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Randomized Prospective Comparison of Forced Air Warming Using Hospital Blankets versus *Commercial Blankets in Surgical Patients*

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Background: **The purpose of this study was to evaluate the efficacy of an experimental approach to forced air warming using hospital blankets or a Bair Hugger warming unit (Augustine Medical Inc., Eden Prairie, MN) to create a tent of warm air.**

Methods: **Adult patients undergoing major surgery were studied. Patients were randomized to receive forced air warming using either a commercial Bair Hugger blanket (control group, n = 44; set point, 43°C) or standard hospital blankets (experimental group, n = 39; set point, 38°C). Distal esophageal temperatures were monitored. Patients were contacted the following day regarding any problems with the assigned warming technique.**

Results: **Surface area covered was 36 ± 12% (mean ± SD) in the experimental group and 40 ± 10% in the control group. Final temperatures at the end of surgery were similar between groups: experimental, 36.2 ± 0.6°C; control, 36.4 ± 0.7°C. A similar number of patients had esophageal temperature less than 36°C at the end of surgery in both groups (experimental, 12 of 39 [31%]; control, 12 of 44 [27%]). The majority of patients were satisfied with their anesthetic and warming technique: experimental, 38 of 39 patients; control, 44 of 44 patients. There were no thermal injuries.**

Conclusions: **Standard hospital blankets heated to 38°C forced air were equally as effective as commercial blankets heated with forced air at 43°C. However, based on concerns expressed by the manufacturer, this experimental technique should not be used until further safety evaluation has been undertaken.**

PATIENTS undergoing major surgery have the potential to develop perioperative hypothermia, defined as a core temperature less than 36°C. Among the methods used intraoperatively to maintain normothermia, one that is particularly effective is forced air warming.[1] The cost of disposable forced air warming blankets may, however, limit the widespread use of this technique. It has been shown that forced air warming with hospital bed sheets was able to heat standardized thermal bodies twice as effectively as commercial blankets using identically warmed 38°C forced air and the Bair Hugger Model 500 Warming Unit (Augustine Medical, Inc., Eden Prairie, MN).[2] With the warming unit set at 38°C (medium setting), air temperatures measured within a simulated full-body field were 33.4–35.8°C beneath the hospital sheets and 31.1–33.9°C with the commercial blanket.[2] No data are available using this hospital blanket warming technique in surgical patients.

The purpose of this study was to evaluate the intraoperative use of forced air warming with hospital blankets at 38°C *versus* single-use commercial blankets in surgical patients. The hypotheses were that compared with forced air warming and commercial blankets, forced air warming with hospital blankets results in similar core temperatures at the end of surgery, similar time spent in the postanesthesia care unit (PACU), similar patient satisfaction, and no thermal injuries.

Methods

The protocol was approved by the MetroHealth Medical Center Institutional Review Board. All patients signed written informed consent. Inclusion criteria were American Society of Anesthesiologists (ASA) physical status I–III, adults, and elective major gynecologic, orthopedic, otolaryngologic, plastic, or general surgery scheduled to last 20 min or more. Exclusion criteria consisted of emergency surgery, pregnancy, head injury, preoperative sublingual temperature 38°C or more or less than 35.5°C, planned intensive care unit admission postoperatively, use of calcium channel blockers, and history of malignant hyperthermia.

Patients were randomized to receive intraoperative forced air warming using either a commercial upper or lower body blanket (control group, n = 45; Bair Hugger Blanket, Augustine Medical, Inc., Eden Prairie, MN) or standard hospital blankets (experimental group, n = 42). A table of random numbers was used for group assignment. A computer generated the random numbers at the beginning of the study. Once consent was obtained, the anesthesia team was notified of group assignment before surgery based on this table of random numbers. Sealed envelopes were not used. In the control group, the Bair Hugger Model 500 Warming Unit (Augustine Medical) was connected to the commercial blanket as per the manufacturer's directions using the high temperature setting (43°C). In the experimental group, the area to be warmed was covered with one hospital blanket. A second hospital blanket was placed over the first and tucked around the edges of the operating room table at the head or the foot of the bed, depending on the site of surgery.

