

Body temperature regulation is impaired in children during anesthesia and can result in increased morbidity and mortality.

We devised the Allon 2000 (AS), a computerized body, consisting of a water-channeled garment (modularly fitted to cover 45-70% body surface without impingement on the surgical field), and a microprocessor-controlled heating/cooling unit that circulates water through the garment. The system was used in 35 children aged 3mo-14yr undergoing surgery lasting at least 30 min (mean 72.43±45.6) under general anesthesia. The AS monitored core and skin temperature to maintain a desired core temp from induction of anesthesia to full extubation (38-180 min). This study received informed consent and IRB-Helsinki Committee approval. Water temp to the garment was limited to a max of 103.1°F (39.5°C). Mean intra- and post-operative core temp was kept to 97.7°F±.57 (36.7°C) and 97.7°F±.51 (36.6°C), respectively. The average difference between core and skin temp readings was only 4.6 F (2.6°C), suggesting the absence of vasoconstriction. Heart rate and blood pressure measurements were stable. Postoperative shivering was absent in 33 children and mild in 2. The AS system is a safe and reliable device for the maintenance of perioperative normothermia in children within a previously unattainable narrow physiologic range.



Ablation of Postoperative Shivering in Pediatric Patients by an Intraoperative Microprocessor Body Thermal Regulation System

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INTRODUCTION

Hypothermia is a common phenomenon among patients undergoing surgery under general anesthesia, and can have untoward pathophysiological consequences.

Pediatric patients are particularly vulnerable to intra- and post-operative hypothermia and its deleterious effects, with resultant increase of morbidity and mortality.

The variety of warming methods and devices that are presently employed during surgery do not monitor/regulate the actual ongoing thermal requirements of patients, are often cumbersome, and may interfere with the surgical field or with the comfort of the surgical team.

AIM OF STUDY

To assess the efficacy and the safety of the ALLON 2000 system to monitor and to maintain normothermia in pediatric surgical patients who are operated under general anesthesia during a period of at least 30 minutes.

STUDY DESIGN

Patients

Thirty-five consecutive children (age 3 mo - 14 yr; mean, 4.3±4.12) undergoing elective surgery:

11 -	Gastrointestinal
10 -	Central venous line insertion
6 -	Neurosurgical
5 -	Orthopedic
3 -	Oncological

The garment was fitted at entry to the operating theater. At induction of anesthesia the AS unit was activated, and set to perfuse the garment with water at temperatures that would maintain the patient's core temperature between 36.8°C and 37.2°C. Core temperature (rectal thermistor probe) and skin temperature (surface probe under the garment) dictated the temperature of water pumped onto the garment.

THE ALLON 2000 SYSTEM

The Allon 2000 is a microprocessor-controlled thermoregulatory device:



A water-channeled disposable garment made of thin plastic film with an inner absorbent lining, is worn by the patient and is modularly fitted so as to cover 40% to 70% of the body surface, while the surgical field remains exposed;

A unit containing power supplies, control and data logging circuitry, and a solid-state thermoelectric device, operates as a heater/cooler pump and perfuses temperature-controlled water through the garment; Interconnecting tubing.

The temperature of the water is controlled and maintained at any set-point between 19°C and 40°C by a servo loop, originating from thermistor sensors on the patient's body.

Recording of Data

Intra-operative period (38 to 180 min; mean[SD], 72[45.6])

Every 15 min: core temperature
skin temperature
water T° at garment inlet and outlet ports
heart rate, blood pressure

Post-operative period (30 to 120 min)

Every 30 min: core temperature, heart rate, blood pressure
Post-operative shivering score (0 to 3)

Overall: Adverse events

Surgical/Nursing team satisfaction
Patient/Parent satisfaction

RESULTS

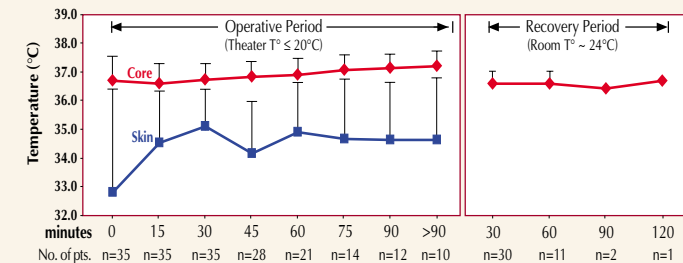


Fig. 2 – Mean±SEM core and skin temperatures of the 35 patients, and mean±SEM water T° at the inlet and the outlet ports of the garment.

