Thermal Effect of a Woolen Cap in Low Birth Weight Infants During Kangaroo Care

Francesco Cavallin, MS,[a] Giulia Segafredo, PhD,[b] Damiano Pizzol, MD,[b,c] William Massavon, MD,[d] Marta Lusiani, MD,[e] Olivier Wingi, MD,[f] Manuela De Vivo, MD,[g] Liviana Da Dalt, MD,[h] Chiara Boscardin, MD,[h] Fabio Manenti, MD,[b] Giovanni Putoto, MD,[b] Daniele Trevisanuto, MD,[h] on behalf of the CAP-KMC Group

abstract

BACKGROUND AND OBJECTIVES: World Health Organization guidelines recommend covering the head during kangaroo mother care (KMC), but the effect of a cap on neonatal thermal control during KMC remains to be defined. Our objective was to assess the effectiveness and safety of a woolen cap in maintaining low birth weight infants (LBWIs) in normal thermal range during KMC.

METHODS: Three hundred LBWI candidates for KMC in 3 African hospitals were randomly assigned to KMC with (CAP group) or without (NOCAP group) a woolen cap in a 1:1 ratio during the first week after birth. Axillary temperature was measured every 6 hours. Maternal and room temperature and adherence to skin-to-skin contact were registered at the same time points.

RESULTS: A total number of 5064 measurements were recorded (median 19 measurements per subject; interquartile range: 10–25). Mean time spent in normal temperature range was 55% (SD 24) in CAP and 56% (SD 24) in NOCAP groups. Multivariable analysis estimated a rate ratio of 0.92 (95% confidence interval: 0.84 to 1.00; $P = .06$) for the effect of the cap versus no cap on time spent in the normal temperature range.

CONCLUSIONS: In these 3 African, low-resource settings and so many days post birth, the use of a woolen cap was safe but provided no advantages in maintaining LBWI in the normal thermal range while being in a KMC ward. LBWIs spent only half of the time in the normal temperature range despite warm rooms and skin-to-skin contact. Maintaining normothermia in LBWIs remains an unfinished challenge in low-resource settings.

[a]Independent statistician, Padua, Italy; [b]Doctors with Africa CUAMM, Padua, Italy; [c]Doctors with Africa CUAMM, Beira, Mozambique; [d]Doctors with Africa CUAMM, Oyam District, Uganda; [e]Doctors with Africa CUAMM, Wolisso, Ethiopia; [f]Department of Pediatrics and Neonatology, Central Hospital of Beira, Beira, Mozambique; [g]Doctors with Africa CUAMM, Aber, Uganda; and [h]Department of Women's and Children's Health, University of Padua, Padua, Italy

Headquarters of Doctors with Africa CUAMM is located in Padua, Italy; a representative agency is located in each African country where Doctors with Africa CUAMM supports projects.

Mr Cavallin was responsible for the statistical design and analysis, drafted the manuscript, and contributed to the interpretation of the results; Miss Segafredo contributed to the design of the trial, coordinated and supervised data collection, and critically reviewed the manuscript; Dr Pizzol contributed to the design of the trial and to the submission to the ethics committee, led the study team in Beira, Mozambique, coordinated and supervised data collection, and critically reviewed the manuscript; Dr Massavon contributed to the design of the trial and to the submission to the ethics committee, led the study team in Aber, Uganda, coordinated and supervised data collection, and critically reviewed the manuscript; Dr Lusiani contributed to the design of the trial and to the submission to the ethics committee, led the study team in Wolisso, Ethiopia, coordinated

WHAT'S KNOWN ON THIS SUBJECT: Kangaroo mother care (KMC) is a low-cost intervention recommended for neonatal temperature maintenance. World Health Organization guidelines recommend covering the head during KMC, but this practice is not consistently followed. The thermal effect of a cap during KMC remains unknown.

WHAT THIS STUDY ADDS: The use of woolen caps did not provide any advantages in maintaining low birth weight infants in the normal thermal range during KMC in low-resource settings. Low birth weight infants spent only half of the time in the normal temperature range despite warm rooms and skin-to-skin contact.

