Early Skin-to-Skin Care with a Polyethylene Bag for Neonatal Hypothermia: A Randomized Clinical Trial

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Objective To determine whether early polyethylene bag use with skin-to-skin care compared with skin-to skin care alone reduce hypothermia among infants born at term in resource-limited settings.

Study design Infants born at term in the tertiary referral center in Lusaka, Zambia, were randomized using sequentially numbered sealed opaque envelopes in 2 phases: after birth (phase 1) and at 1 hour after birth (phase 2) to either skin-to-skin care with polyethylene bags or skin-to-skin care alone. Infant and maternal temperatures were recorded at birth, 1 hour, and every 4 hours until discharge or 24 hours.

Results We enrolled 423 infants from May 2017 to August 2017. The rate of moderate-severe hypothermia (temperature <36.0°C) at 1 hour was 72 of 208 (34.6%) in the skin-to-skin care with a polyethylene bag group compared with 101 of 213 (47.4%) in the skin-to-skin care alone group (relative risk, 0.71; 95% CI 0.56-0.90; $P < .01$; number needed to treat = 8). phase 1 treatment assignment significantly modified the effect of phase 2 treatment ($P = .02$ for interaction effect). Among infants randomized to skin-to-skin care with a polyethylene bag in phase 1, the risk of moderate-severe hypothermia was decreased in infants randomized to continue this intervention until discharge compared with infants randomized to skin-to-skin care alone. The rates of severe hypothermia, hyperthermia, and other adverse events did not differ significantly between groups.

Conclusions Low-cost polyethylene bags started after birth in combination with skin-to-skin care reduced moderate or severe hypothermia at 1 hour and at discharge among infants born at term in a resource-limited setting compared with skin-to-skin care alone. *(J Pediatr 2021;231:55-60)*.

Trial Registration ClinicalTrials.gov: NCT03141723.

Neonatal hypothermia is associated with a greater risk of mortality.[1-3] Skin-to-skin care reduces neonatal hypothermia, sepsis, and death among infants born preterm and with low birth weight.[4] Skin-to-skin care is part of the World Health Organization warm-chain, which also includes warm delivery rooms; immediate drying; breastfeeding; delayed bathing and weighing; appropriate bundling; mother and baby together; warm transportation and resuscitation; and training and awareness raising.[5] Despite widespread adoption of the World Health Organization warm chain, neonatal hypothermia remains common even among infants born at term in warm climates, where the prevalence estimates range from 32% to 85%.[6] Continuous skin-to-skin care may be effective in preventing hypothermia in infants born at term[7] but is difficult to practice continuously right after birth.[7-9]

Polyethylene bags decrease heat loss by evaporation, convection, and radiation[10,11] and prevent neonatal hypothermia immediately after delivery in resource-limited[12,13] and resource-rich locations.[14] The addition of polyethylene bags to skin-to-skin care and other elements of the World Health Organization warm chain may be a cost-effective way to reduce neonatal hypothermia. Studies of polyethylene bags to date have focused on preventing hypothermia in the initial newborn period,[12-14] but hypothermia may persist until discharge.[7] Extending the duration of polyethylene bags may reduce neonatal hypothermia beyond the initial stabilization period.[13] In addition, it is possible that commencing polyethylene bags after the initial stabilization period may prevent hypothermia at discharge. The objectives of this study were to determine whether polyethylene bags combined with skin-to-skin care commenced immediately after delivery would decrease moderate or severe hypothermia at 1 hour after birth, and to determine

NICU	Neonatal intensive care unit
NNT	Number needed to treat
RR	Relative risk

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whether polyethylene bags combined with skin-to-skin care commenced after 1 hour would decrease moderate or severe hypothermia at discharge compared with skin-to-skin care alone in a resource-limited setting.

