Chapter 13

Infant Warming Device or Neonatal Surgery in a Low-Resource Setting

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Background

Thermoregulation is the body's capacity to balance heat generation and heat loss to ensure that the body temperature remains in a range that is suitable for human life. This ability is gradually acquired as a human matures into adulthood. Neonates and infants do not have a fully developed internal regulatory mechanism. This poses a challenge for infants undergoing surgery as they require close monitoring and regulation of their temperature under anaesthesia.

Hypothermia is an observable reduction of the body temperature below 36°C (Leduc & Woods, 2013). The importance of thermal regulation for newborns was discovered in the early 1900s when Pierre Budin reported on a striking variation in mortality rates among infants with different body temperaturess (Day et al., 1964). When the temperature drops below the 36°C threshold, the muscles in the body generate heat by the shivering mechanism. Unfortunately, infants are unable to shiver and their internal organs cannot produce enough heat.

Newborns lose body heat in four distinct ways:

- Evaporation: This is the largest source of heat loss at child birth. It may result from sweating and other forms of heat loss from the skin or breathing. The rate of evaporation largely depends on both the baby's surface area and the prevailing environmental conditions, i.e., vapor pressure and air velocity. During abdominal surgery the rate of heat loss is increased significantly.
- Conduction: This heat loss occurs primarily when the newborn is placed without clothing on a surface such as a table, scale, or bed. Conductive heat loss is greatly influenced by the contact surface area and the difference in temperature between the two surfaces in contact.
- Convection: This heat loss occurs when a newborn is exposed to cool environments, e.g., near open doors, windows or fans. The resultant heat transfer from the newborn to the ambient air or liquid is influenced by the newborn's surface area, rate of air flow and temperature difference.

DOI: http://dx.doi.org/10.15641/0-7992-2544-0
https://openbooks.uct.ac.za/bmeafrica

- Radiation: This heat loss occurs when the newborn is placed near cooler objects such as walls, tables and cabinets, without necessarily maintaining a contact with such surfaces. The rate of heat loss will depend on the difference in temperature between the newborn and the adjacent surfaces, the newborn's surface area, and the separating distance between the baby and the solid surfaces.

Neonates and infants easily lose temperature by evaporation, conduction, convection, and radiation. An incubation system can help reduce such heat loss. However, not all heat loss can be avoided, especially that from radiation. Even mild hypothermia can cause some complications such as vasoconstriction.

Hypothermia frequently occurs in infants, especially in newborns, during surgery and anesthesia. Exposure of the thin and moist skin of neonates to lower temperature and humidity, infusion of cold fluids and ventilation with dry gases makes neonates susceptible to hypothermia. A combination of these factors, along with the neonate's physiological properties of large surface area to body mass ratio and deficiency in subcutaneous fat, increases the risk of an infant becoming hypothermic during anesthesia (IDPH, 2017). A drop in temperature is typically expected after general anesthesia. However, this temperature fall should be averted in infants for various medical reasons. Mild postoperative hypothermia may impede immune responses to perioperative wound infection. Hence, hypothermia should be detected through close perioperative monitoring of body temperature in infants, and appropriately treated.

Neonatal hypothermia remains an important public health challenge and a major cause of morbidity in sub- Saharan Africa (Al Hammadi, et al., 2005). Low-tech measures to prevent heat loss and provide warmth are employed in many African countries. A standard protocol for hypothermia prevention in neonates and infants involves a circulating water mattress set at 40°C; providing airway humidifiers for breathing; maintaining a room temperature of approximately 22°C; warming intravenous fluids and blood products, if used; and using a forced warm air circulating blanket any time the infant's body temperature falls below 35.5°C (Leduc & Woods 2013).

While the use of low-tech measures such as hot water bottles, warm rooms, Kangaroo care, and hot stones may be lifesaving in low income settings (Onalo, 2014), there is a need to develop a more efficient and effective warming device to cater to the needs of neonates and infants. This chapter presents the development of a simple warming device for neonates, for use during and immediately after surgery, motivated by a need identified in Nigeria.

Existing infant warming devices for low-resource settings

An example of an infant warming device developed in India, is made up of a biocompatible bed on which the infant is placed, an overhead heater, a skin temperature probe, and a combination of visual and audio alarms (WHO, 2015:65). The control of heat output can be done either manually or automatically for thermoregulation.