To cite: Cavallin F, Segafredo G, Pizzol D, et al. Thermal Effect of a Woolen Cap in Low Birth Weight Infants During Kangaroo Care. *Pediatrics.* 2018;141(6):e20173073

Globally, 5.8 million children younger than 5 years died in 2015, including 2.6 million neonatal deaths.[1] This burden is especially relevant in sub-Saharan Africa and Southern Asia, which accounts for most of these deaths.[2] Despite overall improvements since 1990, the reduction of neonatal mortality in low-resource countries has been slower than the reduction of maternal and child mortality.[3,4] The day of birth and the early postnatal period are the most vulnerable phases for both mother and neonate.[5,6]

Overall, it is estimated that 15% to 20% of all births worldwide are low birth weight infants (LBWIs), representing more than 20 million births per year, the great majority of them reported in low- and middle-income countries.[7] Low birth weight is also a major contributor to both neonatal and child mortality.[8]

Hypothermia is associated with neonatal morbidity and mortality in high- and low-resource settings.[9–13] Thermal care is a critical and essential component of newborn care in low-resource settings where supportive care is limited.[9–13] Appropriate interventions include warm rooms, skin-to-skin care, protective clothes, and breastfeeding.[14]

Kangaroo mother care (KMC) is a low-cost intervention that includes prolonged skin-to-skin contact (SSC) between mother and newborn, exclusive breastfeeding, early discharge from the health facility, and close follow-up at home.[15] KMC is strongly recommended because it may prevent many complications associated with preterm birth and may also provide benefits to term newborns.[16,17] The World Health Organization (WHO) guidelines recommend that during KMC, the infant's head be covered with a hat or cap to prevent thermal dispersion,[18] but this practice is not consistently followed in low-resource settings.

In previous studies, it has been suggested that the application of woolen hats may reduce the neonatal heat loss immediately after birth, but its effect during the early postnatal period remains to be defined.[19,20] It is unknown whether covering the head of the neonate with a hat or cap during KMC may help temperature maintenance during the early postnatal period. On the other hand, excessive covering of the neonates can result in hyperthermia, which is dangerous and should be avoided.[21,22]

Therefore, our aim in the current study was to evaluate the effectiveness and the safety of a woolen cap in maintaining LBWIs in the normal thermal range during KMC.

METHODS

Study Design

This was a multicenter, multicountry, double arm, unblinded, and randomized clinical trial in which we evaluated the effectiveness and the safety of a woolen cap in maintaining normothermia in LBWIs during KMC.[23]

Settings

The study was conducted at the Central Hospital of Beira (Mozambique), the St. Luke Wolisso Hospital (Ethiopia), and the Aber Hospital (Uganda).[24] In the participating hospitals, KMC represents a standard of care, but the heads of the infants often remain uncovered.

Ethics

Ethics clearance was sought and received by the local ethics committees of the participating centers.[23] Informed written consent was signed by a parent before starting KMC treatment. A senior investigator was available at all times to discuss concerns raised by parents or clinicians during the course of the trial.

Patients

After obtaining written parental consent, all infants with a birth weight <2500 g and who were candidates for KMC based on WHO guidelines were randomly assigned, with a 1:1 ratio, to KMC with a woolen cap (intervention arm: CAP) or to KMC without a woolen cap (control arm: NOCAP).[23] Newborns with major congenital malformations, twins, or without parental consent were excluded from the study.

Random Assignment

Eligible infants were assigned to CAP or NOCAP arms in a 1:1 ratio according to a computer-generated, randomized sequence for each participating hospital. Detailed information is available in the study protocol.[23] Contamination between arms was not allowed.

Procedure

The procedure of initiating, maintaining, and stopping the KMC was based on WHO guidelines.[18] In both groups, mothers were asked to clothe the infant with a prewarmed shirt that was open at the front, a napkin, and socks; however, the use of additional garments was not strictly controlled and was left to maternal decision. All mothers were trained in monitoring the infant's condition and in recognizing dangerous clinical signs during KMC. Newborns randomly allocated to the intervention arm were provided with a woolen cap in addition to standard WHO thermoregulatory practices during KMC.[23] Newborns randomly assigned to the control arm received standard WHO thermoregulatory practices during KMC.

All the caps used for the study were handmade by a group of volunteers in Padua and were standardized by the head size (small or large) (Fig 1). The material (heavy wool) was provided by Doctors with Africa CUAMM.[24] Caps were changed and washed if they were dirty or wet.

