

# BMJ Open Quality Interventions to prevent hypothermia in extremely preterm low-weight infants undergoing cardiac catheterisation

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## ABSTRACT

**Background** In January 2019, a new device called the Amplatzer Piccolo Occluder was approved by the US Food and Drug Administration for percutaneous closure of patent ductus arteriosus in infants weighing more than 700 g and of postnatal age more than 3 days. Premature low-weight infants are predisposed to hypothermia when transported outside of the thermo-neutral environment. At our institution, 90% of extremely preterm low-weight infants developed transient moderate hypothermia in the cardiac catheterisation suite.

**Methods** We conducted a study testing multiple hypotheses aimed at preventing hypothermia in the cardiac catheterisation suite. Interventions included increasing ambient room temperature, reducing exposure to cold environment and reducing overall time spent in the remote location. The primary outcome was the proportion of patients who developed transient hypothermia at the start of the procedure in the cardiac catheterisation suite. The secondary measures included mean core body temperature at four different instances, as well as anaesthesia time, procedure time and radiation exposure.

**Results** During the study period, 10 patients were enrolled in each group. The postintervention group saw a reduction in transient hypothermia from 90% to 40% (absolute risk reduction 50%,  $p=0.02$ ). Data analysis showed an improvement in mean core body temperature ( $35.4^{\circ}\text{C}$  vs  $36.4^{\circ}\text{C}$ ,  $p<0.01$ ) as well as a smaller percentage drop in temperature (4% vs 1.3%,  $p<0.01$ ) between the two groups, both of which were statistically significant. The anaesthesia time, procedure time and radiation exposure reduced between the two groups.

**Conclusion** The application of the interventions reduced hypothermia in this high-risk population. The implementation of a protocol with collaboration of a multidisciplinary team is indispensable in providing optimal care to extremely preterm infants.

## INTRODUCTION

### Problem description

Hypothermia in infants is defined by the WHO as a core body temperature less than  $36.5^{\circ}\text{C}$ .<sup>1</sup> Infants are at increased risk of developing hypothermia due to high surface area to body weight ratio. This risk is further increased in extremely preterm infants, especially those weighing less than 1600 g, who lack the body fat and skin integrity for heat

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Preterm infants are at increased risk of developing hypothermia, which predisposes to pulmonary hypertension, hypoperfusion of vital organs, hypoglycaemia and metabolic acidosis.
- ⇒ The perioperative period is a risk for developing cold stress, especially when the procedure is novel for low-weight infants and performed in and out of the operating room environment.

## WHAT THIS STUDY ADDS

- ⇒ This single-centre project provides multiple measures adapted at our hospital to improve thermal care during these procedures.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ Our interventions can be generalised and adapted in other paediatric and non-paediatric hospitals.

conservation and production. Thus, premature infants are kept in a neutral thermal environment in the neonatal period which ensures ideal conditions.<sup>2</sup>

Transcatheter device closure of patent ductus arteriosus (PDA) has been accepted as an innovative and less invasive alternative to surgical ligation for extremely low birthweight infants. In January 2019, the Amplatzer Piccolo Occluder (Abbott) was approved by the US Food and Drug Administration for PDA closure in premature infants. Since its introduction, extremely low birthweight infants are increasingly undergoing PDA closure in the cardiac catheterisation suite under general anaesthesia. A haemodynamically significant PDA causes pulmonary overcirculation and systemic hypoperfusion. Furthermore, cold stress predisposes to pulmonary hypertension, hypoperfusion of vital organs, hypoglycaemia and metabolic acidosis.<sup>3,4</sup> Therefore, adequate thermal care is crucial to prevent hypothermia in these infants.

## Rationale

In August 2019, we collected data retrospectively to quantify hypothermia in low-weight preterm infants undergoing percutaneous PDA closure in the cardiac catheterisation suite in the past 6 months. We found that 90% of patients developed transient hypothermia at the start of the procedure: 20% mild hypothermia (36°C–36.4°C) and 70% moderate hypothermia (32°C–35.9°C). This translated to heat loss during patient transport, monitor placement, induction of anaesthesia, patient positioning and surgical draping. The contributing factors to hypothermia were identified and addressed by a multidisciplinary team including neonatologists, anaesthesiologists, interventional cardiologists and cardiac catheterisation nursing staff members. This work led to the development of this project to improve thermal care in this vulnerable patient population.

## Specific aim

We aimed to reduce the proportion of transient hypothermia among low-weight preterm infants undergoing percutaneous PDA closure by 50% in 6 months.

## METHODS

### Context

This was a single-centre study conducted at Children's Hospital of Michigan. The population consisted of premature infants in the neonatal intensive care unit (NICU) weighing  $\leq 2.5$  kg at the time of the procedure undergoing transcatheter PDA device closure in the cardiac catheterisation suite.