Many existing radiant warmers had typically been fabricated with quartz or ceramic materials which not only took up to 13 minutes to heat up, but also tended to break down easily. Since each additional minute of cold stress could result in increased infant morbidity, this device was developed not only to provide uniform heating but also a faster warm-up time of not more than 4 minutes. Furthermore, the relatively low power consumption coupled with the durability of the heating element results in considerable cost savings. Adequate provision was also made for infection control.

This device is said to be able to operate in both rural and urban settings as well as different categories of healthcare facilities. Although it can withstand some fluctuations in voltage and occasional spikes, it generally requires a stable power supply. It has been sold in 115 countries including Albania, Algeria, Brazil, Bulgaria, Cambodia, Chile, Dominican Republic, Egypt, Gabon, India, Indonesia, Iraq, Jordan, Kazakhstan, Kenya, Lebanon, Macedonia, Nigeria, Palestinian Territory, Philippines, Syria, South Africa, and Vietnam.

An example of a less-sophisticated portable baby warmer, with dimensions 440 x 290 x 70 mm and weighing 4.1 kg, was developed in the USA and is being sold at a retail price of USD 250 (WHO, 2015:66). It consists of a sleeping bag, a pouch of phase change material and an electric heater. In operation, the pouch is heated for 30 minutes before being placed in the sleeping bag. The device, which does not require a constant supply of electricity and water, and has no moving parts, is capable of maintaining the WHO recommended a temperature of 37°C for between 4 and 6 hours, after which it has to be reheated. This technology is well-suited for use in remote healthcare facilities with relatively low doctor/nurse to patient ratios, and where continuous access to electricity is lacking. The target users are neonatologists and paediatricians for whom baby warmers are critical in providing neonatal care for low birth weight infants, with initial implementation in India.

Development of a prototype surgical infant warmer

The devices mentioned above are not intended for surgery. The prototype described below was specifically designed for this purpose.

When an infant undergoes abdominal surgery at the University College Hospital (UCH) in Ibadan, Nigeria, where the operating rooms are kept at around 23°C, an external device is necessary to

help regulate the infant's core body temperature. The administration of anesthesia and the exposure of the infant's core to the surroundings lead to a decrease in the infant's body temperature. This decrease in body temperature makes the infant susceptible to perioperative hypothermia, which causes increased susceptibility to wound infections which in turn can lead to prolonged hospitalization. Prior to surgery, the administration of anesthesia forces the infant's body temperature to decrease. A study on infants undergoing surgery estimated that anaesthesia without any temperature correction would cause the body temperature to drop an average of 2.1°C (Onalo, 2014). Even small drops in body temperature of 1°C can cause adverse effects in infants. Furthermore, anesthesia has inhibitory effects on autonomous temperature regulatory mechanisms.

Design objective

The objective set by a team of research collaborators from Northwestern University, Evanston, USA and the University of Ibadan, Nigeria, was to design a safe and affordable way to maintain appropriate infant temperature during open abdominal surgery at the UCH. The device is intended for infants with body mass between 1.5 and 3.5 kg. As previously mentioned, there are four methods of heat loss in infants: radiation, conduction, convection, and evaporation. The design of the warming device was based on using the principles of conduction and convection to combat the heat loss that occurs during surgery by placing the infant on top of a warm heating pad. When an infant is placed on a pad that is warmer than the infant's body temperature, there is heat transfer from the surface of the pad to the infant, keeping the baby warm. Using fans within the heating pad, convection disperses the heat from point sources more evenly throughout the surface.

Use environment and users

The user environment for the prototype baby warmer is the UCH in Ibadan, Nigeria. The UCH is one of largest hospitals in Nigeria with 850 beds and 165 examination couches. Paediatricians perform up to 15 major abdominal surgeries on infant patients each week. The hospital needs approximately 40 warming mats for abdominal surgery, other types of surgeries, and post-operative recovery. The warming device is to be used on infants during abdominal surgeries. Since the infants would be under anesthesia during surgery, they were not considered the primary users of the device.