Study duration was until patient discharge, death, or 7 days maximum. In case of documented neonatal hypothermia (temperature <36.5°C) or hyperthermia (temperature >37.5°C) during the course of the study, a prewarmed blanket was added or removed. In case of maternal hyperthermia, the woman was asked to wear lighter clothes. In these cases, neonatal and maternal temperatures were then measured every hour until the normal range was reached. When the data collector approached the mother to measure temperatures and she was not in KMC, she was asked to place her infant in SSC, but temperature was still registered before the change.

Outcomes

The primary outcome was the time spent in the normal thermal range (36.5°C–37.5°C) during KMC. In addition, the time spent in temperature below normal range (<36.5°C) and the time spent in temperature above normal range (>37.5°C) were also evaluated.[15] In each patient, the time spent with temperature in a predefined range was evaluated as the number of readings with temperature in that range on the total available readings.

Secondary outcomes were as follows: (1) respiratory problems, including tachypnea (respiratory rate >60 breaths per minute) and/or dyspnea and/or apnea; (2) sepsis, defined as the presence of at least 2 of the following clinical signs: lethargy, persistent apnea, poor feeding, or fever; (3) mortality before hospital discharge; and (4) in-hospital growth, defined as weight increment from birth to discharge. Information on the number of episodes of apnea (as stated in the study protocol)[23] could not be collected because of organizational problems; thus, the occurrence of respiratory problems was evaluated instead.

FIGURE 1
An infant wearing the woolen cap used in the study.

Data Collection

In all participants, axillary temperature was measured with a digital thermometer (C202; Terumo, Tokyo, Japan) every 6 hours (6:00 AM, 12:00 AM, 6:00 PM, and 12:00 PM). Maternal temperature, room temperature, and adherence to SSC were registered at the same time points. Room temperature was measured by using the same wall thermometers (Oregon Scientific RMR262) in all 3 study sites. Neonatal and maternal characteristics were collected at birth and at admission to the KMC room. Respiratory problems, sepsis, weight at discharge, and death were collected during hospital stay. Additional information on expected serious adverse events (SAEs) was also collected. Data collection was performed by an observer who was not involved in the care of the neonates. All data were anonymized.

Safety

SAEs were defined as unexpected death, apnea not responding to vigorous stimulation, severe hyperthermia (temperature >39°C), and hypothermia (temperature <35°C). All SAEs were followed until complete resolution or until the clinician responsible for the care of the recruited patient considered the event to be chronic or the infant to be stable. A monitoring board, including an independent assessor (not involved in the study) from the University of Padua and assessors from each participating hospital, reviewed all the deaths and adverse events.

Sample Size

The lack of information about this topic (temperature during KMC in the specific scenario of head covering) prevented a mathematical estimation of the sample size. Thus, the sample size was arbitrarily defined to take into account the enrollment rate of each hospital. According to the number of admissions in each participating hospital, we decided to enroll a total of 300 subjects (150 in CAP and 150 in NOCAP arms) as follows: 150 at Central Beira Hospital, 90 at St. Luke Wolisso Hospital, and 60 at Aber Hospital.[23]

Statistical Analysis

The statisticians who analyzed the data were blind to treatment allocation. An interim analysis of the first 100 infants was performed as planned in the study protocol.[23] The interim analysis indicated no reasons for stopping for harm (Supplemental Information), and thus the enrollment continued as planned.

The analysis was based on the principle of "intention to treat," and no infants changed treatment arms during the study. Missing data were handled by performing complete case analyses. Among the outcomes, only in-hospital growth included missing data. Continuous data were expressed as mean and SD or median and interquartile range (IQR), as appropriate.

The effect of the cap on time spent in predefined temperature ranges was assessed by using negative binomial models, adjusting for hospital and clinically relevant confounders (neonatal temperature at admission to the KMC ward, maternal temperature, room temperature, adherence to SSC, birth weight, and postnatal age at admission to the KMC ward). The models included the logarithm of the number of available readings as an offset (to take into account the different lengths of hospital stay of each participant). The negative binomial model was preferred to the Poisson model because of overdispersion.[25]

The effect of the cap on respiratory problems was assessed by using a logistic regression model, adjusting for hospital and clinically relevant confounders (neonatal and maternal temperatures, room temperature, adherence to SSC, birth weight, and postnatal age at KMC admission). The effect of the cap on sepsis was assessed by using a logistic regression model, adjusting for hospital, adherence to SSC, and birth weight. The effect of the cap on in-hospital growth was assessed by using a linear regression model, adjusting for hospital, adherence to SSC, birth weight, and postnatal age at discharge. The low number of deaths prevented any meaningful multivariable analysis of mortality before hospital discharge.

