

# Effectiveness of a Circulating-Water Warming Garment in Rewarming After Pediatric Cardiac Surgery Using Hypothermic Cardiopulmonary Bypass

Pablo Motta, MD, Emad Mossad, MD, Diego Toscana, MD, Sara Lozano, MD, and Steve Insler, MD

**Objective:** To evaluate the effectiveness and safety of the ALLON 2001 microprocessor-based thermoregulation system in pediatric patients undergoing cardiac surgery requiring hypothermic cardiopulmonary bypass compared with the routine thermal care.

**Design:** Prospective randomized clinical study.

**Setting:** Single tertiary academic medical center.

**Participants:** Infants (0-1 year) who underwent congenital heart surgery requiring hypothermic cardiopulmonary bypass (n = 18). Patients with open wounds and/or patients treated with an investigational drug or device within 30 days of surgery were excluded.

**Interventions:** Randomized use of thermoregulation system (warming garment, n = 9) or routine thermal care (control, n = 9) after separating from cardiopulmonary bypass until the arrival to the pediatric intensive care unit (PICU).

**Measurements and Main Results:** There were no statistically significant differences in the demographic data, cardiopulmonary bypass time, operating room time, incidence of deep hypothermic circulatory arrest, and cooling tempera-

ture between the groups. The nasopharyngeal temperature was significantly higher in the warming garment group after separation from cardiopulmonary bypass. Nasopharyngeal temperature at 20 minutes was 36.5°C versus 35.01°C ( $p = 0.0047$ ), at 40 minutes was 36.98°C versus 35.30°C ( $p = 0.034$ ), and at admission to the PICU was 36.09°C versus 35.31°C ( $p =$  not significant). There was no difference in the core-to-peripheral temperature gradient (nasopharyngeal-to-skin temperature) between the 2 study groups at any time point. No adverse events related to the use of the warming garment thermoregulation system were observed.

**Conclusion:** The investigated thermoregulation system was effective in preventing the after-drop of temperature that occurs after cardiopulmonary bypass in small infants compared with routine warming methods.

© 2004 Elsevier Inc. All rights reserved.

**KEY WORDS:** hypothermic cardiopulmonary bypass, pediatric cardiac surgery, hypothermia, thermoregulation system, warming garment

**H**YPOTHERMIA IS a common complication in the postoperative period in children undergoing cardiac and non-cardiac surgery. Deleterious effects of hypothermia are well documented and require treatment.<sup>1-4</sup> Studies of warming devices and hypothermia are limited in children.<sup>5-8</sup>

ALLON 2001 (MTRE Advanced Technologies, Caesarea, Israel) is a new microprocessor-controlled system that supplies water at a regulated temperature to a garment placed on the patient. It has a feedback loop that adjusts the water temperature in relation to the central and peripheral body temperature of the patient.<sup>9,10</sup>

The purpose of this randomized study was to compare the effectiveness of the microprocessor-based thermoregulation system (warming garment [WG]) in pediatric patients undergoing cardiac surgery requiring hypothermic cardiopulmonary bypass (CPB) compared with routine thermal care at this institution. The effectiveness of the system in preventing the after-drop in temperature that occurs after separation from CPB, until arrival to the pediatric intensive care unit (PICU), was evaluated.

## PATIENTS AND METHODS

After receiving approval by the institutional review board and informed consent, the authors randomized 18 infants (0-1 year) who underwent congenital heart surgery requiring hypothermic CPB, using a random number table. Patients were randomly allocated in 2 groups: WG (n = 9) and routine thermal care (CTRL, n = 9). The study was not blinded because the presence of a functioning unit was evident to

the medical personnel; however, the investigators had no prior knowledge of the WG assignment. Exclusion criteria included patients with open wounds and/or patients treated with an investigational drug or device within 30 days of surgery. In the settings of cardiac surgery, the warming garment can cover both lower and upper extremities, lateral portions of the chest, head, and the entire back of the patient, which accounts for about 70% of the total body surface area. The garment can also be wrapped around the intravenous and monitoring catheters and covers the skull, but leaves the face free.

