

Plastic Bags for Prevention of Hypothermia in Preterm & Low Birth Weight Infants.

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1.Introduction:

- **Annually, ~ 3 million infants die during the neonatal period worldwide, >80% of these neonatal deaths attributed to infection, birth asphyxia, complications of premature delivery (hypothermia, congenital anomalies).**
- **Hypothermia contributes to neonatal mortality & morbidity, especially in preterm & LBW infants in developing countries.**

- **Neonatal hypothermia → increased risk of infection, coagulation defects, acidosis, delayed fetal-to-newborn circulatory adjustment, hyaline membrane disease, brain hemorrhage, increased oxygen consumption, mortality.**

- **An immature skin barrier, insensible water loss, evaporative heat loss ...→ hypothermia during the first 30 minutes after birth.**
- **The WHO recommendations: a warm delivery room (25°C), immediate drying & resuscitation under radiant warmers, skin-to-skin contact with the mother, or an incubator.**

- In a Cochrane review (McCall et al), the Neonatal Resuscitation Program, the International Liaison Committee on Resuscitation consensus statement: recommend the use of a plastic bag to prevent hypothermia in preterm infants.
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- The objective: to determine if placing preterm and LBW infants inside a plastic bag at birth maintains normothermia *without causing hyperthermia at 1 hour after birth.*

2.METHODS:

- Infants at 26 - 36 weeks 6 days' gestational age and/or with a birth weight of 1000 - 2500 g born at the University Teaching Hospital in Lusaka, Zambia, were randomized by using a 1:1 allocation & parallel design to standard thermoregulation (blanket or radiant warmer) care or to standard thermoregulation care plus placement inside a plastic bag (*25.4 X 20 x 61 cm & 0.03 mm thick*) at birth.
- The primary outcome measure was axillary temperature in the WHO–defined normal range (36.5–37.5°C) at 1 hour after birth.

- **Secondary outcomes on patients admitted to the NICU: hypotension, hypoglycemia, seizures / first 24 hours after birth, respiratory distress syndrome, bronchopulmonary dysplasia, pneumothorax, sepsis, major brain injury (defined as intraventricular hemorrhage grade 3 or 4 or periventricular leukomalacia), necrotizing enterocolitis, bowel perforation, pulmonary hemorrhage, death before discharge.**

3.RESULTS:

A total of 104 infants were randomized (August – October 2011, the range of ambient temperature in Lusaka, Zambia: 17 - 35°C).