Adherence to SSC was included as a confounder in the models because of its variability, previously reported in similar settings.[15] Adherence to SSC was evaluated as the proportion of readings when the neonate was in SSC with the mother over the total number of readings for each neonate.

In addition, a subanalysis of the effect of the cap on primary outcome was performed in subjects with adherence to SSC ≥70% and in those with adherence to SSC <70%, separately.

All regression models included the hospital as a covariate to account for the center effects.[26] The hospital was included as a fixed effect in the models because of the low number of centers and the large sample size compared with the number of centers.[26] All tests were 2 sided, and a *P* value <.05 was considered statistically significant. Statistical analysis was performed by using R 3.2.2 software (R Foundation for Statistical Computing, Vienna, Austria).[27]

TABLE 1 Maternal and Neonatal Characteristics According to Random Assignment

	All, No. (%)	CAP Arm, No. (%)	NOCAP Arm, No. (%)
Participants, No.			
Patients	300	150	150
Hospital			
Aber (Uganda)	60	30	30
Beira (Mozambique)	150	75	75
Wolisso (Ethiopia)	90	45	45
Maternal characteristics			
Mother age in y, median (IQR)	23 (19–28)	23 (20–28)	23 (19–28)
Antenatal clinic	46 (20.8)	22 (20.4)	24 (21.2)
Comorbidity	15 (5.0)	7 (4.7)	8 (5.3)
HIV	62 (22.9)	32 (23.4)	30 (22.4)
Delivery			
Cesarean	24 (8.0)	13 (8.7)	11 (7.3)
Vaginal	276 (92.0)	137 (91.3)	139 (92.7)
Neonatal characteristics			
Male	155 (51.7)	73 (48.7)	82 (54.7)
Birth wt in g, median (IQR)	1700 (1400–2020)	1800 (1400–2100)	1690 (1385–2000)
Gestational age in wk, median (IQR)	34 (32–36)	34 (32–36)	34 (32–36)
1-min Apgar score, median (IQR)	7 (5–8)	7 (5–8)	7 (5–8)
5-min Apgar score, median (IQR)	8 (7–9)	8 (7–9)	8 (7–9)
KMC admission			
NICU before KMC	297 (99.0)	148 (98.7)	149 (99.3)
Postnatal age at KMC admission in d, median (IQR)	4 (1–7)	4 (1–8)	4 (1–7)

Some data were not available for maternal age (26), antenatal clinic (79), HIV (29), birth wt (7), gestational age (183), 1-min Apgar score (52), and 5-min Apgar score (55).

RESULTS

Patients

From December 2015 to September 2016, 300 infants were enrolled in the study and were randomly assigned to the CAP arm (150 infants) or NOCAP arm (150 infants). There were no dropouts after enrollment. Maternal and neonatal characteristics are shown in Table 1. In the intervention group, all infants wore the cap at the time of temperature measurement. Median length of stay in the KMC ward was 4 days (IQR: 2–9) in the CAP group and 5 days (IQR: 3–9) in the NOCAP group (*P* = .38). All participants were breastfed during the study period.

Settings

Overall, median KMC room temperature was 27.9°C (IQR: 25.4°C–29.4°C) (Supplemental Table 4). Median adherence to SSC was 48%, which by site is as follows: Aber 16%, Beira 41%, and Wolisso 69% (*P* < .0001).

Primary Outcome

At KMC admission, the median infant temperature was 36.6°C (IQR: 36.1°C–37.2°C). A total number of 5064 temperature recordings were collected. Time spent with temperature in predefined ranges is shown in Table 2. Multivariable

TABLE 2 Time Spent With Temperature in Predefined Ranges

	Treatment Arm		Unadjusted Effect of Cap	Adjusted Effect of Cap[a]
	CAP	NOCAP	Rate Ratio (95% CI)	Rate Ratio (95% CI)
No. subjects	150	150	—	—
Total measurements, *n*	2518	2546	—	—
Measurements per subject, median (IQR)	18 (9–25)	17 (10–25)		
Time spent with temperature in normal range (36.5°C–37.5°C), mean % (SD)	55 (24)	56 (24)	0.95 (0.86 to 1.04)	0.92 (0.84 to 1.00)
Time spent with temperature below normal range (<36.5°C), mean % (SD)	31 (29)	33 (29)	0.97 (0.77 to 1.23)	1.06 (0.92 to 1.23)
Time spent with temperature above normal range (>37.5°C), mean % (SD)	13 (17)	11 (14)	1.26 (0.94 to 1.68)	0.90 (0.67 to 1.21)

—, not applicable.

