Circulating-water garment or the combination of a circulating-water mattress and forced-air cover to maintain core temperature during major upper-abdominal surgery

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Key points

- Maintenance of temperature during major surgery can be a challenge.
- Circulating-water garments (CWGs) have been suggested to be effective.
- This study compared CWG with forced-air combined with a circulating-water mattress during upper-abdominal surgery.
- Both methods were comparably effective in maintaining core temperatures.

Background. A recent heat-balance study in volunteers suggested that greater efficacy of circulating-water garments (CWGs) results largely from increased heat transfer across the posterior skin surface since heat transfer across the anterior skin surface was similar with circulating-water and forced-air. We thus tested the hypothesis that the combination of a circulating-water mattress (CWM) and forced-air warming prevents core temperature reduction during major abdominal surgery no worse than a CWG does.

Methods. Fifty adult patients aged between 18 and 85 yr old, undergoing major abdominal surgery, were randomly assigned to intraoperative warming with a combination of forced-air and a CWM or with a CWG (Allon ThermoWrap). Core temperature was measured in the distal oesophagus. Non-inferiority of the CWM to the CWG on change from baseline to median intraoperative temperature was assessed using a one-tailed Student's t-test with an equivalency buffer of $\pm 0.5^\circ\text{C}$.

Results. Data analysis was restricted to 16 CWG and 20 CWM patients who completed the protocol. Core temperature increased in both groups during the initial hours of surgery. We had sufficient evidence ($P=0.001$), to conclude that the combination of a CWM and forced-air warming was non-inferior to a CWG in preventing temperature reduction, with mean (95% CI) difference in the temperature change between the CWM and the CWG groups (CWM–CWG) of $0.46^\circ\text{C} (\pm 0.09^\circ\text{C}, 1.00^\circ\text{C})$.

Conclusions. The combination of a CWM and forced-air warming is significantly non-inferior in maintaining intraoperative core temperature than a CWG.

Trial registry: This trial has been registered at clinical trials.gov, identifier: NCT 00651898.

Keywords: anaesthesia; circulating-water; forced-air; heat; temperature; thermoregulation

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Intraoperative hypothermia (i.e. core temperature $< 36^\circ\text{C}$) is common and results from inhibition of thermoregulatory control by general anaesthesia,1,2 reduced metabolic heat production,3 cold exposure,4 evaporative heat loss from exposed viscera,5 and redistribution of heat from the core to peripheral tissues.6 Even mild perioperative hypothermia can cause a variety of adverse effects, including morbidity myocardial events,7 increased risk of surgical wound infections,8–10 coagulopathy,11 and prolonged post-anaesthetic recovery.12

Full-body forced-air warming reduces cutaneous heat loss to nearly zero,13 but even warming restricted to the upper or lower body reduces heat loss to roughly the metabolic rate13 and thus maintains normothermia during most operations. However, the intraoperative use of forced-air may be insufficient to maintain perioperative normothermia during large intra-abdominal surgeries14 such as orthotopic liver transplants.15

Circulating-water systems that provide both anterior and posterior warming16 are more effective in maintaining intraoperative normothermia during liver transplantation than forced-air warming.14,15 In addition, a recent heat-balance study in volunteers suggested that the greater efficacy of circulating-water garments (CWGs) results largely from increased heat transfer across the posterior skin surface, since heat transfer across the anterior skin surface was similar with a CWG and forced-air cover.17 We thus tested the hypothesis that the combination of a circulating-water mattress (CWM) and upper body forced-air warming...
is not worse than a CWG in preventing temperature reduction during major upper abdominal surgery.

Methods

With approval from the Institutional Review board at the Cleveland Clinic and written informed consent, 50 adult patients aged between 18 and 85 yr old, undergoing major abdominal surgery were enrolled between November 2005 and June 2008; most were orthotopic liver transplants, liver resections, or Whipple procedures. Exclusion criteria included core temperature >38 °C; combined procedures (e.g. simultaneous liver and kidney transplantation); contraindication to forced-air or circulating-water warming (e.g. skin conditions such as rash, abscess, cuts, sores, etc.); anticipated veno-venous bypass for liver transplant; and current encephalopathy or pregnancy.