Methods

This single-center randomized controlled trial was conducted at the tertiary referral center University Teaching Hospital, Lusaka, Zambia, between May 2017 and August 2017. Infants were included if they were inborn and had a gestational age of $\geq 37^{0/7}$ weeks. Infants were excluded if they had any of the following criteria; major congenital anomalies; blistering skin disorders; receiving respiratory support; admitted to the neonatal intensive care unit (NICU); mothers who were clinically unstable; delivered by caesarean; and multiple gestation if birth interval was more than 10 minutes.

After written informed consent was obtained from the mother, either before birth or within 10 minutes after birth, infants were randomized using sequentially numbered sealed opaque envelopes (randomly ordered block sizes 2, 4, 6, and 8) with 1:1 parallel allocation to skin-to-skin care with a polyethylene bag or skin-to-skin care alone. Randomization occurred in 2 phases. In phase 1, infants were randomized within 10 minutes after birth. In phase 2, infants who had completed phase 1 were randomized at 1 hour after birth. Randomization for phase 2 was stratified by phase 1 group assignment using sequentially numbered sealed opaque envelopes (randomly ordered block sizes 2, 4, 6, and 8) with 1:1 parallel allocation. One author prepared the randomization envelopes and generated random allocation sequences independently so that the sequence used was concealed from the remainder of the research team. Masking after group assignment was not performed. Infants from multiple gestation pregnancies were randomized to the same group.

Infants randomized to receive a polyethylene bag were immediately placed in a clear nonmedical polyethylene plastic bag (10 × 8 × 24 inches, 1.2 mil [thousandth of an inch] thick) up to their axillae so that their upper limbs, superior thorax, and head were exterior.[15] Adhesive tape was then wrapped over the bag to secure the bag beneath the infant's axillae. Soiled polyethylene bags were changed as needed. Infants randomized to skin-to-skin care alone in phase 2 and who were initially randomized to skin-to-skin care with a polyethylene bag in phase 1 were immediately removed from a polyethylene bag at 1 hour after birth. Infants in both groups received a hat and were managed using essential newborn care[16] and practices recommended by the World Health Organization warm-chain.[5] Mothers in both groups received counseling regarding the importance of skin-to-skin care, were given a poly-cotton baby-wrap to encourage skin-to-skin care, and could use additional family-provided blankets.[13]

Infant temperatures were recorded at birth, 1 hour, 4 hours, and every 4 hours until discharge or 24 hours, whichever occurred first. Adverse outcomes including skin rashes, admission to NICU, respiratory distress, sepsis, hypotension, hypoglycemia, or seizure, and death were recorded. Additional measurements included maternal axillary temperature, room temperature and humidity, and the duration of skin-to-skin care and polyethylene bags. Infant and maternal axillary temperatures were recorded using a 60-second digital thermometer (Xuerui) to nearest 0.1°C. Room temperature was recorded to nearest 0.1°C and humidity was recorded to nearest percent using a thermo-hygrometer (Ambient Weather). Duration of skin-to-skin contact and polyethylene bag use were reported as percentage of time used. Definitions of neonatal hypothermia from the World Health Organization were used: moderate or severe hypothermia <36.0°C; any hypothermia <36.5°C; severe hypothermia <32.0°C; and hyperthermia >38.0°C.[5]

We calculated that 421 infants were required in phase 1 to detect a 33% relative risk (RR) reduction in the rate of moderate or severe hypothermia at one hour (the primary outcome in phase1), based on an incidence of 38%,[12] with 80% power, and 2-tailed type I error at 0.05. In addition, 300 infants were required in phase 2 to detect a 40% RR reduction in the rate of moderate or severe hypothermia at discharge (the primary outcome in phase 2), based on an incidence of 38%,[12] with 80% power, 2-tailed type I error at 0.05, and 5% loss to follow-up rate. All analyses were by intention to treat. Results were analyzed by χ^2 or Fisher exact tests for categorical data and independent samples t test for continuous data. Continuous data are reported as mean ± SD unless otherwise specified. Additional sensitivity analyses were conducted to examine for evidence of phase 1 carry-over effect using Cochran–Mantel–Haenzel test on the primary outcome. If this test showed significant results, we stratified the analyses of phase 2 results by phase 1 assignment using χ^2 test and estimated the RRs with 95% CIs. A $P < .05$ was deemed significant. SAS, version 9.4, was used in the analyses.