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Fig. 1. Experimental forced air warming technique using the hose of a Bair Hugger Model 500 Warming Unit (Augustine Medical, Inc., Eden Prairie, MN). The warming unit clearly identified the medium temperature setting of 38°C.

Forced air warming between the hospital blankets was provided by the Bair Hugger Model 500 Warming Unit using the medium temperature setting (38°C). The outlet hose from the warming unit was supported such that the outlet opening was directed upward toward the ceiling, creating a tent of air within which warmed air circulated (figs. 1–5). The 38°C temperature setting was chosen to minimize the risk of burns because the maximum temperature using this setting is 39.3°C at the outlet hose and 38.2°C below the hospital blankets.[2] The amount of surface area warmed (percent) was estimated for each patient as follows: arm, 9%; leg, 18%; trunk, 36%; head, 9%; and genitals, 1%.

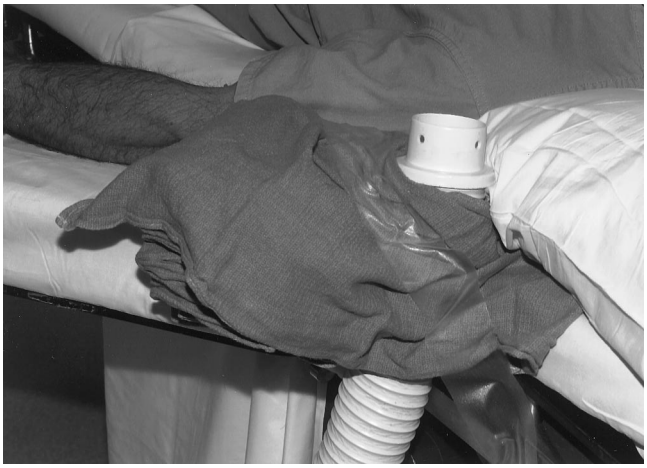

Fig. 2. Experimental forced air warming technique, upper body configuration. The hose was supported so the flow of air was directed upward toward the ceiling.

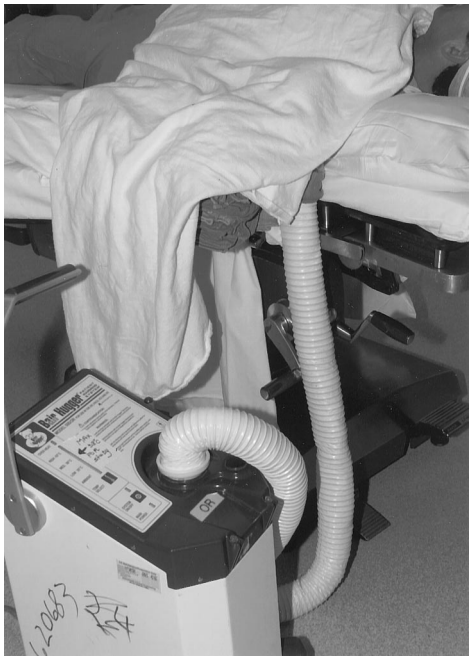

Fig. 3. Experimental forced air warming technique, upper body configuration. The area to be warmed was covered with one hospital blanket. Care was taken not to direct the airstream toward the patient. A second hospital blanket was placed over the first.

General anesthesia, tracheal intubation, and mechanical ventilation were used in all patients. Monitors were electrocardiograph (ECG), noninvasive blood pressure cuff, pulse oximeter, esophageal stethoscope, and end-tidal CO_2. Anesthesia was induced with thiopental, 3–5 mg/kg, midazolam, 1–2 mg, and fentanyl, 1–3 μg/kg. Anesthesia was maintained with isoflurane, supplemented with fentanyl and N_2O, 50–66%. All patients received nondepolarizing neuromuscular relaxants. Anesthetic gases were delivered *via* an endotracheal tube using a circle system, heat and moisture exchanger (Humid-Vent, Gibeck Respiration, Upplands Vasby, Swe-