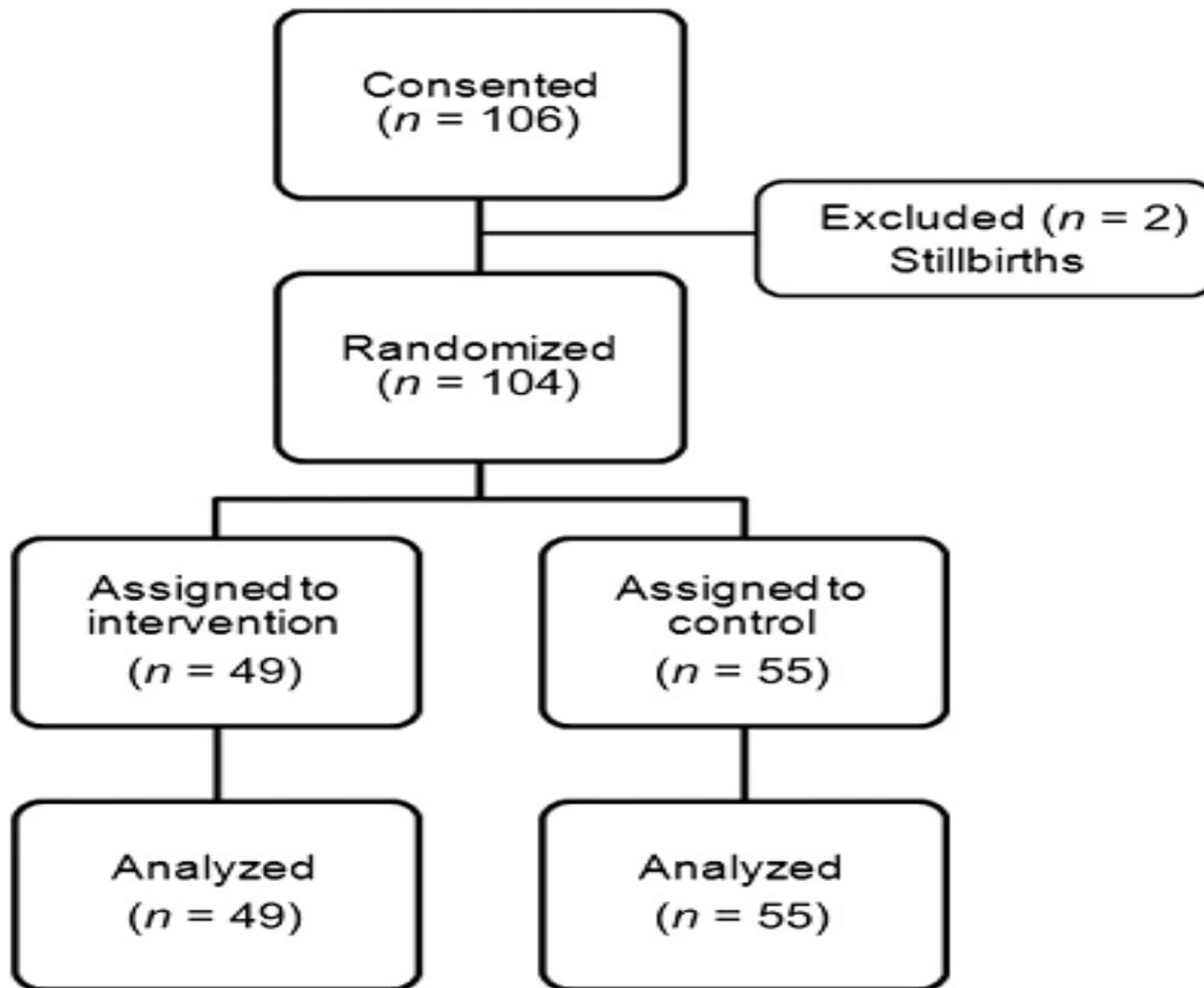


FIGURE 1
Consort diagram.

TABLE 1 Baseline Characteristics

	Intervention Group (<i>n</i> = 49)	Control Group (<i>n</i> = 55)
Mean birth weight, kg (SD)	2.20 (0.56)	2.11 (0.52)
Median gestational age, wk (IQR)	34 (32–36)	34 (31–36)
Gestational age <32 wk (%)	10 (20)	14 (29)
Male gender, <i>n</i> (%)	27 (55.1)	28 (50.9)
Vaginal delivery, <i>n</i> (%)	42 (85.7)	51 (92.7)
NICU admission, <i>n</i> (%)	14 (28.5)	9 (16.4)
Hypothermia at 10 min, <i>n</i> (%) = 86 (83%)	41 (83.7)	45 (81.8)

IQR, interquartile range.

- At 1 hour after birth, infants randomized to plastic bag (n= 49) were more likely to have a temperature in the normal range as compared with infants in the standard thermoregulation care group (n= 55; 59.2% vs 32.7%; relative risk 1.81; 95% confidence interval 1.16–2.81; P= .007).
- The temperature at 1 hour after birth in the infants randomized to plastic bag was $36.5 \pm 0.5^{\circ}\text{C}$ compared with $36.1 \pm 0.6^{\circ}\text{C}$ in standard care infants (P, .001).
- **The duration of use of the plastic bag in hypothermic infants ranged from 80 to 120 minutes. Hyperthermia ($>38.0^{\circ}\text{C}$) or skin side effects did not occur in any infant.**