The water-circulating WG is a microprocessor-based thermoregulation system. The system is comprised of a garment, microprocessor, and a body sensor. The garment is a water-channeled, fitted garment connected by 2 tubes to the base of the microprocessor. The microprocessor controls the heating/cooling, maintaining core temperature in the range of 30° to 40°C/86° to 104°F using a feedback loop received via thermal sensors located on the body. The body sensors are temperature probes that can be located in the rectum, bladder, esophagus, and/or the skin. The microprocessor feedback control of the unit prevents overheating and potential burns by continuously monitoring peripheral and core temperature and controlling water temperature response to those changes.

Patients scheduled for cardiac surgery were admitted to the hospital and received premedication at the discretion of the attending anesthesiologist, usually oral midazolam, 0.5 mg/kg, 30 minutes before coming to the operating room (OR). After arrival to the OR and standard monitors applied, anesthesia was induced with inhalation agents, fentanyl (10-50 µg/kg) and pancuronium (0.1mg/kg). Arterial and central venous catheters and the warming garment were placed on the patient. Temperature was monitored in the skin (right toe) and in the nasopharynx (Mono-a-Therm thermistor, Tyco-Mallinckrodt Medical Inc, St Louis, MO, for use with YSI 700 Series Electronics). After unclamping of the aorta and starting to rewarm from CPB, the WG was programmed to maintain the nasopharyngeal temperature between 36.5° to 37.5°C in the WG group. Control patients received the standard thermal care, which included a warming mattress (Gaymer Inc, Orchard Park, NY), humidified-warmed breathing circuit (Allegiance Health Care Corporation, McGaw Park, IL), and warming room temperature to 20°C after coming off CPB. Normothermia was achieved before withdrawal of CPB. In both groups, the rate of rewarming was 1°C/min, and the temperature of the cardiopulmonary bypass circuit perfusate was

From the Cleveland Clinic Foundation, Cleveland, OH.

Address reprint requests to Pablo Motta, MD, Cleveland Clinic Foundation, Department of Cardiothoracic Anesthesia, 9500 Euclid Avenue, G-30, Cleveland, OH 44195. E-mail: mottap@ccf.org

© 2004 Elsevier Inc. All rights reserved.

1053-0770/04/1802-0006\$30.00/0

doi:10.1053/j.jvca.2004.01.018

**Table 1. Comparison of Characteristics Between Both Populations**

Variable	Warming Garment	Control	p-value
Age (days)	108 ± 106.34	97 ± 98.06	0.8164
Weight (kg)	4.9 ± 2.37	4.2 ± 1.67	0.4868
Height (cm)	58 ± 8.80	56 ± 8.29	0.42
CPB time (min)	99 ± 51.93	115 ± 69.16	0.6012
OR time (min)	313 ± 62.99	314 ± 89.78	0.6469
DHCA (%)	43 ± 35.01	38 ± 27.14	0.8117
Cool Temp NP	24.9 ± 5.91	22.2 ± 4.91	0.3097

Abbreviations: CPB, cardiopulmonary bypass; OR, operating room; DHCA, deep hypothermic circulatory arrest; Temp, temperature; NP, nasopharyngeal.

37°C during rewarming. All transfused blood was heated either through the CPB circuit or using a blood warmer (Hotline L70, Smith Industries Medical Systems, Rockland, MA). All patients were separated from CPB using dopamine at 5 µg/kg/min and morphine at 40 µg/kg/h. The temperature was recorded every 5 minutes after coming off CPB (considered time 0) until arriving to the PICU. The WG was discontinued before transfer to the PICU. Any adverse event (eg, burns, skin abrasion, pressure sores, hyperthermia) was recorded.

A 1°C temperature difference was considered clinically significant between the groups. A minimum sample size of 12 patients was calculated as needed and analyzed to detect clinically relevant difference in the primary outcome of mean core temperature at PICU arrival (temperature difference, 1°C between groups). This determination was calculated based on a statistical power of 0.9, α ≤ 0.05, β = 0.1, and SD from previous research of σ = 0.5°C. However, based on the possibility of some unexpected dropout for the study, the initial number of recruited patients increased to 18 (9 in each group).