[a] Adjusted for hospital, adherence to SSC, neonatal temperature at KMC admission, maternal temperature, room temperature, birth wt, and postnatal age at KMC admission.

TABLE 3 Secondary Outcomes

	Treatment Arm		Unadjusted Effect of Cap	Adjusted Effect of Cap
	CAP	NOCAP		
No. subjects	150	150	—	—
			Odds ratio (95% CI)	Odds ratio (95% CI)
Respiratory problems, *n* (%)	32 (21)	33 (22)	0.96 (0.55 to 1.67)	0.88 (0.49 to 1.58)[a]
Sepsis, *n* (%)	39 (26)	27 (18)	1.60 (0.92 to 2.81)	1.48 (0.82 to 2.69)[b]
Mortality before discharge, *n* (%)	9 (6)	10 (7)	0.89 (0.35 to 2.28)	Not available[c]
			β (95% CI)	β (95% CI)
Percentage of in-hospital growth, mean (SD)	5 (20)	3 (14)	1.58 (−2.58 to 5.73)	3.00 (−0.70 to 6.70)[d]

—, not applicable.

[a] Adjusted for hospital, adherence to SSC, neonatal and maternal temperatures, room temperature, birth wt, and postnatal age at KMC admission.

[b] Adjusted for hospital, adherence to SSC, and birth wt.

[c] The low number of deaths prevented any meaningful multivariable analysis.

[d] Adjusted for hospital, adherence to SSC, birth wt, and postnatal age at discharge.

analysis was used to estimate a rate ratio of 0.92 (95% confidence interval [CI]: 0.84 to 1.00; *P* = .06) for the effect of the cap versus no cap on time spent in the normal temperature range (Table 2).

In addition, in the multivariable analysis, it was shown that caps had no statistically significant effect on time spent with temperature <36.5°C (rate ratio: 1.06; 95% CI: 0.92 to 1.23; *P* = .40) or time spent with temperature >37.5°C (rate ratio: 0.90; 95% CI: 0.67 to 1.21; *P* = .48) (Table 2). Twenty-nine infants (13 in CAP and 16 in NOCAP arms) had episodes of severe hypothermia (<35°C), and 11 (4 in CAP and 7 in NOCAP arms) had episodes of severe hyperthermia (>39°C).

Full results of multivariable analyses are shown in Supplemental Table 5.

Secondary Outcomes

Data on secondary outcomes are shown in Table 3. At multivariable analysis, the cap had no statistically significant effect on respiratory problems (odds ratio: 0.88; 95% CI: 0.49 to 1.58; *P* = .67), sepsis (odds ratio: 1.48; 95% CI: 0.82 to 2.69; *P* = .19), or in-hospital growth (β: 3.00; 95% CI: −0.70 to 6.70; *P* = .11). Nineteen patients died (6.3%) before discharge (9 in CAP and 10 in NOCAP arms). Full results of the multivariable analyses of secondary outcomes are shown in Supplemental Table 6.

Subanalysis

In the 72 infant and mother couples with adherence to SSC ≥70%, multivariable analysis was used to estimate a rate ratio of 0.90 (95% CI: 0.74 to 1.11; *P* = .34) for the effect of the cap versus no cap on time spent in the normal temperature range. In the 228 infant and mother couples with adherence to SSC <70%, multivariable analysis was used to estimate a rate ratio of 0.94 (95% CI: 0.85 to 1.03; *P* = .18) for the effect of the cap versus no cap on time spent in the normal temperature range.

DISCUSSION

In this study, the use of the cap was safe but did not provide any advantages in maintaining LBWIs in the normal thermal range during KMC in African low-resource settings. WHO guidelines recommend the use of a cap or hat as additional thermal protection during KMC.[18] In fact, the surface area of the head represents ~21% of the total body surface area,[28] thus accounting for a relevant amount of heat dispersion.[19] Authors of previous studies showed that the use of a cap could contribute to reducing heat loss immediately after birth,[19,29] but its effect during KMC in the postnatal period remains to be established.

