**Protocol-driven prevention of perioperative hypothermia in the pediatric neurosurgical population**

*Running title: Preventing perioperative hyothermia*

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**Abstract**

*Object:* Perioperative hypothermia (PH) is a preventable, pathological, and iatrogenic state that has been shown to result in increased surgical blood loss, increased surgical site infections, increased hospital length of stay and patient discomfort. Maintenance of normothermia is recommended by multiple surgical quality organizations; however, no group yet provides an ergnomic, evidence-based protocol to reduce PH for pediatric neurosurgery patients. We aim to evaluate the efficacy of a perioperative hypothermia prevention protocol in the pediatric neurosurgery population.

*Methods****:*** A prospective, non-randomized study of 120 pediatric neurosurgery patients was performed. Thirty-eight patients received targeted warming interventions throughout their perioperative (pre-, intra- and post-operative) phases of care. The remaining 82 patients received no extra warming care during their perioperative period. Hypothermia was defined as <36**°**C. The primary outcome of the study was maintenance of normothermia preoperatively, intraoperatively and postoperatively.

*Results:* There was no difference in likelihood of hypothermia between warming group (WG) and control group (CG) on arrival to the OR. However, within an hour of arrival to the 50.6% (n=40) of the CG were hypothermic while only 29.6 % (n=10) of the WG were hypothermic (p = 0.037); the odds ratio for the warming group to be hypothermic at 1 hour was 0.012 (p = 0.0027). Within the first hour of OR, CG patients increased their mean hypothermic deficit from approximately 0.08°C to 0.25°C while those in the WG decreased from 0.11°C to 0.06°C (p = 0.0001).

*Conclusions*: Pre-operative warmingwith a forced air warmer (FAW) may not be warranted. Intraoperatively, a strictly and consistently applied warming protocol made intraoperative hypothermia significantly and dramatically less likely. Implementation of a warming protocol necessitated only limited resources and an OR culture change and was well-tolerated by OR staff.

**Introduction**

Perioperative hypothermia (PH) is a preventable, pathological, and iatrogenic state. Over the past 30 years, a substantial body of literature from multiple specialities has consistently shown that PH is associated with increased risk of surgical site infection, blood loss, postoperative length of stay and patient discomfort.6,22 Despite well-documented risks, there are currently no validated, published protocols for reducing the burden of PH in the pediatric neurosurgical population. Implementation of effective PH prevention protocols will guide quality and safety measures in pediatric perioperative care.

Anesthesia dampens thermal homeostatic responses in patients. Normally, a drop of 0.2**°**C will trigger a thermoregulatory response; with anesthesia the average patient must experience a drop of 0.6-0.8**°**C drop in core temp to trigger this response. Anesthesia also blunts peripheral vasodilation effectively transferring heat from core to periphery and reduces metabolic heat production by 15 to 30%, rendering patients less able to maintain adequate core temperature.4,12,22 Pediatric patients are at particular risk for PH due to: a high surface area to body mass ratio; increased heat loss from the head; smaller stores of fat and a less effective thermoregulatory mechanism.13 Additionally, work of breathing contributes to a significant amount of heat production in neonates and is nearly eliminated during general anesthesia.11 Nonshivering thermogenesis, an important method of heat production for neonates, is impaired by anesthesia.11,23. Additional risk factors for PH include: low body weight (particularly relevant for low birth weight neonates), pre-existing hypothermia, higher ASA class, duration of anesthesia, use of cooled IV fluids, and prone positioning.2,27

*Morbidity of PH*

Hypothermia impairs many physiologic functions resulting in increased morbidity for surgical patients. Hypothermia attenuates immune function, reduces cutaneous blood flow, and is believed to cause tighter binding of oxygen to hemoglobin leading to tissue ischemia. All of these factors are believed to contribute to increased rates of surgical site infections (SSI).21,22,11 Hypothermia induced coagulopathy is thought to be the underlying mechanism for increased surgical blood loss for hypothermic patients.6,19 *Ex vivo* experiments demonstrate decreased hemoglobin and platelets counts during cooling from 37 degrees Celsius to 32 degrees Celsius. The hemoglobin and platelet drop is most substantial in the initial cooling period and these coagulation factors do not return to normal with rewarming.28 Additively, platelet aggregation is impaired by hypothermia. In normal practice, the degree of coagulation impairment may not be apparent since laboratory testing is performed in normothermic conditions and does not account for the patient’s intraoperative temperature. It is estimated that for every 1 degree drop in temperature, 0.5 units of blood is needed due to intraoperative blood loss.11,21,22