- The patients maintained a stable core temperature throughout the intra- and the post-operative periods, with deviations from 37°C never exceeding 1°C. After the first 15 min, skin temperature readings were on the average 2.6°C lower than core temperature, suggesting the absence of vasoconstriction.
- The T° gradient of water at the garment inlet and outlet ports did not vary significantly, suggesting a stability of the patients' thermal requirements. Mean heart rate and diastolic blood pressure measurements were similar during the intra- and post-operative periods. Mean systolic blood pressure was lower during the intra-operative period than postoperatively (100.97±12.46 vs. 120.19±21.94 mmHg; p<.02).
- Post-operative shivering was totally absent in 33 patients and mild in 2.
- No device-related adverse events were noted during surgery or during follow-up, and a high level of satisfaction was reported by the surgical/nursing team and by the patients or their parents.

CONCLUSION

The ALLON 2000 system is a safe, reliable and convenient device for the maintenance of perioperative normothermia in children within a previously unattainable narrow physiologic range.



UTILIZATION OF A UNIQUE THERMOREGULATION SYSTEM IMPROVES HEMODYNAMIC FUNCTION PERIOPERATIVELY IN PATIENTS UNDERGOING CABG SURGERY

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INTRODUCTION

The majority of patients undergoing coronary artery bypass surgery (CABG) exhibit mild to moderate hypothermia (<36°C) throughout the perioperative period. This condition is associated with increased morbidity and mortality as well as increased hospital resource utilization. Of the many effects of hypothermia, a major role is attributed to an increase in circulating catecholamine levels, which induces elevation of systemic vascular resistance (SVR) with a subsequent deterioration in cardiac output.

THE ALLON SYSTEM

The ALLON SYSTEM is a microprocessor supported, feedback controlled thermoregulatory system. By delivering water at a desired temperature to a specially designed garment (Figure 1) worn by the patient during the operation, patient's body temperature is maintained, potentially ameliorating hypothermia and its consequences.

AIM OF THE STUDY

This study was designed to evaluate the efficacy of the ALLON SYSTEM vs. routine thermal care in maintaining body temperature, and to test its effect on patient's hemodynamic status during and after CABG operations.

STUDY DESIGN

Thirty patients, aged 40 to 80, scheduled for elective CABG were randomized to the ALLON SYSTEM (A, n=20), and the routine thermal care (R, n=10) groups.

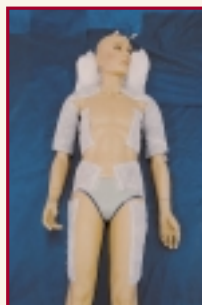
In the A group, the garment was fitted and activated at entry to the O.R. at the time of anesthesia induction. The system was set to perfuse the garment at the desired temperature between 36.5°C - 37.5°C. Rewarming of R group patients was performed using heating lamps and blankets, warm I.V fluids humidifiers and convective air warmers.

The study consisted of the operative phase which was divided into three sub-phases: (1) pre-connection to cardio-pulmonary bypass (CPB); (2) during CPB; (3) following disconnection from CPB and the post-operative phase.

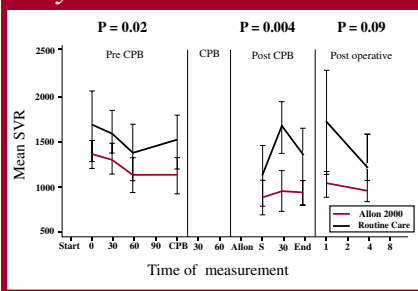
Core body temperature (rectal probe) as well as cardiac index (CI) and SVR (coventional Swan-Ganz catheter) were analyzed throughout the peri-operative period in both groups and then compared.