All data are presented as mean ± SD. The groups were compared for demographic and operative variables. Mean differences between the groups were compared using the Student *t* test.

**RESULTS**

A total of 18 patients were enrolled in the study. The summary of the demographic and operative variables is shown in

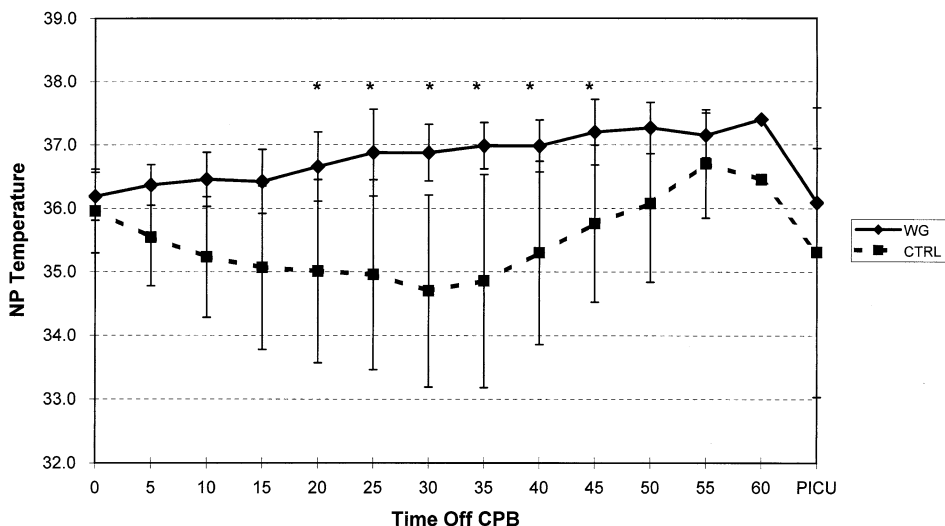
Table 1. There were no statistically significant differences in the demographic data, CPB time, OR time, incidence of deep hypothermic circulatory arrest, and cooling temperature between the groups. The OR temperature after coming off CPB was kept equal (at 20°C) in both groups.

The nasopharyngeal temperature was significantly higher in the WG group between 20 to 40 minutes after coming off CPB and until the admission to the PICU (Fig 1). There was no significant difference in the core-to-peripheral temperature gradient (nasopharyngeal-to-skin temperature) between the groups at any time point (Fig 2). No adverse events were reported with the WG thermoregulation system.

**DISCUSSION**

Induced hypothermia during CPB is a standard technique in pediatric cardiac surgery.<sup>11,12</sup> Hypothermia is achieved for myocardial and neurologic protection.<sup>13,14</sup> Perioperative hypothermia during pediatric and/or adult cardiac surgery and non-cardiac surgery can cause multiple deleterious physiologic derangement, which may contribute to increased morbidity after surgery.<sup>1-4</sup> These include increased risk of coagulation defects and postoperative bleeding, increased incidence of arrhythmia, cardiac dysfunction, shivering and increased oxygen consumption, and delayed awakening. The reported incidence of perioperative hypothermia has been as high as 25% after normothermic CPB and even higher after hypothermic CPB.<sup>15</sup> Incomplete rewarming of peripheral tissues after CPB leaving a large core-to-peripheral temperature gradient at the time of separation from CPB results in a rapid after-drop of body temperature in the postoperative period.<sup>16</sup> The magnitude of the after-drop is directly related to both the magnitude of core temperature cooling and the temperature difference between the warmest site and the coolest site at the end of rewarming.<sup>16</sup> After-drop occurs to a lesser degree in pediatric patients than in