The trial was approved by the University of Alabama at Birmingham institutional review board and the University of Zambia Biomedical Research Ethics Committee. This study was registered with www.clinicaltrials.gov (identifier: NCT0314172). The funders of this study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

This trial was conducted during cold season from May 2017 to August 2017. Four hundred twenty-three infants with a mean gestational age of 39 ± 1 weeks and birth weight of 3220 ± 429 g were enrolled in phase 1 of the study, and 421 infants completed the study as 2 infants (both randomized to skin-to-skin care with a polyethylene bag) were lost to follow-up due to discharge home within 1 hour after birth (**Figure 1**). Three hundred two of the infants who had been

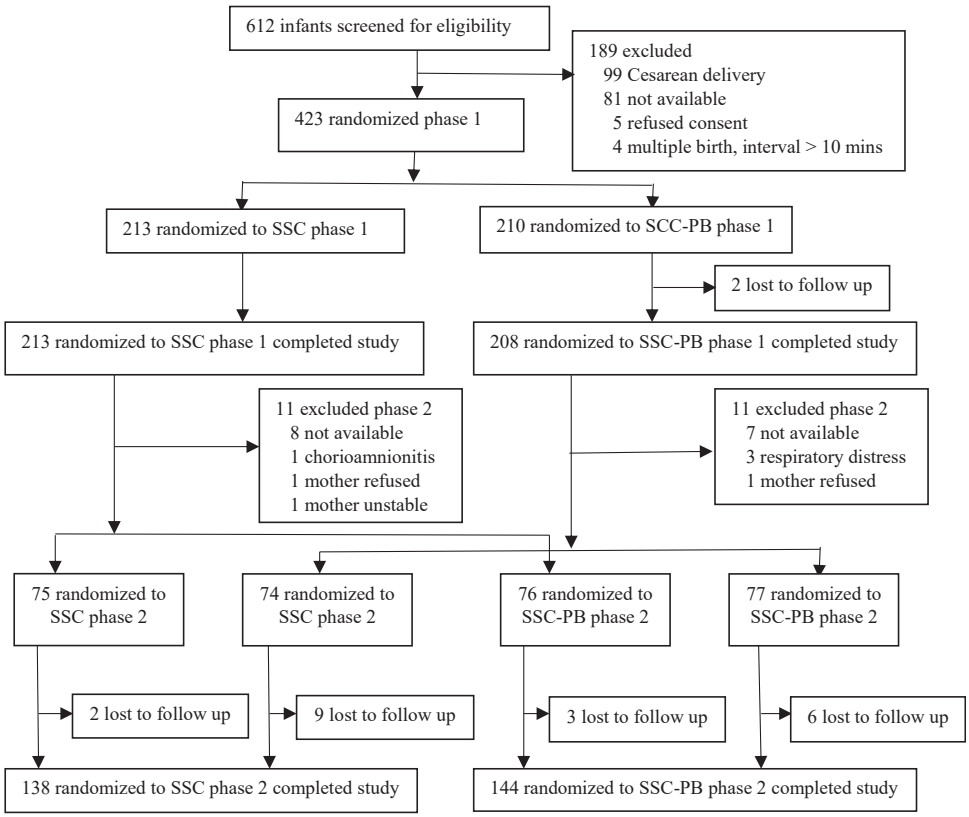

Figure 1. Flow diagram showing screening, randomization, and the number of infants included in phase 1 and phase 2 of the study. *SSC*, skin-to-skin care; *SSC-PB*, skin-to-skin care with a polyethylene bag.

enrolled in phase 1 were subsequently randomized to phase 2 of the study, and 282 infants completed the study as 20 infants were lost to follow-up (11 randomized to skin-to-skin care alone and 9 randomized to skin-to-skin care with a polyethylene bag) due to discharge home within 5 hours after birth (**Figure 1**). There were no differences in the gestational age, birth weight, or sex across study groups (**Table I**). There were no differences in infant temperature, maternal temperature, room temperature, or room humidity between groups (**Table I**).