### Preprocedure

On the day of the procedure, patients in the NICU were transported to the cardiac catheterisation suite accompanied by the procedure room nurse and the anaesthesia team. The cardiac catheterisation suite and the NICU are located on the same floor. The transport time is around 5 min. Most patients were mechanically ventilated in the NICU and a neonatal Ambu bag was used for ventilation on transport. In most cases, the transport incubator was open to allow easy and fast patient access in case of an emergency. On arrival to the cardiac catheterisation suite, patients were carefully moved to the procedure table and were kept uncovered during monitor placement. After induction of anaesthesia, a peripheral intravenous line was sometimes inserted. The patient was positioned, prepped and draped in preparation for the procedure. An underbody Bair Hugger mattress, sometimes preheated, and plastic covers were used to keep the infants warm. Core body temperature was measured by an oesophageal probe, which also served as a landmark on fluoroscopy.

### Procedure

Cardiac catheterisation was performed from the femoral venous access using a 4 Fr Prelude sheath. A 4 Fr Glide catheter was advanced from the femoral vein to the inferior vena cava, right atrium, right ventricle and main

pulmonary artery, and descending aorta through the PDA with an aid of 0.035" Wholey wire. Descending angiography was performed to measure the size of the PDA. The Amplatzer Piccolo Occluder was delivered to the PDA by a specific delivery catheter under fluoroscopy guidance. After a satisfactory position confirmed by transthoracic echocardiography, the device was released. Final transthoracic echocardiography was performed. In this procedure, the role of transthoracic echocardiography is crucial.

### Postprocedure

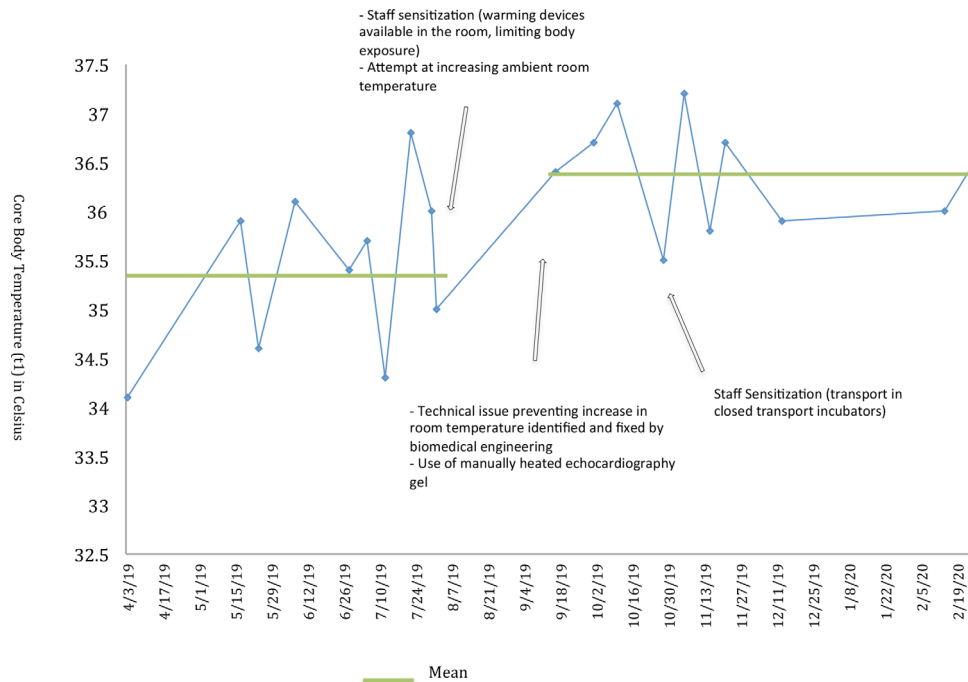
Patients remained intubated for transport to the NICU. On NICU arrival, vital signs including axillary temperature measurement were recorded on the anaesthesia chart.

### Intervention

Due to the severity of hypothermia and its deleterious effect on this population, interventions were implemented as a bundle and not tested individually (figure 1).

The following strategies were adapted in our practice:

- ▶ Procedure room temperature: interventional cardiology procedures were seldom done previously on low-weight infants. Our procedural areas in the cardiac catheterisation suite were not optimal for this population. On attempting room temperature increase, a technical problem was identified. The biomedical engineering department fixed the problem in one of the rooms, which became the dedicated location for procedures performed on infants. The catheterisation suite was heated before patient arrival to the room.
- ▶ Staff awareness: discussions were held with the nursing staff in the catheterisation suite to promote awareness regarding the dangers of hypothermia. They were asked to make sure the procedure room and warming devices such as forced air blanket were preheated before patient arrival and also that plastic drapes and warm linen were available in the room.
- ▶ Body exposure limitation in the preprocedure time: efforts were made to keep the patient covered as much as possible during monitor placement, induction of anaesthesia and positioning. Some infants had challenging intravenous access or endotracheal intubation, resulting in an extended time of body exposure. Therefore, when needed, peripheral intravenous line placement and endotracheal intubation were performed in the NICU prior to the transport.
- ▶ Thermal care during patient transportation: we identified a few patients who became more hypothermic than others. Detailed review of these cases showed that some providers usually transport the patient with an open portable incubator to allow easy patient accessibility. Education was provided about the importance of maintaining thermo-neutrality in this patient population. Closed incubator was strongly encouraged for transport.