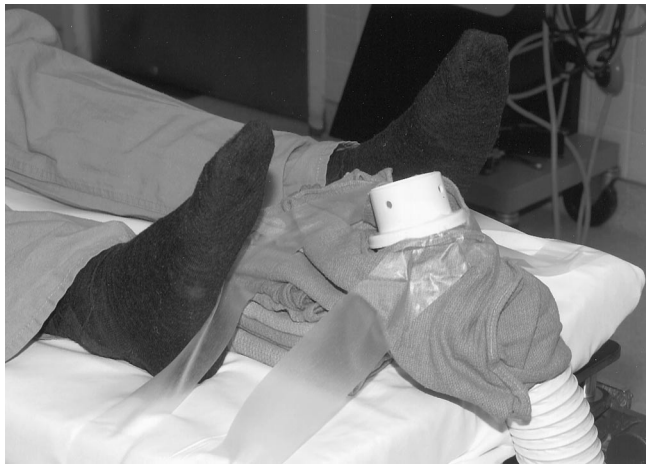

Fig. 4. Experimental forced air warming technique, lower body configuration. The hose was supported so the flow of air was directed upward toward the ceiling.

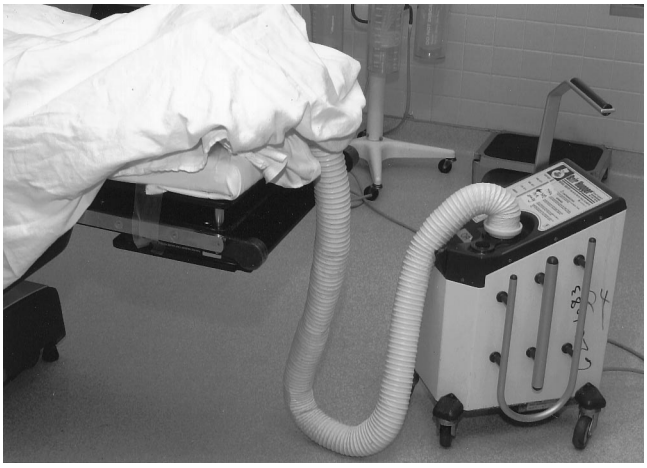

Fig. 5. Experimental forced air warming technique, lower body configuration. The area to be warmed was covered with one hospital blanket. Care was taken not to direct the airstream toward the patient. A second hospital blanket was placed over the first.

den), and CO_2 sodalime absorber. The heat and moisture exchanger was placed between the Y-piece of the circle system and the endotracheal tube. Ventilation was controlled to maintain normocapnia (end-tidal CO_2, 30–35 mmHg) using a fresh gas flow of 2 l/min. The ambient room temperature was set at 21°C. Room temperature fluids were infused as clinically indicated to maintain normovolemia. Forced air warming using the control or experimental technique was begun after tracheal intubation.

Intraoperatively, distal esophageal (core) temperatures were measured at 15-min intervals after tracheal intubation until the end of surgery using an esophageal stethoscope with thermocouple sensor (Mon-a-therm temperature sensor thermistor 400 series, Mallinckrodt Anesthesia Products, St. Louis, MO). The esophageal stethoscope was positioned at the point of maximal heart sounds,[3] and the temperature sensor was continuously displayed (Mon-a-therm Thermistor Monitor, Model 4070, Mallinckrodt Anesthesia Products). Room temperature was continuously displayed using the second channel of the Mon-a-therm device. Preoperatively, sublingual temperatures were measured with an electronic thermometer (IVAC Temp Plus II thermistor, IVAC Corp., San Diego, CA). Sublingual placement of the thermometer and mouth closure was done by postanesthesia care unit (PACU) nurses experienced with the use of this device. At the conclusion of surgery, the forced air warmer was turned off, and the commercial warming blanket was removed. Patients in both groups were transported to the PACU covered with a standard hospital blanket. Any patient developing intraoperative core temperature greater than 37°C had the forced air warming unit turned off to avoid overheating.[4]