The rate of moderate or severe hypothermia at 1 hour after birth was decreased in the skin-to-skin care with a polyethylene bag group compared with the skin-to-skin care alone group (72/208 [34.6%] vs 101/213 [47.4%]; RR 0.71; 95% CI 0.56-0.90; $P < .01$; number needed to treat [NNT] = 8). The temperature at 1 hour after birth was greater among infants in the skin-to-skin care with a polyethylene bag group compared with the skin-to-skin care alone group (36.1°C ± 0.8 vs 35.9°C ± 0.6; $P = .04$) (**Table II**). The rates of any hypothermia, severe hypothermia, hyperthermia, and other adverse events did not differ between groups.

In phase 2, the rate of moderate or severe hypothermia at discharge was decreased in the skin-to-skin care with a polyethylene bag group compared with the skin-to-skin care alone group (10/144 [6.9%] vs 23/138 [16.7%]; RR 0.42; 95% CI 0.21-0.85; $P = .01$; NNT = 10) (**Table III**). The rate of any hypothermia at discharge was decreased among infants in the skin-to-skin care with a polyethylene bag group compared with infants in the skin-to-skin care alone group (RR 0.79; 95% CI 0.63-0.99; $P = .04$; NNT = 8). The mean temperature at discharge was greater among infants in the skin-to-skin care with a polyethylene bag group compared with the skin-to-skin care alone group (36.5°C ± 0.4 vs 36.3°C ± 1.1; $P < .01$). The rates of severe hypothermia, hyperthermia, and other adverse events did not differ between groups.

Sensitivity analyses indicated that phase 1 treatment assignment significantly modified the effect of phase 2 treatment ($P = .0169$ for Cochran–Mantel–Haenzel test). The results of the sensitivity analyses for carry-over effect at phase 2 were confirmed by the Fisher exact test. Stratifying the analyses by phase 1 assignments, it was found that infants randomized to skin-to-skin care with a polyethylene bag in phase 1 had significantly lower risk of moderate or severe hypothermia at discharge when assigned to skin-to-skin care with a polyethylene bag in phase 2 relative to those assigned to skin-to-skin care alone in phase 2 (RR 0.18, 95% CI 0.06-0.60, $P = .005$; NNT = 5) (**Table IV** and **Figure 2** [available at www.jpeds.com]). However, for those assigned to skin-to-skin care alone at phase 1, there were no significant differences found (RR 1.00, 95% CI 0.37-2.71, $P = 1.00$) in

Table I. Baseline and clinical characteristics of the study participants

Characteristics	SSC–polyethylene bag phase 1 (n = 208)	SSC phase 1 (n = 213)	SSC–polyethylene bag phase 2 (n = 144)	SSC phase 2 (n = 138)
Gestational age, mean ± SD	39 ± 1	39 ± 1	39 ± 1	39 ± 1
Birth weight, mean ± SD	3220 ± 400	3221 ± 455	3240 ± 437	3236 ± 412
Female, n (%)	101 (49)	90 (42)	71 (49)	66 (48)
Multiple, n (%)	2 (1)	4 (2)	0 (0)	0 (0)
Infant temperature, study entry, °C, mean ± SD	36.0 ± 0.5	36.0 ± 0.9	36.0 ± 0.6	36.1 ± 0.5
Maternal temperature, study entry, °C, mean ± SD	36.1 ± 0.7	36.2 ± 0.7	36.4 ± 0.6	36.3 ± 0.8
Room temperature, study entry, °C, mean ± SD	27.5 ± 1.8	27.4 ± 1.9	26.8 ± 1.8	26.9 ± 1.9
Humidity study entry, %, mean ± SD	36.7 ± 7.2	36.3 ± 7.5	38.5 ± 6.6	39.1 ± 7.3

SSC, skin-to-skin care.