Hypothermia can lead to increased oxygen requirements, arrhythmia, metabolic disturbances and death in neonates, who are at particular risk from PH. These effects may be more pronounced in preterm and low birth weight babies.2,6,11,16 Drug metabolism is also impaired by hypothermia, leading to increased anesthesia recovery times.12,22

*Methods of temperature measurement*

There are four sites to measure core temperature: pulmonary artery, esophageal, nasopharynx, and tympanic membrane. In the intubated patient, esophageal temperature is a reliable and common temperature assessment location. Infrared tympanic thermometers and temporal artery thermometers do not reflect core temperature and are considered inaccurate for clinical use; however a true tympanic membrane thermocouple is acceptable.2,10,11,17,22,23

*Prevalence of PH in pediatric population*

Much of the data regarding PH comes from the adult and European literature and few data exist for pediatric populations, particularly pediatric neurosurgical populations. A European-wide survey indicated that a mere 40% of patients were warmed intraoperatively and temperature was measured in 20% of cases, demonstrating a dearth of standardization regarding maintenance and surveillance of normothermia.27 Kim *et. al* has conducted the largest study to date on a pediatric PH prevention protocol (n = 7,532) although their methology was limited as the primary outcome was temperature on arrival to PACU13. In their study, 6% of pediatric neurosurgery patients were hypothermic on arrival to PACU. Beedle *et. al* has the second largest series (n = 1,504) and documents a 16 to 26% rate of PH in children (depending on which thermometry device was used) and this group was able to reduce PH to 1.84% after introducing a normothermia protocol2. Pearce *et. al* has conducted the third largest study to date (n = 530) regarding PH in the pediatric population. 52% of patients experienced intraoperative hypothermia. Development of hypothermia was associated with older age, longer duration of anesthesia, increased blood loss and blood transfusion. 57% of hypothermic patients were hypothermic on arrival to PACU compared to 28% in the non-hypothermic group. 8% of patients received blood in the hypothermic group as compared to 1% in the normothermic group. 70% of hypothermic patients underwent intraoperative warming and less than 10% underwent warming measures in PACU.18 In a study of surgical patients which included 848 adult and pediatric neurosurgical patients, implementation of a normothermia protocol lead to 5% rate of PH. There was a 99.4% compliance rate with the normothermia protocol amongst neurosurgical patients. Among all surgical patients, 7.7% of patients were hypothermic on arrival to PACU.24 In a study of neonates undergoing procedures in the NICU and OR, patients who were hypothermic underwent a significantly higher number of cardiac support interventions and had higher adverse respiratory events postoperatively than normothermic counterparts. Neonates who suffered intraoperative hypothermia tended to remain hypothermic in the postoperative period.16 There are no studies to date specifically focusing on only pediatric neurosurgery patients.

*Available protocol-based evidence for PH prevention*

Preoperative hypothermia has been shown to be a risk factor for intraoperative hypothermia; conversely, preoperative warming is effective in maintaining perioperative normothermia.20 Preoperative measures for prevention of PH include forced air warming (FAW); 30 minutes of prewarming prior to transfer to the operating room is endorsed by the Association of periOperative Registered Nurses (AORN) and preoperative FAW is endorsed by both AORN and American Society of PeriAnesthesia Nurses (APSAN).1,2,4,9,24

Intraoperatively, temperature should be measured every 15 minutes.27 While raising ambient temperature is the most logical way to maintain perioperative normothermia, this creates ergonomic issues for the OR staff. Short of an OR at body-temperature, FAW is the most effective and common method to maintain intraoperative normothermia by reducing temperature gradients contributing to heat redistribution losses. FAW is more effective than passive warming with blankets.11,23,24 Any single layer insulation reduces heat loss by 30% and multiple layers may reach a plateau in effectiveness.9 Increasing the amount of body coverage intraoperatively is key.23