**Figure 1** Core body temperature at procedure start (t1) between April 2019 and February 2020.

- ▶ Preheated echocardiography gel and gel removal after ultrasonography: transthoracic echocardiography was performed multiple times during the procedure. The echocardiographic gel was preheated simply by manual friction of the gel package and was immediately wiped after completion of the examination.

**Measures**

The study period was 14 months (January 2019–February 2020), which were divided into two periods: preintervention (January–August 2019) and postintervention (September 2019–February 2020). Data on body temperature were collected at four distinct instances: t0 (baseline temperature at the NICU before transport), t1 (at cardiac catheterisation suite at the start of the procedure), t2 (at cardiac catheterisation at the end of the procedure) and t3 (at the NICU after transport). These data were obtained from the nursing chart in the electronic medical record (EMR) and the anaesthesia record. Body temperature was measured by an oesophageal temperature probe in the catheterisation suite and by a digital thermometer placed in the axilla at the NICU. The primary outcome

was the proportion of hypothermia in the cardiac catheterisation at the start of the procedure (t1).

Subsequent data were also obtained from the EMR, such as demographic data, anaesthesia and procedure interval times and radiation exposure. Data were retrospectively collected three times: once for identification and quantification of the problem and twice after implementation of the measures.

**Analysis**

Data were expressed as mean±SD or number (%) based on the type of variables. To compare variables between the preintervention and postintervention periods, independent sample t-test was used for continuous variables and Fisher’s exact test was used for categorical variables. The statistical package used was StatView V.5.0.1 (SAS Institute). A p value <0.05 was considered statistically significant.

<b>Table 1</b> Patients’ characteristics			
	<b>Group A (n=10)</b>	<b>Group B (n=10)</b>	<b>P value*</b>
Age at procedure (days), mean±SD	24.2±18.1	37.9±29.1	0.22
Weight† (kg), mean±SD (range)	1.1±0.3 (0.72–1.42)	1.2±0.5 (0.72–2.5)	0.48
Gestational age at birth (weeks), mean±SD	25.4±2.8	25.4±2.5	0.99
Male:female	5:5	7:3	0.65

\*P<0.05 is accepted as statistically significant.  
 †At the time of procedure.

**Table 2** Comparison of mean body temperature (°C) at four consecutive instances in preintervention and postintervention patients

Mean temperature (°C)	Group A	Group B	P value
t0	36.9±0.4	36.9±0.3	0.95
t1	35.4±0.9	36.4±0.6	0.007*
t2	36.8±1.5	37.0±0.5	0.46
t3	36.5±1.2	36.9±0.4	0.26

t0: baseline temperature at the NICU before transport; t1: at cardiac catheterisation suite at the start of the procedure; t2: at cardiac catheterisation at the end of the procedure; t3: at the NICU after transport.  
\*Statistically significant.  
NICU, neonatal intensive care unit.

## RESULTS

### Patient characteristics

The total number of infants was 20. Patients were equally divided into two groups: preintervention (group A) and postintervention (group B). The weight range at the time of the procedure was 0.72–1.42 kg in group A and 0.72–2.5 kg in group B. The weight was 1.5 kg or less in all patients except one in group B, weighing 2.5 kg. The mean gestational age was 25.4±2.8 weeks in group A and 25.4±2.5 weeks in group B. All patients except one were born before 28 weeks of gestation. There was no statistical significance between the two groups in terms of age, weight, gestational age and gender (table 1).

### Body temperature

In group B, transient intraprocedural hypothermia (<36.5°C) occurred in 40% of patients: 10% mild hypothermia (36°C–36.4°C) and 30% moderate hypothermia (32°C–35.9°C).

The mean temperature measurements at different instances are shown in table 2. The mean drop in temperature between t0 and t1 was 4% (±2.2) in group A vs 1.3% (±1.2) in group B, with a significant p value of 0.004.

### Anaesthesia time, procedure time and radiation exposure

The anaesthesia time in group A and group B, as shown in table 3, was 145.1±19.2 min and 127.3±17.4 min (p=0.04), respectively. The surgery time in group A and group B was 102.7±25.3 min and 81.4±20.0 min (p=0.05), respectively. Radiation exposure per body weight was 19.7±7.0

μGym<sup>2</sup>/kg in group A vs 15.8±8.6 μGym<sup>2</sup>/kg in group B (p=0.15).

