ISSN: 0972-2408

Vol 20 • No. 4
Jan–Mar 2020

Perinatology

Journal of Perinatal and Neonatal Care

Submit articles ONLINE

Celebrating 20th ANNIVERSARY

Indexed in EMBASE, CINAHL, and Scopus

TempWatch for Monitoring Hypothermia in Very-Low-Birth-Weight Infants: A Randomized Controlled Trial

Pranitha Reddy Muppidi, Srinivas Murki*, Sai Kiran, Tejo Pratap Oleti, Venkat Reddy Kallem, Bhargavi Kamineni, Venkateshwarlu Vardhelli, Deepak Sharma

Abstract

Background: Hypothermia contributes significantly to neonatal morbidity and mortality. In stable, very-low-birth-weight (VLBW) infants, poor weight is often attributed to cold stress and unidentified hypothermia. Continuous temperature monitoring could prevent prolonged hypothermia and subsequently improve weight gain.

Aim: This study evaluated whether continuous temperature-monitoring with a device (TempWatch, BEMPU, Bengaluru, Karnataka, India) or standard intermittent temperature monitoring with a thermometer would result in improved weight gain in stable VLBW infants over 28 days.

Materials and Methods: Preterm infants (*N* = 100) in a hospital kangaroo ward were enrolled in this randomized controlled trial and were segregated into the TempWatch group and control group. Infants in the TempWatch group wore the device for 24 hours a day, and parents confirmed any hypothermia alarms with a thermometer. For the control group infants, parents did standard thermometer temperature monitoring every 6 hours. Weight, length, head circumference, days in the kangaroo ward, and daily episodes of hypothermia were measured.

Results: There were no significant differences in weight gain, length, or head circumference between the TempWatch and

*Correspondence

Dr Srinivas Murki
Chief Neonatologist
Department of Neonatology
Fernandez Hospital
Hyderguda
Hyderabad 500029, Telangana
India

E-mail: srinivasmurki2001@gmail.com

the control groups. However, the detection of hypothermic episodes was significantly higher in the TempWatch group.

Conclusion: TempWatch provides a higher rate of hypothermia detection than a standard monitor, giving clinicians a more accurate picture of the incidence of hypothermia in VLBW infants and allowing for more rapid intervention to address hypothermia.

Additional studies with larger sample sizes are needed to further evaluate the effect of TempWatch on the growth of VLBW infants.

Key Words: BEMPU TempWatch, temperature monitoring, very-low-birth-weight infants, hypothermia, kangaroo care, weight, length, head circumference

Introduction

In resource-restricted settings in low- and middle-income countries, hypothermia (defined by the WHO as body temperature < 36.5°C) is one of the most important risk factors for morbidity and mortality in newborns.[1] Hypothermia at admission to the NICU is directly correlated with poor outcomes, intraventricular hemorrhage, and death.[2] Hypothermia in newborns can lead to increased basal metabolism, cause peripheral vasoconstriction, decrease peripheral perfusion, result in tissue ischemia, and cause metabolic acidosis.[3]

Neonates and very-low-birth-weight (VLBW) infants, or infants whose birth weight is < 1.5 kg,[4] are prone to hypothermia. They suffer from high evaporative losses because their skin is not yet functionally mature; the high transepidermal water loss they experience can result in hypothermia.[5] Additional physiologic risk factors including decreased brown fat, a large surface area–to–body mass ratio, and a poor metabolic mechanism for responding to thermal stress can contribute to their increased susceptibility to hypothermia.[6]

Maintaining normal body temperature in infants has, for decades, been shown to improve their survival and outcomes.[7-9] Such interventions can help reduce neonatal mortality or morbidity by 18% to 42%.[10] It is clear that, if we are to see further improvements in mortality and morbidity in the most immature infants, careful attention must be given to all aspects of basic neonatal care, including thermoregulation. Skin-to-skin care or kangaroo mother care (KMC) is a technique that is shown to be effective in reducing infants' risk of hypothermia compared with the conventional incubator care.[11]

In developing interventions to address neonatal hypothermia, consideration should be given to cost-effective interventions, especially in low-income countries.[12] TempWatch (BEMPU, Bengaluru, Karnataka, India), previously called the BEMPU Hypothermia Alert Device (Figure), is one such intervention. TempWatch is a bracelet device (to be tied on the infant's wrist) that flashes orange light and beeps when an infant is hypothermic, prompting a caregiver to provide thermal care (KMC) to prevent

Figure. The BEMPU TempWatch Device

hypothermia-related injury or death. TempWatch provides continuous temperature monitoring during the entire neonatal period (4 wk). Tanigasalam et al[13] found that TempWatch was an accurate device to detect and alert about neonatal hypothermia with significant sensitivity and specificity. In a study in which 461 infants wore the TempWatch, the device's sensitivity and specificity were found to be 98.6% and 95%, respectively, and positive and negative predictive values were 83.6% and 99.6%, respectively.[13]

There is no published evidence about the incidence of hypothermia in VLBW infants while in KMC and whether continuous monitoring of the infant's temperature affects growth.

