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Polyethylene bags before cord clamping in very preterm infants: a randomised controlled trial

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ABSTRACT

Objective Hypothermia on admission to the neonatal intensive care unit (NICU) is associated with an increased risk of death in preterm infants. There are currently no evidence-based recommendations for thermal care before cord clamping (CC). We wished to determine whether placing very preterm infants in a polyethylene bag (PB) before CC, compared with after CC, results in more infants with a temperature in the normal range on NICU admission.

Design Randomised controlled trial.

Setting Tertiary maternity hospital.

Patients Inborn infants<32 weeks' gestational age (GA).

Interventions Infants were randomly assigned to have a PB placed before or after CC.

Main outcome Rectal temperature within the normal range (36.5°C–37.5°C) on NICU admission.

Results Between July 2020 and September 2022, 198/220 (90%) eligible infants were enrolled in this study; 99 (44 (44%) girls) were randomly assigned to BEFORE and 99 (53 (54%) girls) to AFTER. Median (IQR) GA 29 (27–31) vs 29 (27–31) weeks, mean (SD) birth weight 1206 (429) vs 1138 (419) g, respectively. The proportion of infants who had normal temperature on NICU admission did not differ between the groups (BEFORE 54/99 (55%) vs AFTER 55/98 (56%), p 0.824). The proportion of infants with a temperature outside of the normal range was similar between the groups; hypothermia (BEFORE 34/99 (34%) vs AFTER 33/98 (34%), hyperthermia (BEFORE 10/99 (10%) vs AFTER 10/98 (10%)).

Conclusions Placing a PB before CC did not increase the proportion of preterm infants with normal temperature on NICU admission. A large proportion of preterm infants had abnormal temperature. Further studies on thermoregulation before CC are needed.

Trial registration number NCT04463511

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Hypothermia on admission to the neonatal intensive care unit (NICU) is associated with mortality in preterm infants.
⇒ The vast majority of randomised trials of thermal care interventions were conducted at a time when the cord was clamped immediately after birth.
⇒ Delayed cord clamping (CC) delays the initiation of thermal care, and may increase the risk of hypothermia.

WHAT THIS STUDY ADDS

⇒ Placing preterm infants in a polyethylene bag before CC did not increase the proportion of infants with normal temperature on NICU admission.
⇒ A large proportion of preterm infants had abnormal temperature at NICU admission.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Further studies into the efficacy of additional thermal care interventions before CC are needed.
⇒ Resuscitation guidelines should consider thermal care in the era of delayed CC.

INTRODUCTION

Preterm infants who have abnormal temperature after birth are at higher risk of morbidity and mortality.[1–14] Hypothermia after birth is an independent risk factor for death.[14] Abnormal admission temperature is reported in 5%–85% of newly born preterm infants[3–14] and is a global problem.[8 10 13] During the stabilisation of preterm infants in the delivery room (DR), the WHO and the Neonatal Task Force of the International Liaison Committee on Resuscitation (ILCOR) recommend that normal temperature (36.5°C–37.5°C) is maintained and that hypothermia and hyperthermia are avoided.[15 16]

Newborn infants lose heat rapidly after birth. Evaporative heat loss from exposed wet skin is greatest during the first minutes of life and decreases gradually over the first hour.[17] The trans epidermal water loss of an infant born at 25 weeks' gestational age (GA) is estimated to be 15 times than that of an infant born at term.[18] Similarly, in the DR, radiative heat loss is three times than that of an infant in a double walled incubator.[17] Heat is lost by convection and conduction to a lesser degree.[17 19 20] Measures to improve thermoregulation in the DR must include barriers to heat loss by evaporation and radiation.

For infants<32 weeks' gestation, ILCOR suggests a combination of interventions to prevent hypothermia after birth, including plastic bags/wraps, hats, thermal mattresses, radiant warmers, heated and humidified gases for respiratory support and a room temperature of 23°C–25°C.[16] Despite these interventions, hypothermia in preterm infants remains a problem.

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The polyethylene bag (PB) is a simple, cheap and widely available intervention that reduces heat loss immediately after birth in preterm infants.[21] Covering the infant in a PB from the neck down reduces evaporative and convective heat loss, while allowing the passage of radiant heat from the overhead warmer.[22] Two systematic review and meta-analysis of reported that PB's prevent heat loss and reduce the incidence of moderate and severe hypothermia in preterm infans after birth.[21 23] All of these studies were performed when cord clamping (CC) occurred immediately at birth; hence, the infant was placed under radiant heat and in a PB very shortly thereafter.