RESULTS

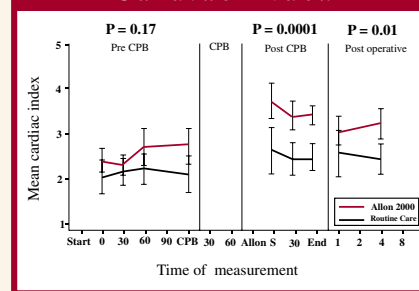
- Body temperature was significantly higher in the A group as compared with the R group during the pre-bypass, post-bypass (p=0.0001), and the postoperative (p=0.02) phases (Figure 2).
- SVR was significantly lower in the ALLON group (p=0.0001 for both the pre- and post-bypass phases, and 0.002 for the post-operative phase; Figure 3).
- Cardiac index was significantly higher in the ALLON group compared to the R group (p=0.001 for the pre-bypass, 0.0001 for the post-bypass and 0.0004 for the post-operative phases; Figure 4).
- These differences were independent of the duration of surgery and the amount of vasoactive drugs administered during and after the operation
- No device-related adverse events were noted perioperatively.



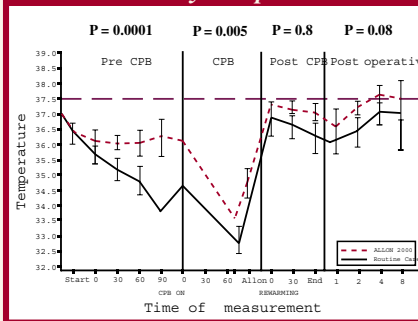
System Vascular Resistance



Cardiac Index



Core Body Temperature



CONCLUSIONS

- The ALLON thermoregulation system was found effective in maintaining patient normothermia and a secure hemodynamic status. Moreover, ALLON thermoregulation proved superior to all other methods of temperature maintenance assessed throughout this study.
- Utilization of this novel technique may reduce patient morbidity and complication rates associated with hypothermia following CABG surgery, especially in patients with severely reduced left ventricular function who may benefit from reduced afterload and an elevated cardiac output.



A Novel Thermoregulatory System Attenuates Myocardial Injury in Patients Undergoing Coronary Artery Bypass Surgery

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Perioperative hypothermia is associated with a variety of adverse events. This study assessed the efficacy of a novel thermoregulation system during coronary artery bypass (CABG) surgery. CABG surgery patients were randomized into two groups: Allon thermoregulation (AT, n=40) and routine thermal care (RTC, n=20) and warmed perioperatively with/without the new device respectively. AT used patients' rectal (core) temperature as input data to maintain water temperature in a circulating garment at a 37°C. Body temperature, patient hemodynamics, and cardiac-specific Troponin I (cTnI) were assessed throughout the perioperative period.

Core temperatures were higher in the AT group at all time points. Cardiac index (CI; L/min) was higher in the AT group: 2.5 ± 0.5 , $2.6 \pm 0.5^*$, $3.2 \pm 0.6^*$, $3.3 \pm 0.5^*$, 3.1 ± 0.7 at the respective time points, compared to the RTC group, 2.3 ± 0.6 , 2.1 ± 0.2 , 2.6 ± 0.7 , 2.7 ± 0.7 , 2.7 ± 0.7 , (*P<0.05). Systemic vascular resistance (SVR; (dyne*sec)/cm⁵) was lower in AT patients. cTnI levels were lower in AT throughout the post cardiopulmonary bypass (CPB) period indicated lesser ischemic damage sustained by the AT patients. Maintenance of perioperative normothermia can be achieved efficiently using the new technology AT system. The beneficial effects of such a strategy include reduced SVR, elevated CI, and attenuation of myocardial injury as assessed by cTnI.

A NOVEL SYSTEM OF THERMOREGULATION ATTENUATES MYOCARDIAL INJURY IN PATIENTS UNDERGOING OFF-PUMP CORONARY ARTERY GRAFTING (OPCAB)



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BACKGROUND

The majority of patients undergoing coronary artery bypass (CABG) surgery demonstrate mild to moderate hypothermia (< 36°C) throughout the perioperative period. Such a condition is associated with increased morbidity and mortality, as well as increased hospital resource utilization. Patients undergoing off-pump coronary artery grafting (OPCAB) may become hypothermic even further, due to the absence of cardiopulmonary bypass re-warming.

Of the many effects of hypothermia, a pivotal role is attributed to the increase in circulating catecholamine levels, which induce elevation of systemic vascular resistance (SVR) with a subsequent deterioration in cardiac output.

THE ALLON SYSTEM

The ALLON system, which was used in our study, is a microprocessor (Figure 1), feedback-controlled thermoregulation system. By delivering water at a pre-set desired temperature to a specially designed garment - ThermoWrap (Figure 1) worn by the patients during the operation, the patient's body temperature is maintained, potentially ameliorating hypothermia and its consequences.