Postoperatively, sublingual temperature (IVAC thermistor) was recorded by the PACU nurses who were unaware of patient group. Initial values were obtained within the first 10 min of arrival to the PACU. Subsequent measures were recorded after 30 and 60 min. Time of PACU discharge was also recorded. All patients were evaluated for evidence of redness, swelling, or blisters (signs of thermal injury) before discharge from the PACU. Patients were contacted the following day by a person not aware of patients group. A standardized questionnaire was used regarding the effectiveness of the anesthetic (excellent, good, fair, poor), level of thermal comfort (comfortable, cold, warm, do not recall), and whether the patient would choose the same anesthetic technique again (yes, no).

Statistical Considerations

The primary hypothesis was that there would be no difference between groups in final core temperature. Assuming a standard deviation of 0.5°C in the control and experimental groups and an α of 0.05, the power of detecting a 0.5°C difference in final core temperature between groups was 0.9 with a sample size of 40 patients in each group. Confidence intervals for the difference in final core temperatures were also calculated using a standard α of 0.05.[5,6]

Parametric data (reported as mean ± SD) were compared between groups using Student's *t* test. Categorical data were compared between groups with Fisher exact test and the Cochran–Mantel–Haenzel test. The relation between end of surgery temperature and surface area covered was determined using analysis of variance of the linear regression between these parameters in each group (GLM procedure). A P value < 0.05 was considered significant.

Results

Four patients were excluded after randomization because of protocol violations as follows: one patient was pregnant (experimental group), one patient had surgery canceled (control group), and two patients in the experimental group received forced air warming with commercial blankets instead of with hospital blankets. Two patients in the control group had unplanned admissions to the intensive care unit because of surgical complications and were excluded from time to discharge analysis. Two patients in the control group had intraoperative warming discontinued because core temperature exceeded 37°C.

The groups were similar with respect to age, weight, ASA physical status, and type of surgery (table 1). There were more women in the experimental than in the control group, and patients in the experimental group were shorter than control subjects ($P < 0.05$). Surface area covered was 36 ± 12% in the experimental group (primarily over the upper body in 17 patients and pri-

Table 1. Patient Data

	Commercial Blanket (Controls, n = 44)	Hospital Blanket (Experimental, n = 39)	*P* Value
Age (yr)	46 ± 12	41 ± 14	0.11
Gender (M/F)	19/25	7/32*	0.018
Height (inches)	67 ± 4	64 ± 4*	0.002
Weight (kg)	87 ± 24	82 ± 26	0.30
Type of surgery			0.97
Gynecologic	10 (23%)	12 (31%)	
Orthopaedic	10 (23%)	2 (5%)	
General	14 (32%)	14 (36%)	
ENT	3 (7%)	5 (13%)	
Other	7 (16%)	6 (15%)	
ASA Physical Status			0.20
1	2 (5%)	6 (15%)	
2	33 (75%)	28 (72%)	
3	9 (20%)	5 (18%)	
Anesthesia time (min)	204 ± 105	178 ± 72	0.14
Surgery time (min)	149 ± 91	131 ± 72	0.27
Fluid balance			
Crystalloid (ml)	2190 ± 1540	1740 ± 950	0.11
Colloid (ml)	500, n = 1	500, n = 1	
Red blood cells (units)	2, n = 1	0	
Blood loss (ml)	250 ± 570	120 ± 190	0.17

Mean ± SD or numbers of patients (%); *$P < 0.05$ between groups.

marily over the lower body in 22 patients) and 40 ± 10% in the control group (upper body blanket = 22 patients; lower body blanket = 22 patients).

In both groups, core temperature decreased to a similar extent after induction (table 2, fig. 6). Average final temperatures at the end of surgery were greater than 36°C in both groups. A similar number of patients were hypothermic at the end of surgery in both groups (experimental, 12 of 39 [31%]; control, 12 of 44 [27%]). There was no relation between surface area covered and core temperature at the conclusion of surgery. There were no differences in final esophageal temperature between the upper and lower body blanket configurations when using the experimental (36.1 ± 0.4 and 36.3 ± 0.7°C) and control (36.3 ± 0.7 and 36.4 ± 0.7°C) techniques.