The newborn resuscitation algorithm recommends that warming should begin immediately after birth and that initial thermal tasks should be complete by 60 s.[16] In 2015, the mean time to placement of a polyethylene wrap was 24 s.[24] ILCOR has since recommended delayed CC for uncompromised preterm infants,[25] and the median time to place a PB is now greater than the 60 s recommended.[26] Without measures to prevent heat loss, the exposed, wet, newly born infant is vulnerable to heat loss during this time. At our centre, the proportion of infants with hypothermia on neonatal intensive care unit (NICU) admission increased (6%[27] vs 54%[28]) since the introduction of delayed cord clamping (DCC). The feasibility and efficacy of initiating warming interventions before CC has not been reported, and there are no recommendations for thermal care before CC. We wished to determine whether placing newly born preterm infants in a PB before CC, compared with after CC, would result in more infants with a temperature in the normal range (36.5°C–37.5°C) on admission to the NICU.

METHODS

Study design

We performed this randomised controlled trial at the National Maternity Hospital (NMH), Dublin, Ireland, a university maternity hospital with >7500 live births per year, with a level 3 NICU to which ~100 infants with a GA<32 weeks are admitted annually. The study protocol was registered on clinicaltrials.gov (NCT04463511) before the first infant was enrolled. We studied infants with the written consent of their parent(s)/guardian(s). We examined the effect of timing of placing preterm infants in a PB, a well-recognised and recommended intervention. Preterm delivery is an emergency and can occur with little warning. Time constraints and parental distress may compromise parental understanding and voluntariness when obtaining informed consent. In order to enrol a representative sample of very preterm infants in our DR study, our research ethics committee approved obtaining retrospective consent where appropriate.

Participants

Inborn infants born before 32 (up to 31^{+6}) weeks GA by best obstetric estimate were eligible for inclusion. Infants for whom intensive care was not planned, and infants with large abdominal wall defects, neural tube defects or imperforate anus were ineligible.

Randomisation and group assignment

Eligible infants were randomly assigned to PB placement 'BEFORE' or'AFTER' CC in a 1:1 ratio. The group assignment schedule was generated in permuted blocks of 4, using a random number table. Groups were stratified by GA ($<28^{+0}$ weeks, 28^{+0} to 31^{+6} weeks). The assignment schedule was concealed from investigators and treating clinicians. Cards indicating the treatment allocation were placed in sequentially numbered sealed opaque envelopes. Infants of multiple births were randomised as individuals. When delivery was imminent, a member of the neonatal team brought the next card in sequence to the DR, and opened it just before delivery. Caregivers were not masked to the group assignment.

Procedures

The DR temperature was recorded at each delivery with a room thermometer. We recorded the maternal tympanic temperature taken closest to the time of delivery. All infants were stabilised on a resuscitation trolley (Panda Warmer, GE Healthcare, Wauwatosa, Wisconsin, USA) with an overhead radiant warmer that was switched on and set to maximum output at least 10 min before delivery. A cotton towel, blankets and a cotton hat were placed under the radiant warmer before delivery. An 11′ × 16′ (279 mm × 406 mm) sterile resealable PB (Resealable Polybag, Helapet, Bedfordshire, UK) was prepared by cutting a hole in the bottom (non-sealable end) of the bag large enough for the infant's head to fit through. For caesarean deliveries, a member of the neonatal team donned a sterile gown, mask and gloves, and cut the hole in the sterile bag using a sterile scissors. After birth, we aimed for CC at or after 60 s of age.

Infants in the intervention group were placed, head first and without drying, into a PB; this occurred at the perineum for vaginal deliveries, and in the sterile surgical field at caesarean sections. After 60 s, the cord was clamped and cut, and the infant was transferred to the resuscitation trolley. Infants in the control group had their cord clamped and cut after 60 s. They were then transferred to the resuscitation trolley and placed head first and without drying into a PB. All infants had a hat placed on their head when they arrived on the resuscitation trolley. A pulse oximeter probe was placed on the right wrist, and the bag was sealed beneath the feet. Stabilisation was carried out as per the ILCOR recommendations.[16] The gases used to provide respiratory support were neither heated nor humidified, and we did not use exothermic mattresses in the DR. After stabilisation, the infant was brought to the neonatal unit in a transport incubator (Isolette TI-500, Draeger Medical Systems, Telford, Pennsylvania, USA), set to an air temperature of 37.0°C.