Aim

In this study, we aim to compare the growth of VLBW infants monitored continuously with TempWatch and the growth of infants receiving standard intermittent temperature monitoring.

Materials and Methods

This randomized controlled trial was conducted in the KMC ward of the NICU at Fernandez Hospital (Hyderabad, Telangana, India) from July 2018 until February 2019. The KMC ward is a stepdown unit in the hospital, where mothers of low-birth-weight infants transition from the NICU to home care by rooming-in with infants under the assistance of a nurse.[14] The institutional ethics committee of Fernandez Hospital provided permission for this study.

Inclusion and exclusion criteria

Singleton birth infants admitted to the KMC ward or shifted to the KMC ward, who weighed > 1200 g, were at gestational age > 32 weeks, who tolerated full feeds or tube feeds of 150 mL/kg/d and were not on intravenous fluids, who were breathing room air, who were hemodynamically stable, who had normal BP, and who could maintain a normal body temperature under incubator care were eligible for inclusion in the study.

Infants with major malformations and those whose parents did not provide consent were excluded.

Study procedure

Using data from a previous study[15] (mean weight gain 24 g/kg/d with SD of 7 g/kg/d) at our center, assuming improved weight gain of 4 g/kg/d in the TempWatch group compared with the standard group, with a power of 80% ($\beta = 0.20$), and type 1 error of 5% ($\alpha = 0.05$), we calculated a sample size of 48 infants in each group. Eligible infants were randomized to the intervention group, in which they were tied the BEMPU TempWatch, or the control group, in which they had standard intermittent monitoring. A randomization sequence was generated on Research Randomizer (randomizer.org). The serially numbered, opaque envelopes containing the group randomization details of the infant were opened only after consent was obtained from the parents. The principal investigator (P.R.M.) was responsible for randomization and enrollment.

Parents of the infants randomized to the TempWatch group were provided a TempWatch device to be tied on the infant's wrist for 24 hours a day, for 28 days, from the day of admission into the KMC ward. When the device beeped, parents had to confirm any hypothermia alarms by measuring and recording core axillary temperature with a digital thermometer (OMRON Management Centre of India, Haryana, India). Temperature was also checked in the TempWatch group every 6 hours. For infants randomized to the control group, the axillary temperature was measured every 6 hours with a digital thermometer. In both the groups, parents were taught to measure axillary temperature with a digital thermometer. Mothers were taught to identify cold stress by touching the infant's stomach and foot soles with the back of their hand. Mothers were instructed to respond to any episodes of hypothermia or cold stress in either group by reinforcing skin-to-skin contact and providing other standard interventions including feeding and appropriate clothing. Other standard practices were followed identically in both the groups, and discharge criteria for the KMC ward were the same.

During the infants' stay in the KMC ward, their weight was measured daily using a portable weighing machine (Tanita Corporation of America, Inc, IL, USA) and was recorded to the nearest 0.1 kg. After discharge,

weekly weight monitoring was done till study completion. Infants were discharged from the hospital if they were hemodynamically stable, were breathing room air, were accepting spoon feeds or breastfeeds, and showed consistent weight gain (weighing > 1400 g) and if their mothers were confident in providing care independently. After discharge, infants were followed up weekly until the time of study completion. Each week, their length was measured with the standard procedure using an infantometer, and their head circumference (HC) was measured with the standard procedure using a nonstretchable tape.

Anthropometric data were entered into Microsoft Excel and analyzed using SPSS version 20.0 (IBM Corp, Armonk, NY, USA).

At the end of the study period, 43 mothers in the TempWatch group completed a questionnaire regarding their perceptions and opinions about the device.

Results

A total of 100 infants were enrolled in the study, and 98 completed the follow-up until 28 days after randomization. One infant in each group missed the post discharge follow-up. Baseline variables for the TempWatch group and the control group were similar (Table 1). Median weight gain per day was similar between the groups from the time of enrollment until the 28th-day follow-up (24.4 [19.4–28] vs 23.9 [18.1–28], P = .85); it was also similar from the time of enrollment until discharge from hospital (28.3 [19.3–37] vs 24.8 [17.4–32], P = .264). There were no statistically significant differences in HC and length between the 2 groups from the time of enrollment until the time of discharge from hospital or from the time of enrollment to the 28th-day follow-up. However, the detection of hypothermic episodes was significantly higher in the hospital and at home in the TempWatch group (Table 2).