STUDY DESIGN

This study assessed the ability of the ALLON thermoregulatory system to maintain normothermia, as well as its impact on hemodynamics and myocardial function in patients undergoing OPCAB surgery.

As a part of a multi-institutional randomized study, first 60 patients were enrolled into two groups: Allon thermoregulation (AT, n=40) vs. routine thermal care (RTC, n=20). In The AT group, ThermoWrap was fitted and activated at the time of anesthesia induction. The system was set to perfuse the ThermoWrap at the desired temperature between 36.5°C - 37.5°C throughout the entire operation and in the immediate postoperative period. Warming of RTC group was performed using blankets, Warming IV fluids, humidifiers and convective air warmers.



Figure 1: A specially designed garment suitable for CABG/OPCAB surgery is fitted around the patient allowing Thermoregulation without impingement of the surgical field.

Core body temperature (Bladder probe) as well as patient hemodynamics: cardiac index (CI) and SVR and cardiac specific troponinI (cTnI) were analyzed throughout the perioperative period in both groups and then compared.

RESULTS

Core body temperature was significantly higher in the AT as compared with the RTC during the entire operation ($p < 0.004$ - $p < 0.0001$) and in the immediate postoperative period ($p < 0.0001$ - $p < 0.002$) (Figure 2).

SVR was significantly lower in the AT treated group ($p = 0.01$ to $p < 0.001$) during the operation and $p < 0.001$ to $p = 0.03$ for the postoperative phase. (Figure 3).

Cardiac Index was greater in the AT group at comparable time points versus the RTC group ($P < 0.05$).

cTnI levels were lower in the AT group mainly from the completion of surgery until 24 hours post-operative ($p = 0.03$), indicating the possibility of less ischemic damage sustained in the AT group intraoperatively.

These differences were independent of the duration of surgery and the amount of vasoactive fluids or blood products administered during and after the operation.

No device-related adverse events were noted during the entire study.

CONCLUSIONS

Maintenance of perioperative normothermia (36.5°C - 37.5°C) during OPCAB procedures can be achieved efficiently using the ALLON thermoregulation system. The system was found to be superior to other routinely used methods of temperature maintenance. Benefits may include lowering afterload, as expressed by reduced SVR, improved CI and attenuation of myocardial injury as assessed by cTnI.

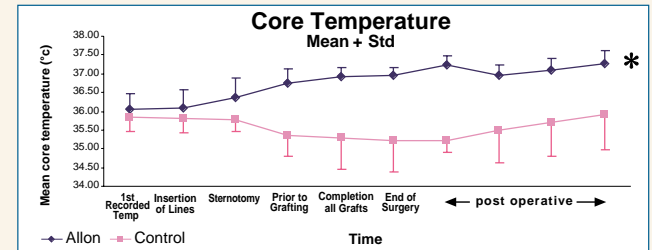


Figure 2 * P<0.05

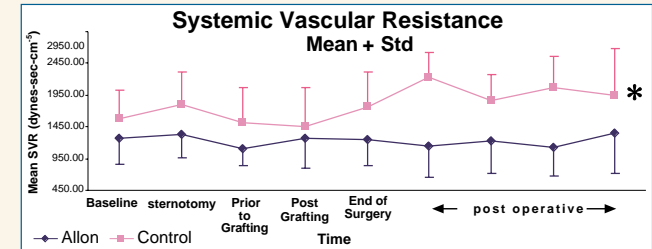


Figure 3 * P<0.05

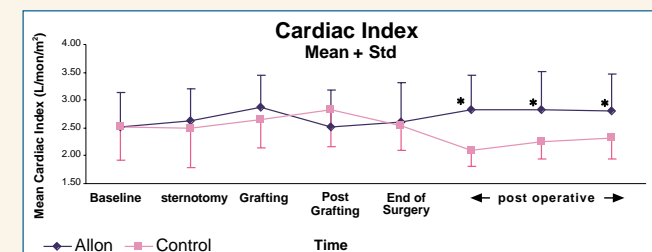


Figure 4 * P<0.05

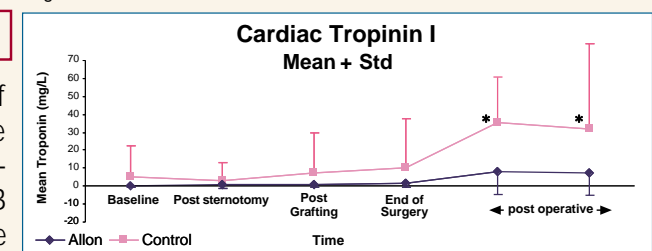


Figure 5 * P<0.05



Maintenance of perioperative normothermia affects immune response regulation and Myocardial function during off-pump coronary artery bypass (OPCAB) surgery.