**Nasopharyngeal Temperature  
Warming Garment Group (WG) vs. Control Group (CTRL)**



**Fig 1. Core temperature from separation of CPB to PICU admission (\*p < 0.05). NP, nasopharyngeal temperature.**

### Nasopharyngeal Temperature - Skin Temperature Warming Garment Group (WG) vs. Control Group (CTRL)

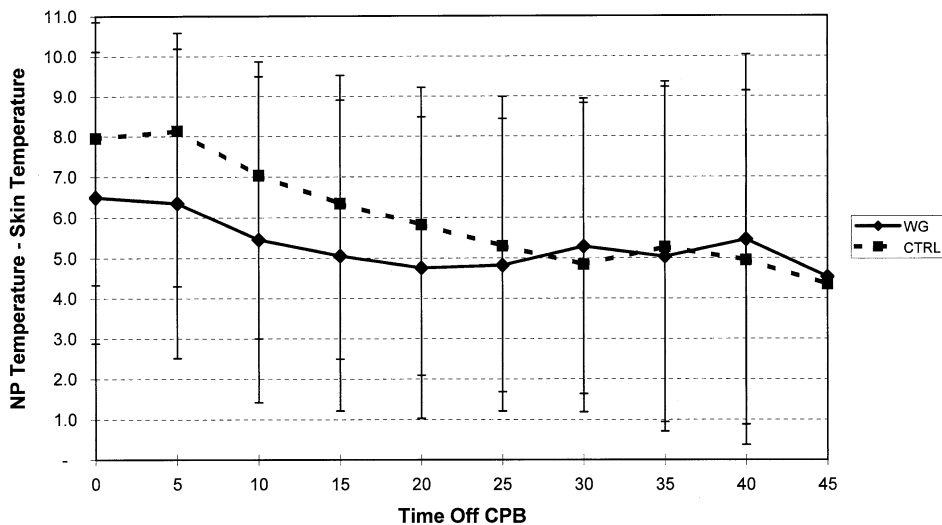


Fig 2. Nasopharyngeal-to-skin temperature gradient. NP, nasopharyngeal temperature.

adults because a smaller fraction of their body mass is peripheral. In essence, infants are almost all core, with less peripheral tissue to which core can be redistributed.<sup>17</sup>

Pediatric patients are particularly susceptible to developing hypothermia in the OR suite. They have a large area of exposure relative to body weight, increased heat loss from the head (thin skull and scalp), and limited stores of subcutaneous fat. Pediatric patients seldom shiver and, to restore normothermia, they increase their metabolism of brown fat (nonshivering thermogenesis), increasing the oxygen consumption.<sup>18</sup>

Several strategies have been used to prevent temperature after-drop in the postoperative period. Devices available include wool blankets, electric blankets, inhalation of warmed humidified gases, forced-air warming blanket, fluid-warming devices, and radiant infrared heaters.<sup>5-10,19-23</sup> Most of the devices used to prevent or treat hypothermia have been tested in the adult population, but only a few studies address this issue in pediatric patients.<sup>5-8</sup>

In adults and pediatric noncardiac population, forced-air warming blankets were more effective than circulating water in preventing intraoperative hypothermia.<sup>6</sup> However, the WG thermoregulation system, because of its ability to deliver heat to a greater percentage of the body, resulted in better maintenance of normothermia compared with forced-air warming blankets applied to the upper extremities in adult population undergoing abdominal surgery.<sup>10</sup> Neshet et al,<sup>8</sup> in a group of 38 children (3 months-14 years) undergoing brief noncardiac operations, also showed the safety and effectiveness of WG thermoregulation system in maintaining body temperature within a narrow range. Postoperative shivering was absent in 95% of these patients.<sup>8</sup>

Several studies of active rewarming in adult cardiac population, using different devices, have shown no difference in temperature or improved ICU outcome with the use of forced-air warming devices in the ICU for the care of immediately post-

operative cardiac surgery patients.<sup>10,21-24</sup> Neshet et al, in an adult prospective clinical trial, showed that using the WG thermoregulation system, in patients undergoing CABG on CPB, maintained normothermia during the entire perioperative period.<sup>10</sup> They also showed that normothermic patients have a beneficial hemodynamic profile with reduced systemic vascular resistance, elevated cardiac index, and lower levels of troponin.<sup>10</sup> In pediatric patients undergoing perfusionless deep hypothermic circulatory arrest, Guvakov et al<sup>7</sup> showed that forced-air warming blankets worked 20% faster than radiant heat in rewarming patients in the ICU. Significant determinants of the rate of instantaneous rewarming were age of patient, time after arrival to the ICU, pulse pressure, and warming device.