Outcome

The primary outcome was rectal temperature within the normal range (36.5°C–37.5°C)[14] on admission to the NICU. Rectal temperature was measured on arrival to the NICU, while the infant was still in the transport incubator and in the PB, with a digital thermometer (Microlife MT-1931, Microlife AG, Widnau, Switzerland) that was validated to detect abnormal temperature in very preterm infants.[29 30]

We recorded the following secondary outcomes: axillary temperature and respiratory support on admission; surfactant administration; abnormal cranial ultrasound (intraventricular haemorrhage (Papile classification≥grade 3) or white matter changes); necrotising enterocolitis (modified Bell's staging criteria≥IIb); late onset sepsis (positive blood culture>72 hours); oxygen requirement at 36 weeks corrected GA; and death before discharge from hospital.

Sample size and statistical analysis

Prior to this study, the proportion of infants with abnormal temperature on admission to the NICU at our centre was 60%.[28] To demonstrate a reduction in the proportion of infants with abnormal temperature on admission to the NICU from 60% to 40% (ie, a relative reduction of 33%) with the application of

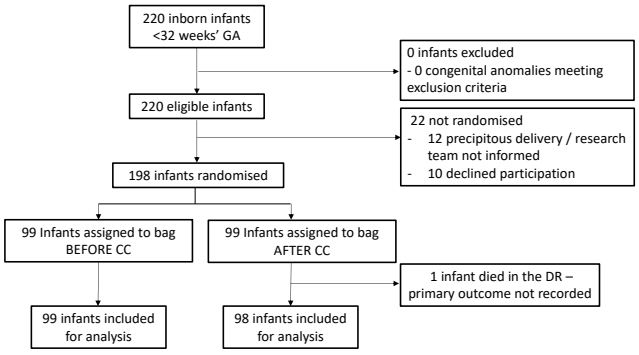

Figure 1 Flow diagram of eligible patients and randomisation process. CC, cord clamping; DR, delivery room; GA, gestational age.

a PB before CC, with 80% power and $\alpha=0.05$, we estimated that we would need to enrol 196 infants. Interim analysis of the primary outcome and selected secondary outcomes was performed by an external reviewer after half of the sample size had completed the study.

Data were analysed using SPSS software V.27.0 (IBM, Armonk, New York, USA). We expressed the primary outcome and other dichotomous variables as numbers and proportions and compared them using non-parametric tests (eg, χ^2 test). We expressed continuous outcomes with normal distribution as mean (SD) and compared them using parametric tests (eg, independent samples t-test). We expressed continuous outcome with non-normal distribution as median (IQR) and compared them using non-parametric tests. We considered p values of <0.05 statistically significant.

RESULTS

Between July 2020 and September 2022, 220 infants<32 weeks' gestation were born at NMH. In total, 198 infants were randomly assigned; 99 (44 (44%) girls) to BEFORE and 99 (53 (54%) girls) to AFTER (figure 1). Their median (IQR) GA was 29 (27–31) vs 29 (27–31) weeks, and mean (SD) birth weight (BW) was 1206 (429) vs 1138 (419) g, respectively (table 1). The minimum GA and BW were 23^{+1} weeks and 485 g, respectively. One infant died in the DR precluding measurement of the primary outcome and was excluded from the analysis. One infant did not have the primary outcome recorded. Prospective consent was obtained for 139 (70%) infants, the remainder were obtained retrospectively. No parent/guardian declined to give consent retrospectively. All infants were treated as per their group assignment. Two infants in the BEFORE group were transferred to the NICU on an open resuscitation trolley under radiant heat; all others were transferred to a transport incubator. All infants were followed from randomisation to death or discharge. The groups were well matched for maternal and neonatal characteristics (table 1). In total, 38 (19%) infants were not exposed to a full course of antenatal steroids.

The proportion of infants with a rectal temperature in the normal range on admission was similar between the two groups overall (BEFORE 54/99 (55%) vs AFTER 55/98 (56%); RR 0.94, 95% CI 0.55 to 1.67, p 0.824).[31] The rate of the primary outcome did not differ between the groups in the GA strata (<28 weeks' GA—BEFORE 19/38 (50%) vs AFTER 21/39 (54%), p 0.736; 28 to 31^{+6} weeks' GA—BEFORE 35/61 (58%) vs AFTER 33/59 (55%), p 0.978) (table 2).