The reason for the current study was that during KMC, which was supposedly the standard of care, the practice of using a cap had not been fully implemented in the trial hospitals.

In the current study, infants spent only half of the time with temperature in the normal range, and the cap did not provide any significant advantages in thermal control. With these findings, we underline the limited capacity for thermoregulation during the first weeks after birth,[14] even with the application of thermal protection strategies, and suggest that the thermal effect of the cap is limited during stay in a KMC ward. The complexity of the scenario (different hospitals, warm KMC rooms, variable adherence to SCC) might have jeopardized the observation of the effect of the cap. However, our study design took into account all potential confounders (environmental and maternal temperature, adherence to SSC during temperature recording, and participating hospital) that could have affected neonatal temperature during KMC. Although the relatively high birth weight of participants might have limited the benefit of the cap on thermal control, in the multivariable analysis, it was shown that the cap had no effect on temperature, adjusting for birth weight and postnatal age. In other words, with our findings, we suggest that the sum of recommended thermoregulatory practices and, more importantly, maternal and staff's education and behaviors play the main roles in influencing thermal control during the neonatal period rather than a single specific intervention (ie, the use of the cap).

Severe hypothermia and hyperthermia are strongly associated with morbidity and mortality in high- and low-resource settings.[9–13,18,19] In the current study, at least 1 episode of severe hypothermia occurred in 1 out of 10 infants during KMC. On the other side, 1 out of 30 infants experienced at least 1 episode of severe hyperthermia, suggesting that severe hyperthermia is less frequent than severe hypothermia, despite SSC and the fact that KMC rooms were usually warmer than WHO recommendations (>25°C).

An association between hypothermia at admission to the NICU and late-onset sepsis has been previously reported in very preterm infants.[30] In the current study, respiratory problems and sepsis occurred in over 20% of the infants, thus confirming the importance of these clinical conditions among LBWIs, even during KMC. However, no statistical differences were found on these secondary outcomes.

During hospital stay, mean growth was not influenced by the use of the cap. The inclusion of in-hospital growth among secondary outcomes was based on the hypothesis that a longer time spent in normothermia could reduce the metabolic expenditure for maintaining the body temperature.

The strengths of this study include the multicenter and multicountry design, which allows a broad generalizability of the findings; the absence of dropouts among randomly assigned patients; and the supervision of skilled health care staff, who ensured the adherence to the study protocol.

The current study has also some limitations. First, adherence to SSC was variable, but this is a well-known situation during KMC; thus, the data in our findings are presented in a real-world context.[31] Second, the standard thermoregulatory practices (ie, the type and the number of the clothes used by the mothers to cover the infant, maternal and staff behaviors, and the presence or absence of air currents created by the open windows) that likely contributed to influence infant temperature were difficult to follow. Third, the collection of the temperature at predefined time points might have affected the observed compliance to SSC, but this approach was chosen to obtain a uniform data recoding within the day and to avoid interfering with routine activities of local health staff. Finally, the sample size could not be calculated a priori because of the lack of information about this specific topic; thus, we decided to avoid any unrealistic estimates in sample size calculation.

CONCLUSIONS

In these 3 African, low-resource settings and so many days post birth, the use of a woolen cap was safe but provided no advantages in maintaining LBWIs in the normal thermal range while being in a KMC ward. LBWIs spent only half of the time in the normal temperature range during KMC, despite warm rooms and SSC. Maintaining normothermia in LBWIs remains an unfinished challenge in low-resource settings. Authors of further studies are required to shed light on the role of the cap in the thermal control of LBWIs during KMC in low-resource settings.

ACKNOWLEDGMENTS

We thank all the mothers of infants enrolled in the study and the midwives and nurses of participating hospitals for their support. We thank the volunteers in Padua (Italy) who handmade the caps used in the study. A complete list of nonauthor contributors appears in Supplemental Information.