Table II. Outcomes at 1 hour by study group for phase 1

Outcomes	SSC–polyethylene bag (n = 208)	SSC (n = 213)	RR (95% CI)	*P* value
Moderate or severe hypothermia, n/N (%)	72/208 (34.6)	101/213 (47.4)	0.73 (0.58-0.92)	<.01
Any hypothermia, n/N (%)	156/208 (75)	172/213 (81)	0.93 (0.84-1.03)	.16
Moderate hypothermia, n/N (%)	72/208 (34.6)	101/213 (47.4)	0.73 (0.58-0.92)	<.01
Severe hypothermia, n/N (%)	0/208 (0)	0/213 (0)	1.02 (0.02-51.4)	1.00
Hyperthermia, n/N (%)	0/208 (0)	1/213 (0)	0.34 (0.01-8.33)	.67
Temperature, °C at 1 h, mean ± SD	36.1 ± 0.8	35.9 ± 0.6	–	.04
Adverse events, n/N (%)*	3/208 (1)	5/213 (2)	0.61 (0.15-2.53)	.50
Duration of SSC (% of time), mean ± SD	18 ± 23	17 ± 22	–	.26
Duration of polyethylene bag (% of time), mean ± SD	84 ± 15	–	–	–

*Adverse events included 3 infants in SSC with a polyethylene bag group admitted to the NICU (1 for transient tachypnea of the newborn, 1 for a minor anomaly, 1 for blood sugar monitoring) and 5 infants in SSC group admitted to the NICU (2 for minor anomalies, 1 for blood sugar monitoring, 2 for antibiotics).

the risk of moderate or severe hypothermia at discharge. Among infants randomized to the skin-to-skin care with a polyethylene bag group in phase 1, the mean temperature at discharge was greater among infants in the skin-to-skin care with a polyethylene bag group compared with the skin-to-skin care alone group (36.6°C ± 0.4 vs 36.3°C ± 0.6; $P < .01$) (Table IV and Figure 2).

The duration of skin-to-skin care did not differ between groups in phase 1 (18 ± 23% of time in the skin-to-skin care with a polyethylene bag group vs 17 ± 22% of time in the skin-to-skin care alone group) or phase 2 of this study 1 (3 ± 9% of time in the skin-to-skin care with a polyethylene bag group vs 5 ± 14% of time in the skin-to-skin care alone group). The duration of polyethylene bags was 84 ± 15% of time in phase 1 and 54 ± 26% of time during phase 2. The length of hospital stay did not differ between groups.

Discussion

This study demonstrated that polyethylene bags in combination with skin-to-skin care compared with skin-to-skin care alone reduces moderate or severe hypothermia, without causing hyperthermia, at 1 hour after birth and at discharge from hospital among infants born at term in a resource-limited setting. The 0.2°C difference between groups is a clinically significant effect, given the relatively narrow range of thermoneutrality in neonates. The current study showed that commencing skin-to-skin care with a polyethylene bag immediately after delivery and then continuing until discharge may have the largest effect on the prevention of neonatal hypothermia.

The results of the current study are generalizable to other resource-limited hospital settings where the World Health Organization warm chain is practiced. The effects of this technique among infants born at term in resource-rich settings is not known but could be easily tested in settings with a relatively high rate of hypothermia. Although the current study was conducted during cold season, the ambient air temperature at study entry was approximately 27°C across groups, which is greater than the delivery room temperature of 23-25°C currently recommended by the Neonatal Resuscitation Program[17] and at the upper end of the 25-28°C range recommended by the World Health Organization.[5] The current study measured axillary temperatures in participants, which may overestimate the incidence of hypothermia compared with rectal temperatures,[18] but this was a nondifferential bias. This was a study of infants who were inborn, and the effect on infants who were outborn is not known.