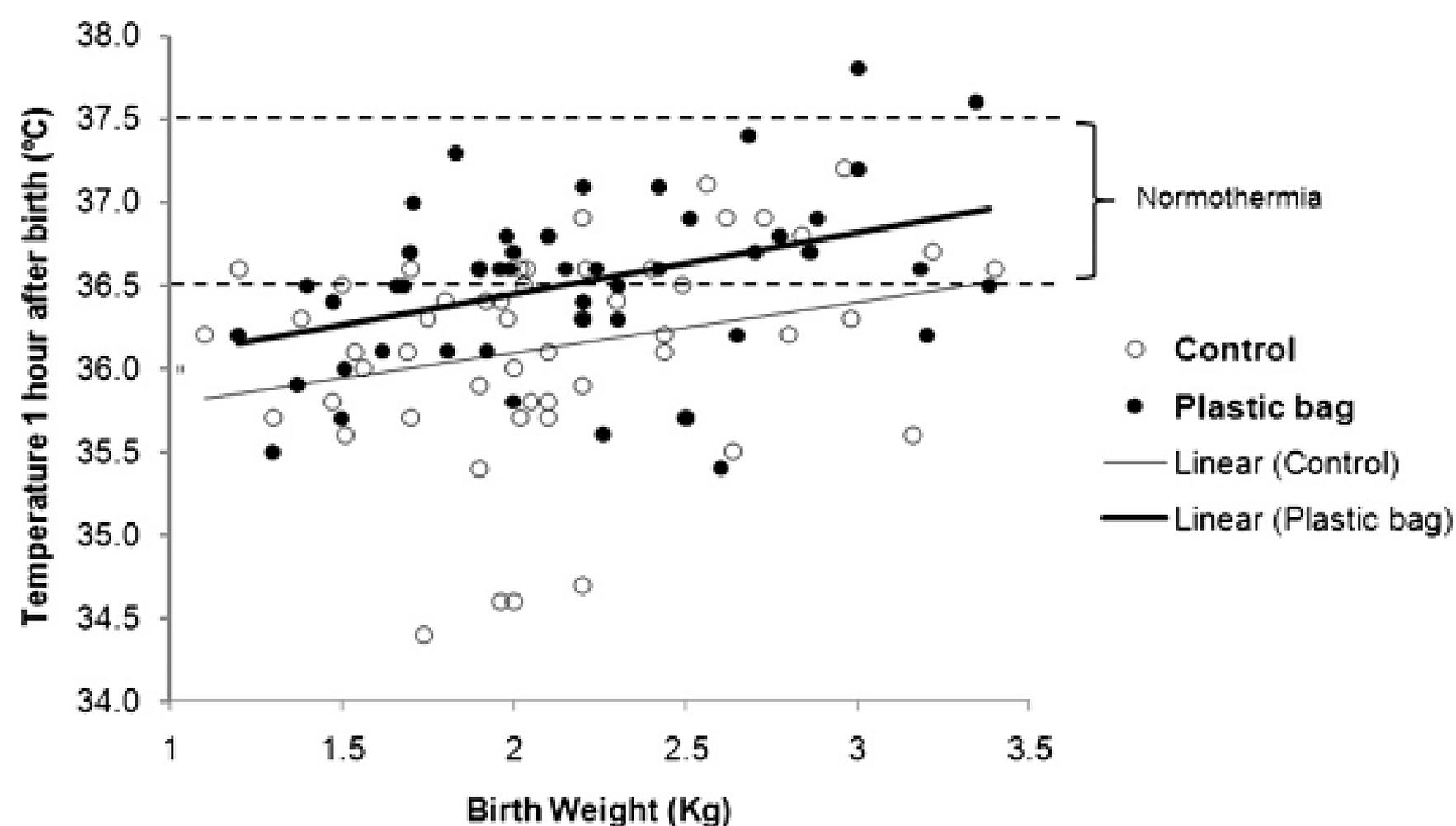


FIGURE 2

Temperature 1 hour after birth in infants randomized to a plastic bag or control group plotted by birth weight. The dotted lines are the limits of normothermia. More infants randomized to a plastic bag compared with control infants had normal temperatures. The effect happened across the birth weight strata. Hyperthermia ($>38^{\circ}\text{C}$) was not seen.

- **23 of the 104 infants (14 in the intervention group and 9 in the control group, $P = .13$) were admitted to the NICU unrelated to the trial interventions.**

Among infants admitted to the NICU, no significant differences were found in mean temperature after 24 hours of admission, length of hospital stay, or death.

- **Hypotension, hypoglycemia, seizures in the first 24 hours after birth, bronchopulmonary dysplasia, pneumothorax, major brain injury, bowel perforation, or pulmonary hemorrhage were not documented in any of the study infants during their NICU admission.**

4.CONCLUSIONS:

- **Placement of preterm/ LBW infants inside a plastic bag at birth compared with standard thermoregulation care reduced hypothermia without resulting in hyperthermia, and is a low-cost, low-technology tool for resource-limited settings where there is limited availability of radiant warmers and incubators.**