Table 1 Infant and maternal demographics

Patient characteristics	BEFORE (n=99)	AFTER (n=98)
Gestational age (weeks)*	29 (27, 31)	29 (27, 31)
Birth weight (g)†	1206 (429)	1138 (419)
Female‡	44 (44)	53 (54)
Antenatal steroids (>1 dose)‡	76 (77)	84 (86)
Multiple birth‡	27 (28)	36 (37)
Caesarean delivery‡	65 (66)	74 (76)
DR temperature (°C)†	23 (1.7)	23 (1.5)
Maternal temperature (°C)†	36.9 (0.37)	36.9 (0.44)
Time cord clamped (s)†	57 (15)	55 (16)
Transport incubator temperature (°C)†	36.1 (0.9)	36.0 (1.0)
Time to NICU admission (min)†	25 (7)	25 (9)
Respiratory support in DR‡	87 (88)	90 (92)
Intubation in DR‡	12 (12)	11 (11)
Surfactant in DR‡	3 (3)	6 (6)
Volume in DR‡	1 (1)	1 (1)

*Median (IQR).
†Mean (SD).
‡n (%).
DR, delivery room; NICU, neonatal intensive care unit.

The proportion of infants with admission temperature outside of the normal range was similar between the groups (table 2 and figure 2).

There was no significant difference in the mean (SD) admission temperature between the groups (BEFORE 36.6°C (0.8) vs AFTER 36.7°C (0.7), p 0.33). There were no significant differences in secondary outcomes between the groups (table 2).

DISCUSSION

In this randomised trial, we found that placing very preterm infants in a PB before CC did not decrease the proportion of infants with abnormal temperature on admission to the NICU.

Preterm infants lose heat rapidly after birth and have limited ability to generate heat.[32] The mainstay of thermal care for preterm infants in the DR is to provide an external heat source (eg, radiant heat, exothermic mattress) and to use additional measures to prevent heat loss (eg, polyethylene wrap/bag and hat). The vast majority of studies that demonstrate the efficacy of a PB were conducted with the infant under radiant heat.[21] The practice of DCC could place preterm infants at increased risk of abnormal temperature as it potentially delays placement of the infant under radiant heat. This study demonstrates that a PB alone will not suffice in maintaining temperature before CC; however, it is reasonable to apply a PB before CC, as it may facilitate earlier assessment and stabilisation measures as indicated by the resuscitation algorithm. Since the introduction of delayed CC, a number of mobile resuscitation trollies (MRTs) have become available. MRTs with external heat sources (overhead radiant warmer (Concord, Concord Neonatal, Leiden, Netherlands), warming mattress (Lifestart, Inspiration Healthcare, West Sussex, UK)) could help to maintain normothermia before CC, but further studies are needed to determine their effect on the temperature of very preterm infants. MRTs are expensive and not widely available in all healthcare settings, therefore

Table 2 Outcomes

Patient outcomes	BEFORE (n=99)	AFTER (n=98)	P value
Primary outcome			
Rectal admission temperature 36.5°C–37.5°C*	54 (55)	55 (56)	0.824
<28 weeks' GA†	19/38 (50)	21/39 (54)	0.736
28–31^{+6} weeks' GA†	35/60 (58)	34/59 (58)	0.978
Secondary outcomes			
Admission rectal temperature (°C)†	36.6 (0.8)	36.7 (0.7)	0.330
Admission axillary temperature (°C)*	36.7 (0.8)	36.7 (0.7)	0.642
Admission rectal temperature<36.5°C†	34 (34)	33 (34)	0.880
Admission rectal temperature<36.0°C†	12 (12)	11 (11)	0.824
Admission rectal temperature<35.5°C†	3 (3)	3 (3)	1.00
Admission rectal temperature>37.5°C†	10 (10)	10 (10)	1.00
Intubated during hospital stay†	52 (53)	60 (61)	0.248
Surfactant during hospital stay†	49 (50)	52 (53)	0.721
Chronic lung disease†	11 (11)	15 (14)	0.4
Late onset sepsis†	7 (7)	10 (10)	0.748
Necrotising enterocolitis†	9 (9)	7 (7)	0.819
Abnormal cranial ultrasound†	9 (9)	8 (8)	0.894
Death before discharge†	17 (17)	18 (18)	0.852

Median (IQR).
*Mean (SD).
†n (%).
GA, gestational age.

alternative interventions to maintain normothermia before CC need to be considered.