This study followed infants until discharge or 24 hours, and although neonatal hypothermia was reduced, important long-term outcomes of this intervention are not known. We did not detect a difference in NICU admission rates in the current study. However, it is possible that the addition of polyethylene bags may reduce NICU admissions in centers

Table III. Outcomes by study group for phase 2

Outcomes	SSC–polyethylene bag (n = 144)	SSC (n = 138)	RR (95% CI)	*P* value
Moderate or severe hypothermia, n/N (%)	10/144 (6.9)	23/138 (16.7)	0.42 (0.21-0.84)	.01
Any hypothermia, n/N (%)	65/144 (45.1)	79/138 (57.2)	0.79 (0.63-0.99)	.04
Moderate hypothermia, n/N (%)	10/144 (6.9)	23/138 (16.7)	0.42 (0.21-0.84)	.01
Severe hypothermia, n/N (%)	0/144 (0)	0/138 (0)	0.96 (0.02-48.0)	1.00
Hyperthermia, n/N (%)	0/144 (0)	0/138 (0)	0.96 (0.02-48.0)	1.00
Temperature, °C, at discharge, mean ± SD	36.5 ± 0.4	36.3 ± 1.1	–	<.01
Adverse events, n/N (%)	0/144 (0)	0/138 (0)	0.96 (0.02-48.0)	1.00
Duration of SSC (%), mean ± SD	3 ± 9	5 ± 14	–	.27
Duration of polyethylene bag (%), mean ± SD	54 ± 26	–	–	–
Length of stay, h, mean ± SD	8 ± 3	8 ± 3	–	.24

that routinely admit infants to the NICU for hypothermia. We excluded infants born by cesarean delivery, as providing skin-to-skin care immediately after birth may not have been possible. However, polyethylene bags may improve thermoregulation among infants delivered by cesarean also. Although the polyethylene bag covered up to the axillae, allowing the hands, upper chest, and head direct skin-to-skin care, it is possible that this could interfere with acquisition of maternal microbiome after birth.[19]

An important limitation of the current study was the low rate of compliance with skin-to-skin care in all groups despite encouragement and assistance provided by the study team. Few randomized controlled trials of skin-to-skin care have enrolled mother–infant dyads immediately after birth.[4] In a randomized controlled trial, skin-to-skin care for less than 80% of the time immediately after birth did not prevent hypothermia.[7] Compliance with skin-to-skin can be difficult to maintain, as mothers may require medical treatment such as laceration repair immediately after delivery, may want to sleep, may not understand, or be aware of the benefits of skin-to-skin care immediately after delivery.[7] Previous studies have identified multiple social and environmental barriers to effective continuous skin-to-skin care.[8] A survey in a resource-limited environment suggested that the majority of mothers felt that providing skin-to-skin care limited to 1 hour per day was practical, and most respondents felt that longer durations of skin-to-skin care were impractical.[9]

The current study was limited to infants born at term. The association between neonatal hypothermia and mortality is stronger among infants born preterm compared with infants born at term.[3] Previous studies have shown that polyethylene bags prevent neonatal hypothermia in both infants born at term and preterm during initial stabilization.[12,13,20] The current study extended the duration of polyethylene bag use compared with previous studies[12,13,20] and shows that longer use of polyethylene bags is feasible and may reduce neonatal hypothermia before discharge. We also observed that commencing polyethylene bags at 1 hour after birth was not associated with a lower rate of hypothermia at discharge. This finding is consistent with data suggesting that