Table 1. Baseline Variables in the TempWatch and the Control Groups

Parameter	TempWatch Group, n = 50	Control Group, n = 50	P Value
Birth Weight, g	1182.6 ± 219	1211.8 ± 246	.53
Gestation, wk	30.48 ± 2.2	30.48 ± 2.0	.63
Male Infants, n (%)	32 (64)	23 (46)	.07
Female Infants, n (%)	18 (36)	27 (54)	.07
Cesarean Delivery, n (%)	43(86)	46(92)	.338
IUGR, n (%)	11 (22)	6 (12)	.83
Singleton, n (%)	33 (66)	30 (60)	.53
Maternal Hypertension, n (%)	25 (50)	30 (60)	.315
Antenatal Steroids, n (%)	44 (88)	48 (96)	.14
RDS, n (%)	36 (72)	32 (64)	.391
PDA, n (%)	8 (16)	6 (12)	.564
Sepsis, n (%)	12 (24)	14 (28)	.832
Antibiotics, d	5.04 ± 7	4.74 ± 5	.81
BPD, n (%)	7 (14)	5 (10)	.53
Time to Reach Full Feeds, d	7.58 ± 3.8	6.94 ± 3.8	.405
Time to Regain Birth Weight, d	12.22 ± 5.3	11.96 ± 4.5	.791
TPN, d	5.7 ± 3.8	4.76 ± 3.8	.22
MOM at Enrollment, n (%)	37 (74)	39 (78)	.64
Age at Enrollment, d	23.82 ± 15.6	22.76 ± 15.2	.732
Weight at Enrollment, g	1373.4 ± 166	1374.8 ± 142	.964
HC at Enrollment, cm	28.164 ± 1.0	28.59 ± 1.0	.047
Length at Enrollment, cm	40.65 ± 2.1	40.7 ± 1.9	.901

BPD, bronchopulmonary dysplasia; HC, head circumference; IUGR, intrauterine growth restriction; MOM, mother's own milk; PDA, patent ductus arteriosus; RDS, respiratory distress syndrome; TPN, total parenteral nutrition.

Table 2. Detection of Hypothermic Episodes By TempWatch Versus Standard Monitoring

Parameter	TempWatch Group	Control Group	P Value
Median Weight Gain in the Hospital After Enrollment, g/d	28.3 (19.3–37)	24.8 (17.4–32)	.264
Weight Gain From the Day of Enrollment Till 28 Days, g/d	24.4 (19.4–28)	23.9 (18.1–28)	.85
Days Spent in the KMC Ward After Enrollment, Mean ± SD	6.3 ± 2.9	5.9 ± 3.1	.21
Hypothermia Episodes (< 36.5°C) in the Hospital KMC Ward, Mean ± SD	1.44 ± 2.2	0.24 ± 0.62	< .001
Hypothermia Episodes at Home After Discharge From the KMC Ward, Mean ± SD	9.6 ± 8	0.20 ± 0.76	< .001
Hypothermia Episodes During the Total Study Period (28 d), Mean ± SD)	11 ± 8	0.42 ± 1.2	< .001

Responses on the feedback questionnaire were positive.[16]
KMC, kangaroo mother care.

Discussion

While the incidence of neonatal hypothermia is high, standard monitoring with a thermometer only allows for intermittent detection of hypothermia. As the consequences of neonatal hypothermia can be life-threatening, it is crucial that hypothermia is detected as early as possible and that timely intervention is provided. Results from this study are promising in demonstrating TempWatch's ability to detect hypothermia at a significantly higher rate than with standard monitoring. Given TempWatch's high rate of hypothermia detection, it has the potential to facilitate early intervention to address hypothermia, preventing serious consequences in newborns.

Given the potential for thermal care, such as KMC, to promote better infant growth outcomes,[17] it is important to understand whether the TempWatch device, which promotes thermal care, also improves growth. While this study did not demonstrate significant differences in weight, length, and HC, conducting a study with a larger sample size could offer more insight into TempWatch's potential effect on these growth indicators and other clinical end points.

The positive feedback received from mothers on surveys suggest that they appreciated the role of TempWatch in promoting behavioral changes in hypothermia management. In future studies, we will implement similar surveys to obtain additional qualitative data on whether TempWatch effectively promotes behavioral change.

Merits

This was a randomized controlled trial comparing 2 groups where continuous temperature monitoring was done in preterm infants with a device. Good compliance to the device was observed, and follow-up rates were high. Parents found the device easy to use. The device was helpful in detecting subacute hypothermia. A single, trained nurse recorded anthropometric measurements in every visit, minimizing variation in the measurement process. The number of false alarms were negligible.

Parents were happy to have a device to monitor temperature continuously. TempWatch helped in bringing about behavioral changes among caregivers. They were more aware of thermoregulation, and it also helped in promoting KMC.