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BACKGROUND

Mild perioperative hypothermia (approximately $<36^{\circ}\text{C}$), is common in every major surgery effects from 50% to 75% of the patients. It has been shown that Perioperative hypothermia affects immune function. Recent evidence suggests that the proinflammatory cytokines may have a roll in the immune regulation as well as cardiovascular activity. We assessed the effects of temperature control on immune function during OPCAB surgery.

STUDY DESIGN

Sixty patients undergoing OPCAB surgery were randomized into two groups and warmed perioperatively with Allon thermoregulation system (AT, n=40) or routine thermal care (RTC, n=20). Warming of RTC group was performed using blankets, warming IV fluids, humidifiers and convective air warmers. Body temperature, hemodynamic parameters: cardiac index (CI) and systemic vascular resistance (SVR), Cardiac proteins and interleukin (IL)-6, -8 and -10 levels were uninterruptedly assessed perioperatively.

RESULTS:

- Core body temperature was significantly higher in the AT as compared with the RTC group during the entire operation. (Figure 2), from following sternotomy to the end of surgery.
- Cardiac index (CI; L/min) was higher in AT from the end of surgery ($P<0.05$) and until 24 hours.

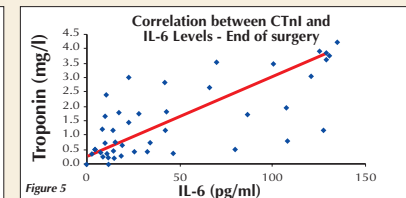
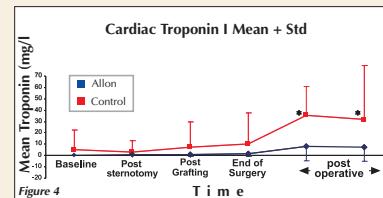
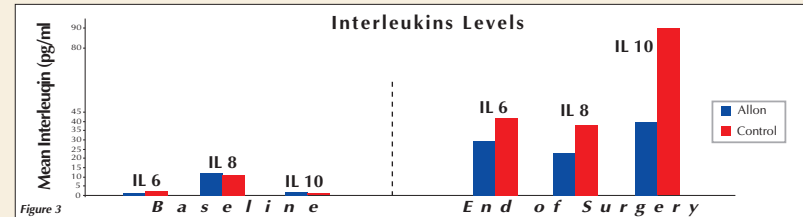
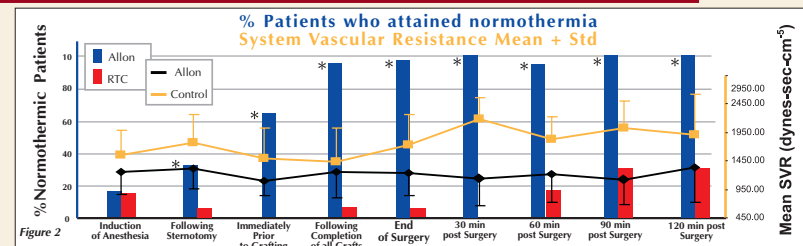
- Systemic vascular resistance (SVR, $[\text{dyne}\cdot\text{sec}]/\text{cm}^5$) was lower in AT group during the entire perioperative period ($p<0.001$), (Figure 2).
- Interleukins levels were higher than baseline levels in both groups at the end of surgery ($P<0.001$) and were shown higher in the RTC group. (Figure 3)
- Both groups' cytokines levels correlated with the duration of the procedure.
- Lower CTnl levels were obtained in the AT group as to compare with the RTC group, from the end of surgery and until 24 hours post-operative. ($p=0.03$). (Figure 4).
- CTnl levels correlated with IL-6 levels, IL-8 and IL-10 values as correlated with the duration of the procedure. (Figure 5)

THE ALLON 2001 SYSTEM



Figure 1

The Allon 2001 system is designed to maintain preset body temperature in the perioperative period. By using a feedback mechanism the system delivers water (between 19°C to 40.8°C) to a specially designed garment - ThermoWrap (Figure 1) worn by the patients.