In the postoperative period, active warming is one hour faster than passive warming in achieving normothermia.29 Munday *et. al* and Bernard *et. al* assert that patients should not be transferred from PACU to the ward until normothermia is achieved.4,17

*Culture of implementing PH prevention protocols*

Several studies document deficits in nursing staff’s educational awareness regarding measurement and prevention of PH, as well as, associated morbidity of PH.8 There are no studies regarding physician awareness of these topics. Awareness campaigns and implementation of protocols are effective in changing staff knowledge and behavior regarding PH. Implementing normothermia measures into workflow is also effective. For example, including space to document temperature and hypothermia interventions intraoperatively for anesthesia providers increases measurement compliance.9,13 Limiting factors may include availability and cost of equipment.9,26 Surgeon preference for cooler ambient temperature is a pervasive factor in the OR.11,14 A compromise to keep the room warm during anesthesia induction and draping of the patient and then reducing the room temperature to a comfortable level thereafter is reasonable.14

**Methods**

IRB approval was obtained. We undertook a non-randomized prospective trial of 120 pediatric patients at Norton Children’s Hospital who underwent any neurosurgical procedure during the period from March 2013 to March 2015. Patients underwent non-random assignment: patients having surgery with Surgeon 1 received the normothermia protocol as outlined below and patients having surgery with Surgeon 2 and 3 underwent standard thermal care per hospital protocol.

Our normothermia protocol was developed by our surgical staff based on best available evidence for the pediatric population. In the preoperative period, patients initial temperature was recorded with a tympanic thermometer (Welch Allyn Braun Thermoscan® Pro 6000) and then q15 minutes thereafter. While temperature measured in the ear has been shown to be less accurate compared to other measurements, this method was selected in our pediatric hospital given the balance between invasiveness and precision. Temperature was measured immediately prior to OR transfer. Family was educated on the importance of warming. Patients had a FAW (3MTM Bair HuggerTM) placed preoperatively. Intraoperatively, OR temperature was set to 75**°**F at least 15 minutes prior to patient arrival, “French fry” radiant lights were placed over the bed prior to patient arrival and were carefully maintained over the patient during anesthesia induction, surgical preparation and draping. A FAW was placed and carefully covered with blankets to avoid altering circulating air patterns in a way that might increase the risk of infection.15 Temperature was measured intraoperatively via esophageal probe every 15 minutes and recorded by anesthesia staff. Postoperatively, three blankets were placed on the patient making sure to cover the patient’s head, “French fry” lights were placed over the patient during undraping and transfer to the hospital bed, and temperature was measured via tympanic thermometer upon arrival to PACU.

Temperature was recorded by nursing and anesthesia staff at the required time points per protocol. The intervention and control groups were compared on descriptive and procedure-related characteristics using independent samples t-tests for continuous variables and chi-square and Fisher’s exact tests for categorical variables.

**Results**

During the study period 38 patients underwent surgery with Surgeon 1 and were assigned to the WG and 82 patients underwent surgery with Surgeon 2 and 3 and were assigned to the CG. Average age at surgery was 8 years old for both groups. 57.9% of the WG was male as compared to 47.6% of the CG. Average operative time for the warming group was 218 minutes versus 172 minutes in the CG (p=.024). Type of procedure being performed was also analyzed between groups: control group had a higher percentage of cranioplasties (62% vs. 40%) and the intervention group had a higher percentage of “other” procedures compared to the control group (24% vs. 6%). There were no other significant differences between the two groups (Table 1). 

To determine whether patients were more likely to be hypothermic, a standard test of proportion was utilized to analyze the proportion of hypothermic patients in the WG versus CG at both 1 hour and 2 hours intraoperative. If the analysis started with the last preoperative temperature, at 1 hour intraoperative 51.2% (n=42) of the CG versus 31.6% (n=12) of the WG experienced at least one hypothermic temperature (p=.044). At 2 hours intraoperative, 57.3% (n=47) of the CG versus 36.8% (n= 14) WG experienced at least one hypothermic temperature (p=.037). Similar results were found when the time interval analyzed began with the first intraoperative temperature (excluding the last preoperative temperature): at 1 hour intraoperative 50.6% (n=40) of the CG versus 29.4% (n=10) of the WG experienced at least one hypothermic episode (p=0.037). At 2 hours intraoperative 54.9% (n=45) of the CG versus 31.6% (n=12) of the WG (p=0.017).