Patients were randomly assigned to CWG (Allon Therm-Wrap, MTRE Advanced Technologies, Or-Akiva Industrial Park, Israel) which was set to servo-control to a distal oesophageal temperature of 37 °C (n = 25) or CWM (Gaymar Meditherm III, Orchard Park, NY, USA) set to 41 °C combined with upper body (model 522) and lower body (model 525) Bair-Hugger covers (Arizant Medical, Eden Prairie, MN, USA) connected to two Bair-Hugger warmers model 750 set on ‘high’ (=43 °C) (n = 25). Randomization was based on computer-generated codes that were maintained in sequentially numbered opaque envelopes. Randomization envelopes were opened just before patients were transported to the operating theatre.

Posterior skin surface warming began once the patients were transferred to the operating theatre table via the CWG or CWM depending on the group assignment. After induction of general anaesthesia, tracheal intubation and line insertion, anterior surface warming was started by covering the large parts of the lower extremities, the upper and lateral chest (above the nipple line) using either CWG or upper and lower body forced-air warmers. The warming with either method was discontinued when distal oesophageal (core) temperature was >37.5 °C, and was re instituted when temperature was 37.0 °C or less.

Anaesthesia was maintained with isoflurane in an air/oxygen mixture with intermittent doses of fentanyl and pancuronium. The ambient temperature in the operating theatre was maintained constant at ~21 °C. All i.v. administered fluids were warmed using the Belmont Instrument Fluid Management System (FMS 2000, Billerica, MA, USA).

A distal oesophageal probe (Acoustoscope, oesophageal stethoscope 18 Fr with temperature sensor-thermistor, Level 1, Rockland, MA, USA) was inserted after induction of general anaesthesia. Distal oesophageal temperature, mean arterial pressure (MAP) from a radial catheter, and heart rate (HR) were recorded at 15 min intervals throughout surgery, and were also available electronically at 1 min intervals from our anaesthesia record-keeping system (ARKS).

Demographic and morphometric characteristics were recorded. Additionally, we recorded the total dose of fentanyl and propofol. Isoflurane expired concentration was recorded at 15 min intervals. Past medical history and length of surgery were collected. Total volume and type of infused fluids (crystalloids and colloids) and also estimated blood loss and urine output were collected.

Statistical methods

Twenty-five patients per group were planned in order to have 90% power at the overall 0.025 significance level to reject the null hypothesis that the CWM temperature change is worse (lower) than CWG by at least 0.5 °C in a test of non-inferiority. Our null and alternative hypotheses were thus:

Null (H0): mean CWM change – mean CWG change less than −0.5 °C,

Alternative (H1): mean CWM change – mean CWG change greater than or equal to −0.5 °C.

The primary outcome of temperature change was calculated as the median of intraoperative minute-by-minute temperatures minus the incision temperature (when oesophageal temperature monitoring started).

Non-inferiority of the CWM to the CWG on temperature change was tested univariably at the 0.025 level by one-tailed Student’s t-test using a non-inferiority delta of −0.5 °C and multivariably using analysis of covariance to adjust for imbalance on baseline variables. In addition, if non-inferiority was concluded, we planned to test for superiority at the 0.025 level using one-tailed t-tests (given that direction would be known from the non-inferiority test).

Comparisons between the CWM and the CWG groups in the MAP and HR were performed by two-tailed Student’s t-tests. The significance level was 0.025 for the primary outcome one-tailed tests, standard for non-inferiority designs, and 0.05 for non-primary outcome tests for superiority. SAS 9.2 software (SAS Institute, Cary, NC, USA) was used for all analyses.

Results

Data analysis was restricted to 36 patients (CWG: 16 and CWM: 20) who completed the protocol. Six of the enrolled patients in the CWG group and three enrolled patients in the CWM group did not have surgery because of problems related to the donor liver (Table 1). In three and two patients who were assigned to the CWM and the CWG, respectively, we were unable to complete the study because of technical difficulties identified in Table 1.