CONCLUSIONS:

OPCAB surgery was associated with clear alteration of the immune regulation as expressed by elevation of the investigated cytokines. The clear and significant correlation between these cytokines and CTnl suggests a direct damaging effect on the myocardium. Maintenance of normothermia with the Allon System throughout the entire perioperative period showed reduced levels of IL-6 and IL-10, as well as CTnl suggesting enhanced immune response to stress and lesser direct damage to the myocardium.



Novel Feedback Controlled Circular Water Warming System (Allon 2001) Is Superior to Forced Warmed Air Device in Maintaining Normothermia in Infants Undergoing Major Surgery

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Abstract

Hypothermia caused by anesthesia and cold environment are especially difficult to compensate in infants due to their relatively large body surface and limited thermogenesis. Although normothermia is usually attained by the end of surgery, the deleterious effects of intraoperative hypothermia remain remarkable. In this prospective study we compared the Allon 2001 system with the forced warmed air device in infants undergoing major abdominal surgery.

Methods

The Allon 2001 system is designed to keep preset body temperature. It has central and peripheral temperature sensors and a central heating/cooling unit that circulates warm/cold water to the flexible water channeled (ThermoWrap™) garment. Thirty-three infants scheduled for elective major abdominal surgery were randomly allocated into two groups. In the Allon group (n=20) patient temperature was controlled using the Allon system with infant garment while in the Warmed Air Device (WAD) group (n=13) patients were warmed using Bair Hugger with the original U-shaped tubular cover. After inhalational anesthesia induction with halothane in nitrous oxide/oxygen plus I.V. midazolam and atracurium followed by intubation, epidural catheter was inserted and loading dose of ropivacaine 2mg/kg was given. Anesthesia was maintained with nitrous oxide/oxygen and isoflurane along with continuous epidural infusion of bupivacaine 0.125% with fentanyl 1-2 mcg/ml. We kept operating room temperature at 21°C. Unpaired t-test was used for statistical analysis with significance of p<0.05.

Results

There was no significant difference between the two groups in terms of demographic data, surgery and starting temperature. Although core temperature dropped in both groups during the first 30 min. of anesthesia reaching 35.8°C in the Allon group and 35.1°C in the WAD group, it started to rise in the Allon group and reached 36.7°C within 90 min. while continued to fall in the WAD group. Infants in the WAD group had decreasing body temperature until 60 min. of anesthesia and started increasing afterward, reaching 36.4°C at 150 min. The temperature difference between the two groups became statistically significant after 30 min. of anesthesia. Hypothermia lasted for 75 min. in the Allon group and for 180 min. in the WAD group. We did not encounter any complications related to the use of the Allon 2001 system.

Conclusions

Our study proved that Allon 2001 system is more effective than warmed air device in maintaining normothermia in infants during major surgery. This safe, reliable and easy to use device keeps patient temperature within previously unattainable narrow range.



1. **ThermoWrap**, a disposable active heat exchange garment covering the patient during operation/treatment.
2. **Allon 2001 Controller**, an algorithm driven heat pump that supplies water at desired temperature into the ThermoWrap.
3. **Body Temperature Sensors**, which provide continuous feedback to enable closed loop temperature management.

Demographic data

	Allon Group N=20	WAD Group N=13	p
Age (months)	11.89 (8.74)	14.20 (10.47)	*NS
Weight (kg)	8.34 (2.92)	8.69 (2.97)	*NS
Anesthesia duration (minutes)	185.00 (75.12)	169.37 (54.32)	*NS
Surgery duration (minutes)	158.14 (70.01)	141.25 (53.35)	*NS
Initial Core Temperature (°C)	36.80 (0.64)	36.63 (0.63)	*NS

The values are Mean and Standard Deviation (SD)
p<0.05 values are considered significant *NS = Non Significant

Conclusions

1. The Allon 2001 system is more effective than forced air warming system in maintaining normothermia in infants during major surgery.
2. Core temperature increased faster with the Allon system and the total duration of normothermia was significantly longer in the Allon group than in the WAD group.
3. The use of the device was simple and safe. After activation of the system, the anesthesiology team did not have to take any action in connection with thermoregulation.
4. Due to closed loop feedback mechanism, it is capable of keeping patient temperature within narrow range, thus preventing intraoperative hypothermia.