Postoperatively, there were no differences in temperature between groups. Time spent in the PACU was similar in the experimental (102 ± 49 min) and control (99 ± 38 min) groups. The majority of patients were

Table 2. Perioperative Temperature Data

	Commercial Blanket (Controls, n = 44)	Hospital Blanket (Experimental, n = 39)	*P* Value
Temperature (°C)			
Operating room, initial	21.8 ± 1.8	22.3 ± 2.2	0.32
Operating room, final	22.4 ± 1.6	23.0 ± 2.0	0.12
Preoperative sublingual	36.7 ± 0.5	36.7 ± 0.4	0.74
Lowest esophageal	35.8 ± 0.5	35.8 ± 0.5	0.85
Time to lowest esophageal (min)	28 ± 26	38 ± 40	0.19
Final esophageal*	36.4 ± 0.7	36.2 ± 0.6	0.22
Preoperative, lowest	0.8 ± 0.7	0.9 ± 0.5	0.69
Preoperative, final	0.3 ± 0.8	0.5 ± 0.5	0.19
Number of patients with final esophageal < 36.0°C	12 (27%)	12 (31%)	0.81
Number of patients with final esophageal < 35.5°C	4 (11%)	4 (10%)	1.00
PACU			
Sublingual, within 10 min of arrival	36.3 ± 0.7	36.1 ± 0.7	0.13
Sublingual, after 30 min	36.4 ± 0.6	36.3 ± 0.5	0.33
Sublingual, after 60 min	36.5 ± 0.6	36.3 ± 0.5	0.10

Mean ± SD or number of patients (%).

PACU = postanesthesia care unit; *Mean final temperature difference between groups = 0.17°C (95% confidence intervals: −0.095, 0.431°C). Two patients in the commercial group had their postoperative temperatures measured in the intensive care unit.

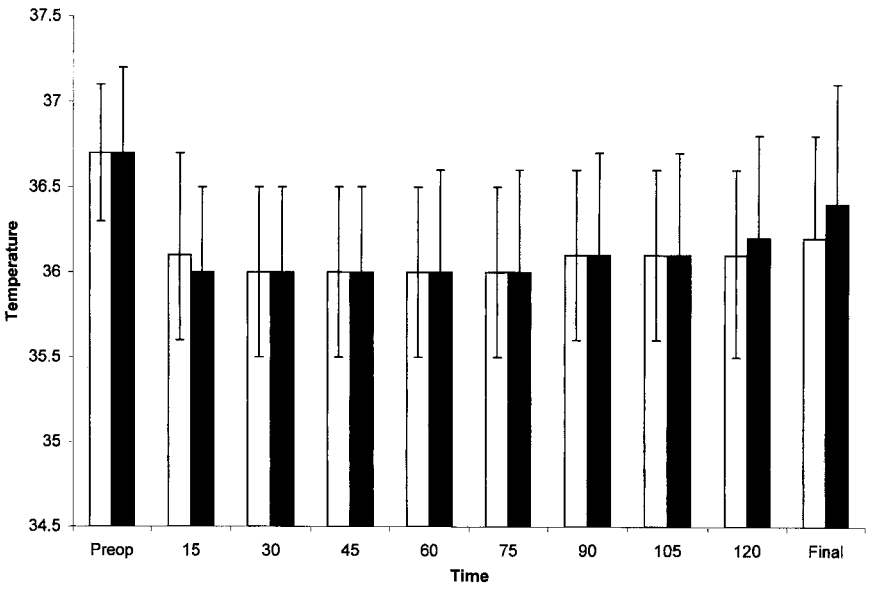

Fig. 6. Esophageal temperatures (°C, mean ± SD) in patients receiving forced air warming using hospital blankets (experimental, open rectangles) or commercial blankets (control, darkened rectangles). Time = min after induction of anesthesia; Preop = preoperative; Final = end of surgery. There were no significant differences between groups.

satisfied with their anesthetic and warming technique (table 3). There were no thermal injuries observed or reported.

