen patients remained intubated and sedated during the 2-h postoperative period (10 in the forced-air warmer group and 6 in the control group; $P > 0.05$, Fisher exact test). These patients were not taken into account for the calculations of the thermal comfort score data.

In conclusion, although previous attempts to warm patients during surgery with water-filled blankets or mattresses have been unsatisfactory, the new device tested proved equivalent to the widely used convective air-warming system in patients undergoing major abdominal surgery in cold ORs. The investigated water warming system, by virtue of its ability to deliver heat to a greater percentage of the body, results in better maintenance of intraoperative normothermia than does forced-air warming applied only to the upper extremities, as is common practice. This difference might well have disappeared if a greater portion of the body were warmed earlier during anesthesia in the forced-air warmer group. A clinician's decision to use the water-garment system should, given the current data, be based on other factors, such as ease of use and applicability to the given surgical situation, not on some intrinsic superiority of the one system *versus* another.

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