Effective rewarming on CPB, through increasing the temperature of the perfusate on rewarming, and the total rewarming time, decreases the incidence of postoperative hypothermia and energy expenditure.<sup>25</sup> This fact has to be balanced with the association between overwarming on CPB (nasopharyngeal temperatures  $>38^{\circ}\text{C}$ ) and increased postoperative neurologic morbidity.<sup>26</sup> Hyperthermia will increase  $\text{O}_2$  consumption, predispose to junctional ectopic tachycardia, and can increase cerebral infarct size in focal ischemia animal models.<sup>27</sup> Hyperthermia itself is a phenomenon that can develop after pediatric cardiac surgery.<sup>27</sup> The magnitude of the hyperthermia could have a sufficient magnitude and duration to affect the outcome of ischemic brain injury and hemodynamic instability after these procedures.<sup>27</sup>

The safety of the use of warming devices deserves intense scrutiny. Warming devices with feedback of patient temperature, as WG thermoregulation system, will avoid hyperthermia in pediatric cardiac surgery, possibly preventing a worse neurologic outcome. The feedback mechanism maintains a narrow core-to-peripheral temperature gradient and avoids excessive skin warming, thus improving perfusion while preventing inadvertent skin injury (Fig 2). In the Close Claim Project data-

base, among the 3,000 claims, there were 54 burns, 28 resulting from devices used to warm patients. Intravenous fluid bag or bottles warmed in an oven were responsible for 18 (64%); only 8 were caused by electrical warming equipment.<sup>28</sup>

The investigated WG thermoregulation system was effective in preventing the after-drop of temperature that occurs after CPB. The use of WG reached statistically significant difference between 20 and 40 minutes after coming off CPB compared with the control group. The temperature was also higher on

arrival to the PICU in the WG group. The advantage of WG is the larger warming surface area covered (70%-80%) compared with forced-air warming blankets, which can render this device more effective.<sup>9</sup> The limitations of this study are the unblinded nature of the design; the need for a much larger population to show an impact on outcome, bleeding risk, and transfusion and inotropic requirements; and the lack of a comparison group with an active warming system as the forced-air warming devices.