Strengths and limitations

We studied small preterm infants who are at high risk of abnormal temperature after birth. Our sample had minimal selection bias and was representative of all potentially eligible infants (90%) born at our hospital during the study period, including 38 (19%) infants who were not exposed to a full course of antenatal steroids, and may not have been included if we were not permitted to seek deferred consent. We included infants of mothers with peripartum fever, who have been excluded from some randomised trials on thermoregulation.[33–36] The assignment schedule was concealed from investigators and treating clinicians, and all infants received the intervention as per their group assignment.

This study was performed at a single centre, and, though representative, our sample size was relatively small. It was not possible to blind this study due to the nature of the intervention, introducing the risk of performance bias. Temperature is, however, an objective outcome.

The overall incidence of normothermia on admission was higher than our pretrial estimate (55% vs 40%). Apart from the study intervention, there were no changes in the thermal care provided in the DR management between the two studies. This difference may be explained by a larger sample size or may be due to the Hawthorne effect.

The overall rate of abnormal temperature is high in this study (45%). The majority of these infants are hypothermic (35%). Although placing an infant in a PB before CC does not increase the incidence of admission normothermia, further investigation into the efficacy of simple, cheap and readily available interventions that can be accessed in all healthcare settings is needed. Overall, 10% of infants were hyperthermic on admission. This is similar to other DR studies that report an increasing incidence of hyperthermia as a consequence of uniformly applying warming interventions to prevent hypothermia.[27 34 37] Hyperthermia in newly born preterm infants may be harmful.[3 13] In order to avoid overheating a proportion of infants, a more individualised approach to thermal care may be more appropriate. Continuous temperature monitoring in the DR could allow caregivers to tailor thermal care management in real time for individual infants (ie, add an exothermic mattress if an infant is hypothermic or place the infant on servocontrol if they are hyperthermic), thus increasing the likelihood of achieving normothermia.

There was no difference in our secondary outcome of mean (SD) rectal temperature on admission. In fact, the mean rectal admission temperature was in the normal range for both groups. Solely reporting mean temperature as an outcome in studies of thermal care can be misleading. Had we not chosen to report the proportion of infants with temperature outside of the normal range, we may have been falsely reassured by our results and failed to identify how frequently abnormal temperature occurs.

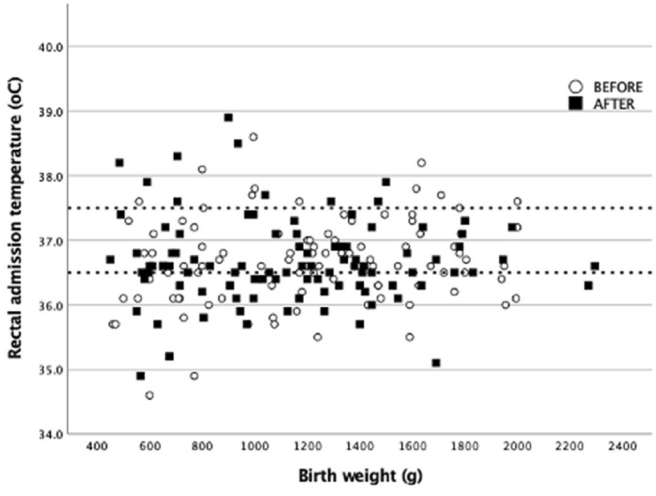

Figure 2 Scatterplot of birth weight (g) and rectal temperature (°C) on neonatal intensive care unit admission. The area between the hatched lines represents the normal temperature range (36.5°C–37.5°C). Open circles represent infants in the 'before' group. Black squares represent infants in the 'after' group.

CONCLUSION

Placing very preterm infants in a PB before CC did not increase the proportion of infants with a normal temperature on admission to the NICU. The rate of abnormal temperature was high, and further studies into the efficacy of additional thermal care interventions are needed.

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Contributors EAD conceptualised and designed the study, coordinated and supervised data collection, drafted the initial manuscript and critically reviewed and revised the manuscript. CPFOD and LKMcC conceptualised and designed the study and critically reviewed and revised the manuscript for important intellectual content. CMNiC and LEG collected data and critically reviewed and revised the manuscript. LKMcC is the guarantor. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Competing interests None declared.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval This study involves human participants and was approved by the research ethics committee, The National Maternity Hospital, Dublin, Ireland, reference EC19.2020.We studied infants with the written consent of their parent(s)/guardian(s).

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. Data will be made available upon reasonable request.

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