ABBREVIATIONS

CI: confidence interval
IQR: interquartile range
KMC: kangaroo mother care
LBWI: low birth weight infant
SAE: serious adverse event
SSC: skin-to-skin contact
WHO: World Health Organization

and supervised data collection, and critically reviewed the manuscript; Dr Wingi contributed to the design of the trial, led the study team in Beira, Mozambique, coordinated and supervised data collection, and critically reviewed the manuscript; Dr De Vivo contributed to the design of the trial, led the study team in Aber, Uganda, coordinated and supervised data collection, and critically reviewed the manuscript; Prof Da Dalt contributed to the design of the trial and to the interpretation of the results and critically reviewed the manuscript; Dr Boscardin contributed to the design of the trial, led the study team in Beira, Mozambique, contributed to data collection, and critically reviewed the manuscript; Drs Manenti and Putoto contributed to the design of the trial, developed the idea into a formal grant application, contributed to the interpretation of the results, and critically reviewed the manuscript; Dr Trevisanuto contributed to the study concept, study design, submission to the ethics committee, data interpretation, and writing of the manuscript and critically reviewed the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

This trial has been registered at www.clinicaltrials.gov (identifier NCT02645526).

DOI: https://doi.org/10.1542/peds.2017-3073

Accepted for publication Mar 7, 2018

Address correspondence to Daniele Trevisanuto, MD, Department of Women's and Children's Health, University of Padua, Azienda Ospedaliera of Padua, Via Giustiniani 3, 35128 Padua, Italy. E-mail daniele.trevisanuto@gmail.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Supported by a grant from the Chiesi Foundation, Parma, Italy.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. GBD 2015 Child Mortality Collaborators. Global, regional, national, and selected subnational levels of stillbirths, neonatal, infant, and under-5 mortality, 1980-2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet*. 2016;388(10053):1725–1774
2. Blencowe H, Cousens S. Addressing the challenge of neonatal mortality. *Trop Med Int Health*. 2013;18(3):303–312
3. Lawn JE, Blencowe H, Oza S, et al; Lancet Every Newborn Study Group. Every Newborn: progress, priorities, and potential beyond survival. *Lancet*. 2014;384(9938):189–205
4. Bhutta ZA, Das JK, Bahl R, et al; Lancet Newborn Interventions Review Group; Lancet Every Newborn Study Group. Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost? [published correction appears in *Lancet*. 2014;384(9940):308]. *Lancet*. 2014;384(9940):347–370
5. Lawn JE, Kerber K, Enweronu-Laryea C, Massee Bateman O. Newborn survival in low resource settings–are we delivering? *BJOG*. 2009;116(suppl 1):49–59
6. St Clair NE, Batra M, Kuzminski J, Lee AC, O'Callahan C. Global challenges, efforts, and controversies in neonatal care. *Clin Perinatol*. 2014;41(4):749–772
7. World Health Organization. *Global Nutrition Targets 2025: Low Birth Weight Policy Brief*. Geneva, Switzerland: World Health Organization; 2014
8. United Nations Inter-agency Group for Child Mortality Estimation (UN-IGME). *Levels & Trends in Child Mortality Report 2015*. New York, NY: UNICEF; 2015
9. Kumar V, Shearer JC, Kumar A, Darmstadt GL. Neonatal hypothermia in low resource settings: a review. *J Perinatol*. 2009;29(6):401–412
10. Lunze K, Bloom DE, Jamison DT, Hamer DH. The global burden of neonatal hypothermia: systematic review of a major challenge for newborn survival. *BMC Med*. 2013;11:24
11. Mullany LC, Katz J, Khatry SK, LeClerq SC, Darmstadt GL, Tielsch JM. Risk of mortality associated with neonatal hypothermia in southern Nepal. *Arch Pediatr Adolesc Med*. 2010;164(7):650–656
12. Sodemann M, Nielsen J, Veirum J, Jakobsen MS, Biai S, Aaby P. Hypothermia of newborns is associated with excess mortality in the first 2 months of life in Guinea-Bissau, West Africa. *Trop Med Int Health*. 2008;13(8):980–986
13. Kambarami R, Chidede O. Neonatal hypothermia levels and risk factors for mortality in a tropical country. *Cent Afr J Med*. 2003;49(9–10):103–106
14. Lunze K, Hamer DH. Thermal protection of the newborn in resource-limited environments. *J Perinatol*. 2012;32(5):317–324
15. Boundy EO, Dastjerdi R, Spiegelman D, et al. Kangaroo mother care and neonatal outcomes: a meta-analysis. *Pediatrics*. 2016;137(1):e20152238
16. Conde-Agudelo A, Díaz-Rossello JL. Kangaroo mother care to reduce morbidity and mortality in low birthweight infants. *Cochrane Database Syst Rev*. 2016;(8):CD002771
17. Moore ER, Bergman N, Anderson GC, Medley N. Early skin-to-skin contact for mothers and their healthy newborn infants. *Cochrane Database Syst Rev*. 2016;11:CD003519
18. World Health Organization. *Managing Newborn Problems: A Guide for Doctors, Nurses, and Midwives*. Geneva, Switzerland: World Health Organization; 2003
19. Stothers JK. Head insulation and heat loss in the newborn. *Arch Dis Child*. 1981;56(7):530–534
20. Lang N, Bromiker R, Arad I. The effect of wool vs. cotton head covering and length of stay with the mother following delivery on

