

Heat Loss Prevention in Very Preterm Infants in Delivery Rooms: A Prospective, Randomized, Controlled Trial of Polyethylene Caps

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Objective To evaluate in preterm infants whether polyethylene caps prevent heat loss after delivery better than polyethylene occlusive wrapping and conventional drying.

Study design This was a prospective, randomized, controlled trial of infants <29 weeks' gestation including 3 study groups: (1) experimental group in which the heads of patients were covered with a polyethylene cap; (2) polyethylene occlusive skin wrap group; and (3) control group in which infants were dried. Axillary temperatures were compared at the time of admission to the neonatal intensive care unit (NICU) immediately after cap and wrap removal and 1 hour later.

Results The 96 infants randomly assigned (32 covered with caps, 32 wrapped, 32 control) completed the study. Mean axillary temperature on NICU admission was similar in the cap group ($36.1^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$) and wrap group ($35.8^{\circ}\text{C} \pm 0.9^{\circ}\text{C}$), and temperatures on admission to the NICU were significantly higher than in the control group ($35.3^{\circ}\text{C} \pm 0.8^{\circ}\text{C}$; $P < .01$). Infants covered with polyethylene caps (43%) and placed in polyethylene bags (62%) were less likely to have a temperature $<36.4^{\circ}\text{C}$ on admission to the NICU than control infants (90%). In the cap group, temperature 1 hour after admission was significantly higher than in the control group.

Conclusions For very preterm infants, polyethylene caps are comparable with polyethylene occlusive skin wrapping to prevent heat loss after delivery. Both these methods are more effective than conventional treatment. (*J Pediatr* 2010;156:914-7).

Hypothermia after delivery is a world-wide problem associated with morbidity and mortality.¹⁻⁴ The conventional approach of drying the baby with a pre-warmed towel and radiant warmers is unsuccessful in a large proportion of very preterm infants.⁴⁻⁶ Polyethylene occlusive skin wrapping will reduce postnatal heat loss in very preterm babies.^{5,7,8} The use of a head cap will also reduce heat loss⁹; however tubegauze or stockinet caps are ineffective.⁹⁻¹¹ Although the head of a preterm infant should not be left uncovered, it remains unclear whether covering the head of a preterm baby with plastic wrapping effectively prevents heat loss. We conducted a prospective, randomized, controlled trial in very preterm infants to evaluate whether a polyethylene cap prevents heat loss after delivery better than polyethylene occlusive wrapping and conventional drying. We also assessed body temperature 1 hour after admission to the neonatal intensive care unit (NICU) to evaluate whether the polyethylene cap prevents postnatal heat loss.

Methods

The study was conducted with infants <29 weeks' gestation at the Pediatric Department, Medical School, University of Padua, Azienda Ospedaliera di Padova, Padua, Italy, from December 2007 to February 2009. Exclusion criteria included presence of congenital anomalies with open lesions (eg, gastroschisis, meningomyelocele) and babies whose deliveries were not attended by the neonatal team. The study was approved by the Azienda Ospedaliera-Padova Research Ethics Committee. When possible, parental consent was obtained before delivery; the remaining parents received a parent information form after initial stabilization of their baby. The trial is registered at www.clinicaltrials.gov (NCT00930917).

Interventions

All infants were cared for in the delivery room with radiant warmers (Babytherm 8004/8010, Dräger Medizintechnik GmbH, Lubeck, Germany), which were turned on approximately 10 minutes before birth and set to manual control with maximum output. Polyethylene caps (DeGusto Dolomiti, Belluno, Italy) and polyethylene bags (Vedovato SNC, Camposampiero, Padova, Italy, isolation transport bag 35 cm x 40 cm) were placed on the radiant warmer bed before delivery. In the cap group, the head of the infant was covered with a polyethylene cap quickly after

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NICU Neonatal intensive care unit



Figure 1. Preterm infant with polyethylene cap.

birth (**Figure 1**); only the body was dried. Infants in the wrap group were put into the polyethylene bag, while still wet, up to their necks; only the head was dried. Infants in the control group were placed in pre-warmed towels after drying, according to the International Guidelines for Neonatal Resuscitation.