Discussion

The results of this study demonstrated that forced air warming with commercial blankets and hospital blankets were effective in maintaining normothermia. At the end of surgery and postoperatively, average temperatures were 36°C or more in both groups, and there were no thermal injuries.

The forced air warming technique using the commercial blanket (control group) consisted of heated air from the warming unit that inflated a specially designed single-use blanket. The blanket design contains a series of hollow tubes with rounded upper surfaces and flattened lower surfaces joined in a parallel array. Once inflated, the blanket directs heated air onto the patient through exit ports in the undersurface of the blanket. Heat transfer using the commercial blanket has been evaluated in an experiment using standardized thermal bodies containing 1-l lactated Ringer's solutions: temperatures within the thermal bodies were measured, and delivered energy was calculated.[2] At the 38°C setting, the energy delivered to the standard thermal bodies was estimated at 5.2–5.4 kcal per 3 h. At the 43°C setting, the energy delivered was 9.0–9.8 kcal per 3 h.[2]

In contrast, the forced air warming technique using hospital bed sheets heated the standardized thermal bodies twice as effectively as the commercial blankets using the 38°C setting, which resulted in a correspondingly higher heat transfer of 10–13.4 kcal per 3 h.[2] The present study used hospital blankets instead of bed sheets because the blankets were readily available for covering patients in the operating rooms and were a well-accepted means of covering the patient intraoperatively. Nonetheless, it is possible that differences exist in heating abilities and energy transfer beneath bed sheets *versus* blankets.

The increased heat transfer to standard thermal bodies using hospital bed sheets described by Dr. Kempen is likely the result of greater volumes of heated air leaving the warming device per unit time and a greater resultant

Table 3. Postoperative Interview

	Commercial Blanket (Controls, n = 44)	Hospital Blanket (Experimental, n = 39)	*P* Value
Effectiveness of anesthetic	Excellent: 33 (75%) Good: 11 (25%)	Excellent: 26 (67%) Good: 12 (31%) Fair: 1 (3%)	0.48
Would choose same anesthetic technique again	Yes: 44 No: 0	Yes: 39 No: 0	—
Level of thermal comfort	Comfortable: 20 (45%) Cold: 5 (11%) Warm: 1 (2%) Do not recall: 18 (41%)	Comfortable: 13 (33%) Cold: 8 (21%) Warm: 3 (8%) Do not recall: 14 (36%) No comment: 1 (3%)	0.97

Data are number of patients (percent). There were no significant intergroup differences.

air flow velocity and convection beneath the bed sheets compared with the commercial blanket.[2] As well, the nature of the inflated commercial blanket may facilitate influx of ambient air or egress of warm air with resultant decreased temperatures within the commercial blanket.[2]

In the experimental group, care was taken to direct the outlet of the warming unit hose upward at all times so patient skin was never directly exposed to heated air immediately inside the end of the outlet hose. Care was also taken to avoid the 43°C setting (high), which can result in skin burns because delivered air temperatures at this setting may be 45 or 46°C.[7,8] It has been previously shown that with the Bair Hugger Warming Unit at the 38°C setting (medium), the maximum temperatures measured were at the hose outlet, and these temperatures did not exceed 39.3°C.[2] Thus, use of the experimental technique would not be expected to result in any patient burns, a finding confirmed in the present study.

Although we did not encounter any burns, it must be emphasized that the present study was not designed nor powered to evaluate the risk of thermal injury when using the experimental technique. The incidence of thermal injury may be just low enough that 83 patients was too small a sample to see the problem. Further, if the temperature of the warmer is accidentally changed to the high setting during the case or if the hose is accidentally bumped such that airflow is redirected to the patient's skin surface, local burning may occur. Patients with decreased cutaneous blood flow, such as the elderly population, or patients with peripheral vascular disease and hypovolemia may also be at greater burn risk. The manufacturer of the forced air warming system has issued a warning label to specifically remind clinicians that using forced air warming units without attaching a blanket can lead to traumatic thermal injury.