## REFERENCES

1. Sessler DI: Complications and treatment of mild hypothermia. *Anesthesiology* 95:531-543, 2001
2. Insler SR, O'Connor MS, Leventhal MJ, et al: Association between postoperative hypothermia and adverse outcome after coronary artery bypass surgery. *Ann Thorac Surg* 70:175-181, 2000
3. Frank SM, Fleisher LA, Breslow MJ, et al: Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events. *JAMA* 277:1127-1134, 1997
4. Kurz A, Sessler DI, Lenhardt R: Perioperative normothermia to reduce the incidence of surgical wound infection and shorten hospitalization. *N Engl J Med* 334:1209-1215, 1996
5. Bissonnette B, Sessler DI: Passive or active inspired gas humidification increases thermal steady-state temperatures in anesthetized infants. *Anesth Analg* 69:783-787, 1989
6. Kurz A, Kurz M, Poeschl G, et al: Forced-air warming maintains intraoperative normothermia better than circulation-water mattresses. *Anesth Analg* 77:89-95, 1993
7. Guvakov D, Cheung AT, Weiss SJ, et al: Effectiveness of forced air warming after pediatric cardiac surgery employing hypothermic circulatory arrest without cardiopulmonary bypass. *J Clin Anesth* 12:519-524, 2000
8. Neshner N, Wolf T, Uretsky G, et al: A novel thermoregulatory system maintains perioperative hypothermia in children undergoing elective surgery. *Pediatr Anesth* 11:555-560, 2001
9. Janicki PK, Higgins MS, Janssen J, et al: Comparison of two different temperature maintenance strategies during abdominal surgery. *Anesthesiology* 95:868-874, 2001
10. Neshner N, Wolf T, Kushnir I, et al: Novel thermoregulation system for enhancing cardiac function and hemodynamics during coronary artery bypass graft. *Ann Thorac Surg* 72:S1069-1076, 2001
11. Greeley WJ, Kern FH, Ungerleider RM, et al: The effects of hypothermic cardiopulmonary bypass and total circulatory arrest on cerebral metabolism in neonates, infants and children. *J Thorac Cardiovasc Surg* 101:783-794, 1991
12. Swain JA, McDonald TJ Jr, Giffith PK, et al: Low-flow hypothermic cardiopulmonary bypass protects the brain. *J Thorac Cardiovasc Surg* 102:76-84, 1991
13. Minamisawa H, Smith M-L, Siesjö BK: The effect of mild hyperthermia and hypothermia on brain damage following 5, 10, and 15 minutes of forebrain ischemia. *Ann Neurol* 28:26-33, 1990
14. Kader A, Frazzini VI, Baker CJ, et al: Effect of mild hypothermia on nitric oxide synthesis during focal cerebral ischemia. *Neurosurgery* 35:272-277, 1994
15. Baker J, Baker AJ, Mazer D: Determinants of postoperative hypothermia after normothermic cardiopulmonary bypass. *J Cardiothorac Vasc Anesth* 9:154-157, 1995
16. Rajek A, Lenhardt R, Sessler DI, et al: Tissue heat content distribution during and after cardiopulmonary bypass at 31°C and 27°C. *Anesthesiology* 88:1511-1518, 1998
17. Huang FY, Wang MJ, Huang HH: Differences in temperature changes between pediatric and adults patients after cardiopulmonary bypass. *J Cardiothorac Vasc Anesth* 7:66-68, 1993
18. Kruz A, Sessler DI, Narzt, et al: Morphometric influences on intraoperative core temperature changes. *Anesth Analg* 80:562-567, 1995
19. Hynson JM, Sessler DI: Intraoperative warming therapies: A comparison of three devices. *J Clin Anesth* 4:194-199, 1992
20. Ginsberg S, Solina A, Papp D, et al: A prospective comparison of three heat preservation methods for patients undergoing hypothermic cardiopulmonary bypass. *J Cardiothorac Vasc Anesth* 14:501-505, 2000
21. Villamaria FJ, Baisden E, Hillis A, et al: Forced-air warming is no more effective than conventional methods for raising postoperative core temperature after cardiac surgery. *J Cardiothorac Vasc Anesth* 6:708-711, 1997
22. Janke EL, Pilkington SN, Smith DC: Evaluation of two warming systems after cardiopulmonary bypass. *BJA* 77:268-270, 1996
23. Pathi V, Berg GA, Morrison J, et al: The benefits of active rewarming after cardiac operations: A randomized prospective trial. *J Thorac Cardiovasc Surg* 111:637-641, 1996
24. Patel N, Knaple DM, Smith CE, et al: Simulated clinical evaluation of conventional and newer fluid-warming devices. *Anesth Analg* 82:517-524, 1996
25. Hanhela R, Mustonen A, Korhonen I, et al: The effects of two warming strategies on heat balance and metabolism after coronary artery bypass surgery with moderate hypothermia. *Acta Anesth Scand* 43:979-988, 1999
26. Buss MI, McLean RF, Wong BJ, et al: Cardiopulmonary bypass, rewarming, and central nervous system dysfunction. *Ann Thorac Surg* 61:1423-1427, 1996
27. Bissonnette B, Holtby HM, Davis AJ, et al: Cerebral hyperthermia in children after cardiopulmonary bypass. *Anesthesiology* 93:611-618, 2000
28. Cheney FW, Posner KL, Caplan RA, et al: Burns from warming devices in anesthesia. *Anesthesiology* 80:806-810, 1994