Table IV. Phase 2 outcomes stratified by phase 1 group assignment

Phases	SSC–polyethylene bag (n = 73)	SSC (n = 73)	RR (95% CI)	*P* value
Phase 1 SSC				
Moderate or severe hypothermia, n/N (%)	7/73 (9.6)	7/73 (9.6)	1.00 (0.37-2.71)	1.00
Any hypothermia, n/N (%)	33/73 (45.2)	40/73 (54.8)	0.83 (0.59-1.14)	.25
Moderate hypothermia, n/N (%)	7/73 (9.6)	7/73 (9.6)	1.00 (0.37-2.71)	1.00
Severe hypothermia, n/N (%)	0/73 (0)	0/73 (0)	1.00 (0.02-49.74)	1.00
Hyperthermia, n/N (%)	0/73 (0)	0/73 (0)	1.00 (0.02-49.74)	1.00
Temperature, °C, at discharge, mean ± SD	36.5 ± 0.4	36.2 ± 1.4	–	.14
Adverse events, n/N (%)	0/73 (0)	0/73 (0)	1.00 (0.02-49.74)	1.00
Duration of SSC (%), mean ± SD	1 ± 5	4 ± 12	–	.06
Duration of polyethylene bag (%), mean ± SD	52 ± 27	–	–	–
Length of stay, h, mean ± SD	8 ± 4	7 ± 3	–	.43
Phase 1 SSC-polyethylene bag	SSC–polyethylene bag (n = 71)	SSC (n = 65)	RR (95% CI)	*P* value
Moderate or severe hypothermia, n/N (%)	3/71 (4.2)	15/65 (23.1)	0.18 (0.06-0.60)	.005
Any hypothermia, n/N (%)	32/71 (45.1)	38/65 (58.5)	0.77 (0.56-1.07)	.12
Moderate hypothermia, n/N (%)	3/71 (4.2)	15/65 (23.1)	0.18 (0.06-0.60)	.005
Severe hypothermia, n/N (%)	0/71 (0)	0/65 (0)	0.92 (0.02-45.55)	.97
Hyperthermia, n/N (%)	0/71 (0)	1/65 (1.6)	0.31 (0.01-7.37)	.47
Temperature, °C, at discharge, mean ± SD	36.6 ± 0.4	36.3 ± 0.6	–	.008
Adverse events, n/N (%)	0/71 (0)	0/65 (0)	0.92 (0.02-45.55)	.97
Duration of SSC (%), mean ± SD	5 ± 12	5 ± 16	–	.92
Duration of polyethylene bag (%), mean ± SD	54 ± 24	–	–	–
Length of stay, h, mean ± SD	8 ± 3	8 ± 2	–	.43

polyethylene bags prevent rather than delay hypothermia.[21] Reassuringly, there were no cases of hyperthermia seen among infants randomized to polyethylene bag until discharge. Compliance with polyethylene bag use was high during the first hour after birth but decreased in the subsequent hours before discharge. Decreased compliance with polyethylene bags over time may have been related to soiled bags or cultural norms of dressing infants in new baby clothes. In addition, lack of masking may have encouraged mothers to remove the polyethylene bag when infants were no longer hypothermic.

Low-cost polyethylene bags commenced immediately after delivery and continued until discharge are a cost-effective method for prevention of heat loss and hypothermia among infants born at term. ■

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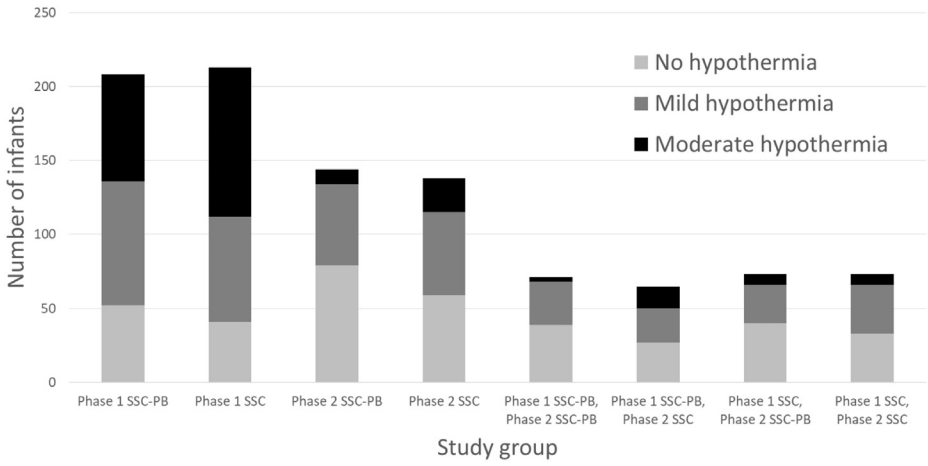

Figure 2. Number of infants with hypothermia by group assignment in phase 1 and phase 2. *SSC-PB*, skin-to-skin care with a polyethylene bag.