The primary users are doctors, including surgeons and the anesthesiologists, and nurses. The surgeon must be able to complete the abdominal surgery properly without any obstruction or hindrance from the warming device, while the anesthesiologist must have access to device feedback at all times. It was considered important that the temperature readout be visible even at a distance of 60 cm (two feet) away from the device. Another important factor was ease of use in setting up, cleaning, and maintaining the device. While the primary users influenced the bulk of the form and function of the warming device, the secondary users including manufacturers and

distributors also had an impact on the product design. The device should be easy to manufacture and shipped across countries and continents.

Design considerations

The following design requirements were considered in consultation with the operating room staff for the development of the warming device.

Portability: Since it was anticipated that the device would be transported by nurses from the operating theatre to the recovery area after each surgery, it was resolved that the device should be so light in weight that it could be easily moved and carried by a single individual. The maximum weight was set at 18 kg (40 lbs.).

Affordability: To create a financially feasible device the budget was set at $300 per device.

Sanitation: The entire device must be easily cleaned and sanitized between each surgery. This applies not only to the body of the device, but also to the control pad.

Safety: The device must ensure infant safety by integrating safety features and failsafes to prevent any thermal, electrical or mechanical failures.

Adjustability: To account for fluctuating operating room temperature and infant body temperature, the device must operate between 32 and 43°C.

User-friendliness: To allow for ease of use by nurses and anesthesiologists, the temperature controls should be intuitive. Also, the device must display temperature readings to allow anesthesiologists and nurses to make necessary adjustments.

Quick setup: To allow for seamless integration into current operating room procedures, device setup and heating to the desired temperature must be accomplished in less than 15 minutes, as stated by consultant paediatricians at UCH, Ibadan.

Heating technology assessment

Several heating technologies currently being used in medical grade products were assessed. Water mattresses were eliminated from the design consideration because they are heavy, bulky, and prone to leaking, which defied the design requirement of portability. Forced-air warming technology was cost-prohibitive, and thus not considered, despite being the current medical standard in developed countries. A systemic fluid warming technology which warms intravenous fluid entering the patient was considered to be outside the scope of the project because its uses are primarily for cardiac surgery and severe accidental hypothermia and it is invasive. Radiant heating technology

such as an incubator was also eliminated due to the fact that it loses heat to its surroundings and obstructs access to the infant.

After completion of the technology assessment, a decision was taken to focus on the design of an electrically powered heating element that would not warm the surroundings and would not require consumables. This choice offered more flexibility for choosing a heating technology that could be integrated well into the body of the device.

Warming pad prototype one

The first warming pad prototype developed in 2016 is shown in Figure 1. Each heating pad consisted of top and bottom covers, a heating element, a temperature sensor and foam insulation. The resistive heating element is covered by an appropriate plastic material for protection from extremely reactive chemicals such as iodine. The foam insulation underneath the heater ensures most of the heat is thermally conducted up towards the infant. The bottom layer seals and protects the internal components. When heating, each pad emits approximately 27 watts, enough to heat the area to the desired temperature in less than 15 minutes. A microcontroller controls the logic and software of the temperature controller. It receives feedback from a waterproof temperature sensor located inside the top pad and displays the temperature on an LCD Screen. It can adjust the power of the pads using a potentiometer located inside the temperature sensor.

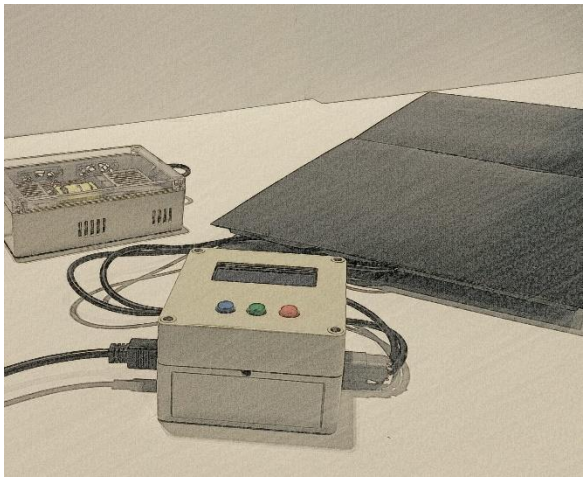

Figure 1: Warming pad prototype one

Preliminary evaluation by consultant paediatricians at UCH revealed that the warming device was too heavy and difficult to transport. Furthermore, the cost of supplies alone for the single prototype (excluding manufacturing cost) was approximately $310, which exceeded the set budget of $300. It was necessary to revise the design to remedy these problems.