There is concern that forced air warming units may be a source of microbial pathogens and increased risk of perioperative surgical wound infection.[9] Avidan *et al.*[10] placed Agar plates directly in the air stream of nine Bair Hugger warming units and one Warm Touch unit (Mallinckrodt Anesthesia Products, St. Louis, MO). These authors found that four of these plates grew potentially pathogenic organisms. In three instances, the site of colonization was in the hose. When a microbial filter was attached to the end of the hose or when the warmers were set to deliver heated air through the commercial blankets, organisms were no longer detectable. The authors concluded that the warming units were a potential source of nosocomial infection.[10] Other factors that could influence rate of surgical wound infection include dose of bacterial contamination, virulence, and host resistance.[11] Of note, the use of forced air warming with a lower body commercial blanket did not increase the risk for airborne bacterial wound contamination in the operating room.[12] The present study was not designed to determine the incidence of infections. Further microbiology and clinical studies are required before this experimental warming technique can be widely adopted.

Despite randomization, there were more women of shorter stature in the experimental compared with the control group. It is unlikely that gender differences could have affected the results of this study, although it is recognized that cyclic variation in the basal body temperature of the female subject is mainly induced by the central effect of progesterone. Gender differences in thermoregulation are attributed largely to the presence of progesterone and other chemical regulation in the female subject and to lower metabolic rate and thicker subcutaneous fat in female subjects than in male subjects.[#]

Two patients received commercial blankets instead of the experimental technique at the discretion of the attending anesthesiologist. Their final core temperatures were 37.5 and 36.5°C. Subsequent analysis of the data according to treatment assigned and treatment received did not change the overall results.

Even with the use of forced air warming, many patients (27–31%) had intraoperative hypothermia. It is likely that the number of patients hypothermic at the end of surgery could be further decreased by combining forced air warming with intravenous fluid warming, as has been previously demonstrated.[4] This is because the thermal stress of infusing cold or inadequately warmed intravenous fluids in anesthetized patients may result in considerable decreases in mean body temperature (an approximate 0.3°C decrease per liter room temperature crystalloid).[13] Use of warmed intravenous fluids without forced air warming has previously been associated with maintenance of normothermia in surgical patients during general[4,14,15] and regional anesthesia.[16] Prewarming before induction of anesthesia has also been shown to be effective in maintaining perioperative normothermia.[17]

The ability to detect a treatment effect with a given level of confidence depends on the size of the treatment effect, the variability within the population, and the size of the samples used in the study. The number of patients used in the current study was based on a power analysis to detect a 0.5°C difference in final core temperature between groups with an α of 0.05 and a β of 0.1 (power of 90%). Thus, the power of this study (90%) was sufficient to detect a clinically relevant difference. Further, the use of a sensitive measurement technique, such as distal esophageal thermometry, maximizes the power. If the power of a study is the probability of correctly accepting the null hypothesis ($1-\beta$) and if one accepts a maximum value for β of 0.1 (power of 90%), then when the treatments are found to have no difference, the null hypothesis may be correctly accepted.[18] The

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upper limit of the 95% confidence interval (0.431°C) was less than the critical difference of 0.5°C chosen in the study. The lower limit of the 95% confidence interval (−0.095°C) was less than 0. Therefore, there is evidence that the two treatments are equivalent in terms of final core temperature.[6] The study was not designed to prove that the two treatments were equivalent in terms of toxicity, long-term adverse effects, or costs.

In summary, the study showed that compared with forced air warming and commercial blankets, forced air warming with hospital blankets resulted in similar final core temperature, a similar incidence of perioperative core hypothermia, a similar time spent in the PACU, similar patient satisfaction, and no thermal injuries. When using forced air warming techniques, care must be taken to avoid overheating the patient. Based on concerns expressed by the manufacturer, however, the experimental method of forced air warming with hospital blankets should not be used until further evaluation has been undertaken.

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