infant temperature. *Int J Nurs Stud*. 2004;41(8):843–846

21. Wyllie J, Bruinenberg J, Roehr CC, Rüdiger M, Trevisanuto D, Urlesberger B. European Resuscitation Council guidelines for resuscitation 2015: section 7. Resuscitation and support of transition of babies at birth. *Resuscitation*. 2015;95: 249–263
22. Wyckoff MH, Aziz K, Escobedo MB, et al. Part 13: neonatal resuscitation: 2015 American Heart Association guidelines update for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2015;132(18, suppl 2):S543–S560
23. Trevisanuto D, Putoto G, Pizzol D, et al. Is a woolen cap effective in maintaining normothermia in low-birth-weight infants during kangaroo mother care? Study protocol for a randomized controlled trial. *Trials*. 2016;17(1):265
24. Organizzazione Medici con l'Africa CUAMM. Available at: www.mediciconlafrica.org. Accessed March, 2018
25. Cameron AC, Trivedi PK. Regression-based tests for overdispersion in the Poisson model. *J Econom*. 1990;46(3):347–364
26. Kahan BC. Accounting for centre-effects in multicentre trials with a binary outcome - when, why, and how? *BMC Med Res Methodol*. 2014;14:20
27. R Core Team. *R: A Language and Environment for Statistical Computing*. Vienna, Austria: R Foundation for Statistical Computing; 2016. Available at: https://www.R-project.org/
28. Klein AD, Scammon RE. The regional growth in surface area of the human body in prenatal life. *Proc Soc Exp Biol Med*. 1930;27(5):463–466
29. Trevisanuto D, Doglioni N, Cavallin F, Parotto M, Micaglio M, Zanardo V. Heat loss prevention in very preterm infants in delivery rooms: a prospective, randomized, controlled trial of polyethylene caps. *J Pediatr*. 2010;156(6):914–917, 917.e1
30. Laptook AR, Salhab W, Bhaskar B; Neonatal Research Network. Admission temperature of low birth weight infants: predictors and associated morbidities. *Pediatrics*. 2007;119(3). Available at: www.pediatrics.org/cgi/content/full/119/3/e643
31. Shamba D, Schellenberg J, Hildon ZJ, et al. Thermal care for newborn babies in rural southern Tanzania: a mixed-method study of barriers, facilitators and potential for behaviour change. *BMC Pregnancy Childbirth*. 2014;14:267

Thermal Effect of a Woolen Cap in Low Birth Weight Infants During Kangaroo Care

Francesco Cavallin, Giulia Segafredo, Damiano Pizzol, William Massavon, Marta Lusiani, Olivier Wingi, Manuela De Vivo, Liviana Da Dalt, Chiara Boscardin, Fabio Manenti, Giovanni Putoto, Daniele Trevisanuto and on behalf of the CAP-KMC Group

Pediatrics 2018;141;
DOI: 10.1542/peds.2017-3073 originally published online May 22, 2018;

PEDIATRICS®
OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Thermal Effect of a Woolen Cap in Low Birth Weight Infants During Kangaroo Care

Francesco Cavallin, Giulia Segafredo, Damiano Pizzol, William Massavon, Marta Lusiani, Olivier Wingi, Manuela De Vivo, Liviana Da Dalt, Chiara Boscardin, Fabio Manenti, Giovanni Putoto, Daniele Trevisanuto and on behalf of the CAP-KMC Group

Pediatrics 2018;141;
DOI: 10.1542/peds.2017-3073 originally published online May 22, 2018;