Warming pad prototype two

The warming pad Prototype Two design was implemented using a foldable fabric design as shown in Figure 2. The fully rigid casing used in the first prototype was first considered again. However, it would require manufacturing processes such as vacuum forming which could consume about one-third of the allotted budget of $300 set for the device. Though this price would decrease with mass production, the primary concern was the weight of the rigid HDPE polyethylene. Thus, further ideas were explored since a hard casing might not mitigate the clients' previous concerns about high weight and low portability.

Figure 2: Warming pad prototype two

Therefore, the idea of a soft casing and a foldable fabric design was adopted. Above the heating element and sensors was placed a thin layer of polyethylene electrical insulation and vinyl foam. The bottom-most layer is a rigid polyurethane thermal insulation material with a relatively low thermal conductivity constant of 0.03 W (mK)-1, which prevents heat loss through the bottom of the device while providing structural strength. The material is lightweight and low cost at $25 per device, lending to the portability and affordability of the device. The electrical element is insulated with lightweight polyethylene film as a safety feature to separate the infant from any electrical currents. Furthermore, the film costs only $3 per device. To keep the inner components together, the entire stack of components was wrapped with a polyethylene stretch wrap. This method addressed not only the lightweight issue but also cost effectiveness.

The electronic components of the device allow real-time temperature monitoring and control. The device has two temperature sensors placed above the heating element and below the polyethylene electronic insulation, near the intended positions for the shoulders and buttocks of the infant. A microcontroller reads the temperature sensor output from the sensors and then adjusts the voltage across the heating element to control the device temperature in real-time.

Safety features were incorporated into the device to protect the heating element from power surges. The sharp increase in voltage or current during a power surge can cause too high current to run through and damage the heating element. The operating rooms at UCH are powered by 220-240 V wall outlets. However, Nigeria has a serious deficit with provision of power and has been known

to have power outage for up to 14.5 hours a day. As a result, most hospitals that conduct surgeries have backup generators that may result in power surges. Therefore, it is important to cut current through the heating element during a power surge. A watchdog microcontroller was installed which detects current going through the heating element and cuts power to the heating element if the current exceeds a set threshold. In addition, the temperature sensors could be damaged by electrostatic discharge, which is a sudden flow of electricity that can produce high voltages. Therefore, an electrostatic discharge protection diode was installed.

The component cost of the second prototype was $186, which was within the set budget of $300. This cost, however, excludes potential labour and facility costs that would be incurred during manufacturing. The manufacturing cost is yet to be fully determined.

Conclusion

Two prototypes of a low-cost and portable surgical warming pad have been developed for potential deployment in a typical neonatal surgical ward in developing countries. The second prototype provides adjustable heat production throughout surgery and postoperative recovery and is easily set-up and cleaned. In addition, it serves as a comfortable surface for infant patients and is lightweight and foldable to enhance portability. Optimizing manufacturing costs for the device and meeting government regulations are under consideration.

Acknowledgement

Research reported in this publication was supported by the Fogarty International Center of the National Institutes of Health under award number D43TW009374.

References

Al Hammadi, T., Sinha, T., Ahmed, O. K. & Hamouda, S. B., 2005. Hypothermian in infants: the important factors. *Qatar Medical Journal.* 14(2):37–39.

Day, R.L., Caliguiri, L., Kamenski, C., and. Ehrlich, F. 1964. Body temperature and survival of premature infants. *Pediatrics.* 34:171–181.

IDPH, 2017. *Pediatric and Neonatal Care Guidelines*, Illinois: Illinois ESF-8 Plan: Pediatric and Neonatal Surge Annex.

Leduc, D. & Woods, S. 2013. *Canadian Paediatric Society – Community Paediatrics Committee Position Statement: temperature measurement in paediatrics.* Available: http://www.cps.ca/en/documents/position/temperature-measurement [2019, May 06].

Onalo, R. 2014. Neonatal hypothermia in sub-Saharan Africa: a review. *Nigerian Journal of Clinical Practice.* (16)2. DOI: 10.4103/1119-3077.110120.

WHO. 2015. *WHO compendium of innovative health technologies for low-resource settings 2011–2014*. Available: https://www.who.int/medical_devices/innovation/compendium/en/ [2019, May 06].