Limitations

The severity of hypothermia could not be assessed with the device, as standard temperature monitors would be required for this. The cost of the device is also a factor that could hinder its use in low-resource settings. There are many other confounding variables that can affect the growth of the infant, but as the study was a randomized controlled trial, we assumed that they did not affect the result. As the baseline growth and nutrition characteristics, educational interventions to measure and manage hypothermia, and KMC hours were similar between the groups and as there was very low incidence of moderate or severe hypothermia, TempWatch did not cause a significantly different growth difference in stable VLBW infants. A quality-improvement project could be used to test how the device performs in a real-life scenario.

Conclusion

There was no enhanced weight gain nor improvement in other growth indicators (length and HC) seen in the TempWatch and the intermittent monitoring groups. However, TempWatch was very useful in detecting hypothermic episodes throughout the monitoring period, and it detected hypothermia at a significantly higher rate than by standard monitoring.

References

1. World Health Organization. Thermal protection of the newborn: a practical guide. https://apps.who.int/iris/bitstream/handle/10665/63986/WHO_RHT_MSM_97.2.pdf;jsessionid=C46F28CB39FE791BEDFBF7117BDAE807?sequence=1. Accessed January 21, 2020.
2. Miller SS, Lee HC, Gould JB. Hypothermia in very low birth weight infants: distribution, risk factors and outcomes. *J Perinatol.* 2011;31(S1):S49–S56.
3. Anto AA, Mathew S, Shekharappa CB. Accuracy of touch method for assessing temperature in newborn. *Indian J Child Health.* 2018;5(7):477–480.

4. World Health Organization. Feeding of very-low-birth-weight infants. https://www.who.int/. Updated April 12, 2019. Accessed May 24, 2019.
5. Agren J. Water transport through perinatal skin: barrier function and aquaporin water channels. http://www.diva-portal.org/smash/get/diva2:162520/FULLTEXT01.pdf. Accessed January 21, 2020.
6. The Royal Children's Hospital Melbourne. Thermoregulation in the preterm infant. https://www.rch.org.au/. Updated November 2016. Accessed May 24, 2019.
7. Silverman WA, Balnc WA. The effect of humidity on survival of newly born premature infants. *Pediatrics*. 1957;20(3):477–486.
8. Silverman WA, Fertig JW, Berger AP. The influence of the thermal environment upon the survival of newly born premature infants. *Pediatrics*. 1958;22(5):876–886.
9. Buetow KC, Klein SW. Effect of maintenance of "normal" skin temperature on survival of infants of low birth weight. *Pediatrics*. 1964;34(2):163–170.
10. Darmstadt GL, et al. Evidence-based, cost-effective interventions: how many newborn infants can we save? *Lancet*. 2005;365(9463):977–988.
11. McCall EM, et al. Interventions to prevent hypothermia at birth in preterm and/or low birthweight infants. *Cochrane Database Syst Rev*. 2008(1):CD004210.
12. World Health Organization. WHO/UNICEF joint statement on home-based care of newborns. https://www.who.int/maternal_child_adolescent/news_events/news/2009/09_07_08/en/. Published July 8, 2009. Accessed May 24, 2019.
13. Tanigasalam V, et al. Hypothermia detection in low birth weight neonates using a novel bracelet device. *J Matern Fetal Neonatal Med*. 2019;32(16):2653–2656.
14. Fernandez Hospital. Kangaroo mother care (KMC). https://www.fernandezhospital.com/. Accessed May 24, 2019.
15. Ghavane S, et al. Kangaroo mother care in kangaroo ward for improving the growth and breastfeeding outcomes when reaching term gestational age in very low birth weight infants. *Acta Paediatr*. 2012;101(12):e545–e549.
16. Reddy MP, et al. Neonatal hypothermia monitoring and alerting device, acceptability among mothers and caregivers. *Int J Res Rev*. 2019;6(12):217–220.
17. Conde-Agudelo A, Belizán JM, Diaz-Rossello J. Kangaroo mother care to reduce morbidity and mortality in low birthweight infants. *Cochrane Database Syst Rev*. 2011;(3):CD002771.

Author Affiliations

Dr Pranitha Reddy Muppidi, Fellow in Neonatology; **Dr Srinivas Murki,** Chief Neonatologist; **Dr Sai Kiran,** Consultant Neonatologist; **Dr Tejo Pratap Oleti,** Chief Neonatologist; **Dr Venkat Reddy Kallem,** DNB Resident; **Dr Bhargavi Kamineni,** Fellow in Neonatology; **Dr Venkateshwarlu Vardhelli,** DNB resident; **Dr Deepak Sharma,** DNB Resident, Department of Neonatology, Fernandez Hospital, Hyderguda, Hyderabad 500029, Telangana, India