For the other interventions (oxygen administration, ventilation, intubation, chest compressions, and medications), all infants were treated according to the International Guidelines for Neonatal Resuscitation.⁶ Immediately after birth, an oximetry sensor (OxiMax, Tyco Healthcare Group LP, Nellcor Puritan Bennett Division, Pleasanton, California) was placed on the right hand of all infants and then connected to an oximeter (Philips, Hewlett Packard, M3046A, M4, Boeblingen, Germany). A transport incubator (MOG 500, Ginevri, Tecnologie Biomediche, Cecchina, Roma, Italy) was used to transfer the infants from the delivery room to the NICU. The infants were then placed in a double walled incubator at 35°C temperature and 70% humidity (Drager 8000 SC, Drager Medical AG & Co KGaA, Lubeck, Germany). At this point, the cap or the wrap was removed. In all the mothers, axillary temperature (Geratherm, Medical AG, Germany) was recorded within 30 minutes of delivery.

Outcomes

The primary outcome measure was axillary temperature on admission to the NICU (immediately after cap and wrap removal) and again 1 hour later. Axillary temperature was measured by using a digital thermometer (Terumo Digital Clinical Thermometer C202, Terumo Corporation, Tokio, Japan). The occurrence of hypothermia, defined as axillary temperature <36.4°C, at NICU admission was also evaluated. Secondary outcomes included mortality before hospital discharge, presence of major brain injury (sonographic evidence of intraventricular hemorrhage with ventricular dilatation, parenchymal hemorrhagic infarction, or periventricular leukomalacia), tracheal intubation at birth, Apgar

scores, delivery to admission time, blood gas analysis, and serum glucose concentration on NICU admission.

Sample Size

On the basis of an earlier study,⁸ the means' variance was equal to 0.18 (according to temperature at NICU admission of 36.5°C for treatment groups and 35.6°C for control group) and SD equal to 1.3. To detect a mean difference of 0.9°C between the treatment groups and control group in axillary temperature required the enrollment of 32 subjects per group, for an alpha of 0.05 and 80% power.

Random Assignment

Eligible infants were assigned to 1 of the 3 study groups (cap, wrap, or control group) according to a computer-generated, randomized sequence balanced in blocks of 6 subjects. The randomized allocation was concealed in double-enclosed, opaque, sealed, and sequentially numbered envelopes. In the delivery room, the next sequential randomization envelope was opened only when the infant was considered to be eligible by the attending neonatologist. The assigned procedure (cap, wrap, or conventional treatment) was then performed. Multiple births were separately randomized.

Statistics

Continuous data were expressed as means plus or minus SD. The mean temperature at NICU admission and 1 hour later were compared in the groups by using the Kruskal-Wallis non-parametric test and Wilcoxon non-parametric test adjusted with Bonferroni correction for multiple comparisons. The Fisher exact test was used for categorical data. Analysis of covariance was performed to check the relation between temperature and groups, adjusting for birth weight. A *P* value <.05 was considered to be significant.

Results

Of the 117 infants screened for the study, 21 were excluded from the study because the neonatal team did not attend the delivery (*n* = 13), because parents refused to participate (*n* = 5), or because of the presence of congenital malformations (2 anomalies with open lesions and 1 Trisomy 13). Baseline characteristics of infants and their mothers were similar in the 3 groups (**Table I**).

Mean axillary temperatures at NICU admission and 1 hour later were different in the 3 groups (Kruskal-Wallis non parametric test, *P* = .001 and *P* = .0008, respectively). Mean axillary temperatures at NICU admission and 1 hour later were similar between the cap group and wrap group. In these groups, temperatures on admission to the NICU were significantly higher than in the control group. In the cap group, temperature 1 hour after admission was significantly higher than in the control group. One hour after admission, no significant difference was found in axillary temperature between the wrap group and the control group (**Table II**). Adjusting for birth weight, temperature at NICU admission remained significantly higher in the cap group

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