To determine how much colder patients were, we used a repeated measures linear mixed model with the total hypothermic deficit as the outcome. The total hypothermic deficit a given time period is simply the total number of **°**C below 36 for all patients in that time period. This was then calculated as the total hypothermic burden per patient by dividing by the number of patients in each respective group. As time passes, the WG maintains a steady and minimal hypothermic burden but the CG increases its hypothermic burden with time. The increase in hypothermic burden from last preoperative temperature to 1 hour intraoperative was significantly higher as compared to the intervention group (.079**°**C versus .23**°**C, p=0.001; Figure 1 shows the change in total hypothermic deficit from last preoperative temperature to 1 hour intraoperative.

When the same analysis was run excluding the last preoperative temperature, the difference in hypothermic burden between WG and CG was even more robust, with a p=0.0001 (Figure 2). The odds ratio of hypothermia at each time interval was modeled using a repeated measures generalized linear mixed model with hypothermia “yes/no” as the outcome. The WG was less likely to be hypothermic at each time point intraoperatively, becoming statistically significant at 30 minutes intraop with an OR = 0.16 (95% CI 0.035-0.72); OR = 0.107 at 45 minutes (95% CI 0.023-0.504) and OR 0.072 at 1 hour (95% CI 0.014-0.366).

In order to better visualize this data, we created a composite variable called “hypothermic burden,” combining the incidence of hypothermia with the hypothermic deficit. At each time period, the total **°**C below 36**°**C for all patients was calculated – the “total hypothermic deficit.” This was multipled by the proportion of patients suffering PH at that time period. Thus, hypothermic burden (Figure 3) is equal to:

Hypothermic Burden = [Total hypothermic deficit] x [(# of PH patients) / (total patients)]

All patients were warm on arrival to PACU regardless of control or experimental group so statistically analysis of this time period was not carried out.

**Discussion**

The general incidence of pediatric PH is not well known but our results suggest that without a carefully maintained normothermia protocol, more than 50% of pediatric neurosurgery patients will experience PH, defined as a core temperature < 36**°**C. This incidence is similar to the results obtained by Pearce *et. al* who quoted a 52% rate of intraoperative hypothermia, defined by their group as an intraoperatively measured temperature of < 36**°**C for greater than 5 minutes.18 Using our normothermia protocol measures, we were able to reduce that incidence to about 33% in the WG as well as dramatically reduce the degree to which a given PH patient was hypothermic. Our protocol was effective in reducing both the incidence of hypothermia as well as the hypothermic deficit in a statistically significant fashion.

Unexpectedly, preoperative warming interventions had little effect on the incidence or burden of hypothermia intraoperatively. Intuitively presented in Figure 3, note that the hypothermic burden looks nearly identical in the WG and CG between T0 and T1. The significant difference in hypothermic burden then starts almost immediately after OR arrival, peaking at about 1 hour into OR time. This suggests to us that pre-operative warming – while the patients’ thermoregulatory responses are intact – is much less useful than making sure that the patient is adeuqately protected once reaching the OR. This interpretation is supported by the measures linear mixed model analysis of the total hypothermic deficit proportion analysis (figures 1 and 2): the degree of PH was similar regardless of whether the last preoperative temperature was included or excluded. Induction and preparation appear to be the key vulnerable time period for development of PH due to maximal skin exposure and anethesia-induced alterations in thermoregulation. The odds ratios make clear that without effective warming measures during this period, patients are more than 66 times more likely to become hypothermic at 1 hour intraoperatively, leaving them with a temperature deficit that can take up to 2 hours form which to recover (Figure 3, intraoperative time 2 hours is T8). In the WG, the few patients who suffered PH were able to regain normothermia by 15 minutes and then had a statistically significant difference in hypothermia incidence at time point 45 minutes, indicating a cumulative physiological effect with time.