## DISCUSSION

Our study described a multidisciplinary approach to prevent the development of hypothermia in extremely preterm low-weight infants undergoing transcatheter PDA device closure. With the implementation of multiple measures, we were able to achieve more than 50% reduction in the development of transient intraoperative hypothermia at the start of the procedure, which was statistically significant. Also, we were able to achieve a statistically significant improvement in mean core body temperature at the beginning of the procedure, thus reflecting a smaller percentage of temperature drop during patient transport, monitor placement, induction of anaesthesia, patient positioning and surgical draping. The results have proven that our measures to provide better thermal care were successful.

Small observational studies have shown increased mortality among preterm patients with hypothermia at birth.<sup>5</sup> Thus, maintaining a normal perioperative core body temperature is a goal of optimal anaesthetic care. We implemented multiple interventions to ameliorate thermal care in our susceptible infants.

A recent retrospective observational study by Hubbard *et al*<sup>6</sup> on anaesthetic management of catheter-based PDA closure in neonates weighing <3 kg indicates that the prevalence of postoperative hypothermia is 3%. Similar approaches to thermal care were used in our study, such as transportation in prewarmed transport incubators, limiting cold exposure by placement of intravenous catheter and endotracheal tube in the NICU, forced air warming device, as well as increasing ambient air temperature. Note that hypothermia is defined in the latter study as a body temperature <36°C. In our study, we defined hypothermia as a temperature <36.5°C, according to the WHO definition.<sup>1</sup> After our interventions, postoperative temperature was >36°C in all patients except for only one.

Moreover, we observed a decrease in the anaesthesia and procedure interval time between the two groups. Since transcatheter PDA closure in very low-weight infants is a relatively new and technically challenging treatment, we attribute the shortening in anaesthesia and procedure time to a steep learning curve among our interventional cardiologists as well as efforts to reduce the

**Table 3** Mean anaesthesia time (min), procedure time (min) and radiation exposure per body weight (μGym<sup>2</sup>/kg) in the preintervention and postintervention groups

	Group A	Group B	P value
Anaesthesia time (min)	145.1±19.2	127.3±17.4	0.04*
Procedure time (min)	102.7±25.3	81.4±20.0	0.05
Radiation exposure (μGym <sup>2</sup> /kg)	19.7±7.0	15.8±8.6	0.15

\*Statistically significant.

overall time spent at a remote location. Radiation dosage was decreased over time, thus reducing the radiation hazard in this vulnerable population. This was attributed to technical improvement among the proceduralists.

Although our initiative was successful, our long-term goal is to completely eliminate perioperative hypothermia in these susceptible patients. One of the major hurdles faced was providers' compliance to changing their behaviour. Transporting a ventilated infant in a closed incubator can be of utmost challenge to some providers. We were able to overcome this difficulty by holding meetings to address people's concerns, stressing on the importance of maintaining a thermal-neutral environment during transport and providing education to increase familiarity with transport incubators for easy accessibility in case of an emergency. We believe that regular monitoring of thermal care, appreciation and feedback to the staff, as well as awareness among newly hired providers are crucial in maintaining the implemented measures. The checklist on thermoregulation improvement (online supplemental file 1) is now accessible to all providers and added to the anaesthesia protocol for cardiac catheterisation procedures at our institution.

We believe that our project is generalisable to other hospitals. It is based on team awareness of the dangers of hypothermia and the simple methods of heat conservation in infants, including procedure room warming, forced air warming device, minimal body surface exposure, careful anaesthesia planning and transport in a neutral thermal environment. This project demonstrated the importance of a protocol development in order to achieve adequate care in this vulnerable patient population.

Our project had some limitations. First, this was a retrospective study. Second, the number of patients included in the study was limited due to the study's short total period (14 months) and the fact that this novel technique is reserved for a failed conservative or pharmacological management of PDA at our institution. Third, sustainability data beyond February 2020 were beyond the scope of this study. However, our interventions were mostly implemented in August and September 2019 and we observed continued improvement through February 2020. The intervention seems to have translated to sustained practice changes, but sustainability audit should also be made. Fourth, due to the small number of cases and the distant interval separating them, a plan-do-study-act strategy was not adapted in our study. In contrast, a bundle of changes were concomitantly implemented and hence we were unable to determine the effect of each individual intervention on improved thermal care. Moreover, a lack of process measures limits the correlation between the interventions and the outcomes of the study.

## CONCLUSION

Perioperative hypothermia in extremely preterm infants is of major concern, most notably for procedures requiring transport outside of the NICU. The application of the interventions reduced hypothermia in this high-risk population. The collaboration of a multidisciplinary team is indispensable in providing optimal care to premature infants.

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