Warming in three of the 20 patients in the CWM group was discontinued according to the study protocol when their distal oesophageal temperature exceeded 37.5 °C, one patient at 30 min after incision and the other two at about 3 h after incision. Their temperatures were nonetheless included in our analysis.

The randomized CWM and CWG groups were fairly well balanced on baseline and intraoperative variables (Table 2). Mean core temperatures over time did not differ markedly between the treatment groups (Fig. 1). The mean difference (95% CI) in temperature change from incision to median
intraoperative temperature between the CWM and the CWG groups [CWM mean (SD) increase of 1.1 (0.9) minus CWG increase of 0.63 (0.7)] was 0.46°C (−0.09°C, 1.00°C), where the lower limit of the 95% CI was greater than −0.5°C, Table 1, leading to a conclusion of non-inferiority. We were not able to conclude superiority of CWM to CWG at the planned 0.025 level because the confidence interval overlaps zero change, that is, the CMW mean change was not significantly higher than the CWG mean change (P=0.0499). Multi-variable assessment of non-inferiority and superiority adjusting for ASA status, EBL, and fentanyl, and variables on which the randomized groups appeared somewhat imbalanced had very similar results and reached the same conclusions.

No significant difference was found in the median intraoperative MAP [mean (SD) of 78.2 (7.4) vs 79.0 (9.9), P=0.76] or HR [85.9 (7.3) vs 86.3 (16.8), P=0.94] between the CWM and CWG groups, respectively.

**Discussion**

This study was based on a previous volunteer study which showed that the CWG transfers more heat than forced-air alone, but that the difference is largely explained by the fact that the CWG included posterior heating.17 This observation suggested that the combination of forced-air and a CWM would provide comparable benefit. Our results support this theory: there was no clinically important difference between the systems we tested, and the observed mean increase in core temperature was found to be significantly non-inferior with the combination of forced-air and a CWM than with the CWG. We thus conclude that the combination of forced-air and a CWM maintains core temperature during major abdominal surgery and the CWG.

Core temperatures increased throughout most of surgery even though we enrolled only patients having major upper abdominal surgeries. In fact, we needed to discontinue combination warming in three of 20 CWM patients (15%) because their distal oesophageal temperatures exceeded 37.5°C. It thus seems likely that forced-air alone would have been sufficient in most patients. An important point, though, is that we used two forced-air covers, one for the lower body and another for the upper body. This is not the way the systems are normally used, but has the advantage of doubling heat transfer.13

We only tested one forced-air system (from Arizant Medical). However, the efficacy of various forced-air systems is comparable.19 It is thus likely that our results apply to other forced-air systems. In contrast, newer
circulating-water systems differ considerably in their efficacy. For example, ‘energy transfer pads’ from Kimberly Clark (Roswell, GA, USA) are about 25% more effective than CWG For example, ‘energy transfer pads’ from Kimberly Clark (Roswell, GA, USA) are about 25% more effective than CWG For example, ‘energy transfer pads’ from Kimberly Clark (Roswell, GA, USA) are about 25% more effective than CWG. The number of patients included at each time point (n) is also shown; the number of patients decreased over time because some operations lasted longer than others (one temperature was missing at 30 min for technical reasons). Mean core temperatures with the CWM were significantly non-inferior to mean core temperatures with the CWG (multivariable

\[ P < 0.001 \].)

A limitation of our study is the five CWM and nine CWG patients (28% of 50) who were randomized but whose data were not available for analysis, either due to technical problems with the warming device or due to major changes in the patient surgical plans (Table 1). The resulting smaller-than-planned sample size could have reduced the power of our study, but this proved not to be the case since the primary outcome was statistically significant.

In summary, average core temperature change was not worse with the combination of a CWM and forced-air warming compared with a CWG during major abdominal surgery.

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Conflict of interest

None declared.

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References

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