The hypothermic burden was extremely low in our experimental group. Analysis of the control group raises a few key points in the standard patient: (1) induction is a sensitive time for development of intraoperative hypothermia, (2) the peak hypothermic burden in unprotected patients is reached at 45 minutes to 1 hour, and (3) after 1 hour, physiologic counterregulatory mechanisms will start to reverse the pattern of intraoperative hypothermia. The incidence of hypothermia in our experimental group still appears to be higher than that quoted in the available but limited literature for pediatric patients, but we would note that the hypothermic events were relatively shallow – the actual hypothermic burden was only slightly below 36**°**C. This likely demands refinement of the warming protocols – either to alter the protocol or to improve adherence. It is worth noting that of the 8 patients in the WG who had any episode of intraoperative hypothermia, 7 occurred relatively early in our study and may reflect poorer protocol adherence or implementation. It is also possible that our WG patients had higher rates of hypothermia compared to non-neurosurgical series due to the cranial surgical location and extent of heat loss through this area of the body.

*Implications for surgical quality*

The Centers for Medicare and Medicaid Services (CMS) established the Surgical Care Improvement Project (SCIP) to reduce surgical site infections nationally by 10%. *Inf10* of the SCIP measures calls for maintenance of perioperative normothermia. Hospital compliance with these measures is reported in the SCIP database and is a determinant in hospital reimbursement. It is unclear whether these incentive based practices change healthcare outcomes but these programs do increase reportability and compliance with required measures.26 SCIP was created in conjunction with the Physicians Quality Reporting Initiative (PQRI) which provides a 2% Medicare bonus to anesthesia providers for reporting maintenance of normothermia and use of FAW.22 SCIP follows similar projects including the National Surgical Quality Improvement Project (NSQIP) and the World Health Organization (WHO) Surgical Safety Checklist which are both validated and meaningful measures that have reduced surgical site infections.26 The National Quality Forum has also put forth perioperative temperature management standards. Most metrics relate to reporting or outcomes and few focus on process.3 As evidence based guidelines grow, more metrics relating to process may develop.

Pay for performance measures are increasingly more important for hospital and individual providers and is an integral part in attempting to provide more value in healthcare. CMS has delegated $1.35 billion to continue for a 1.5% pay-for-reporting bonus and Medicare has given $9 million in incentive based payments.10 At this time normothermia requirements are focused on hospitals and anesthesia providers but as available evidence for normothermia grows, similar pay-for-performance measures may be applicable to surgeons.

Cost for a surgical site infection ranges from $10 to 25K and shunt infections are known to be the most costly surgical site infection of all.5,25 PH prevention strategies are relatively low cost (~$10), safe and easily implemented.10

**Conclusion**

Without a specific perioperative warming regimen, more than 50% of pediatric neurosurgery patients experience PH. While preoperative warming does not appear to impact hypothermic burden in this study, it is clear that intraoperative warming protocols reduce both the risk of any hypothermia as well as reduce the total hypothermic deficit. Only limited resources were required for implementation at a low cost; staff comfort was not significantly affected – though this data was not explicitly collected, only rarely was OR staff behavior affected and complaints were minimal. Resource costs in the US healthcare environment clearly outweigh the risks of increased blood loss, surgical site infections and hospital length of stay. Pediatric neurosurgery centers may implement this or similar protocols in order to reduce the hypothermic burden of pediatric neurosurgical patients. Further refinement and improved adherence to this protocol will further reduce the incidence of hypothermia sustained in even warming group patients.

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Figure 1. Estimated mean hypothermic temperature deficit per patient in the CG (dashed) versus WG (solid) at each time period from last preoperative to 1 hour intraoperative. Shadowed lines are the mean hypothermic burden per patient and the,shadowed lines represent the upper and lower limits of the 95% confidence interval.

Figure 2. Estimated mean hypothermic temperature deficit in the CG (dashed) versus WG (solid) at each time period from first intraoperative to 1 hour intraoperative. Black lines are the mean hypothermic burden per patient and the shadowed lines represent the upper and lower limits of the 95% confidence interval.

Figure 3. The hypothermic burden = (total hypothermic deficit) x (ratio of patients hypothermic/total patients) at each time interval for WG versus CG. Time intervals are every 15 minutes with T0 as first intraoperative temperature.