

Original Research Article

A randomized control trial of hypothermia alert device in low birth weight newborns and the effect on kangaroo mother care and weight gain

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Received: 10 November 2017

Revised: 10 March 2018

Accepted: 06 August 2018

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ABSTRACT

Background: Lack of thermal protection is one of the major challenges faced by developing nations for newborn survival. Early detection and subsequent prevention of hypothermia through Kangaroo Care could lead to significant health outcomes for the newborn. Hypothermia alert device is a bracelet that monitors for early hypothermia by sensing the extremities and sounding an alarm for parents to take action.

Methods: In a randomized controlled trial, the effect of the hypothermia alert device on KMC compliance at home and weight gain of newborns on 4th week follow-up was evaluated. New borns discharged from the neonatal intensive care unit at Indira Gandhi Institute of Child Health (IGICH). Neonates who were LBW (less than 2500 grams) were included in the study once they were stable and ready for discharge. Neonates were given a hypothermia alert device to monitor their temperatures for hypothermia for 4 weeks. Weekly follow-ups were held with parents and to record measurements of growth. Additionally, parents were given a KMC diary to track sessions of KMC. Neonates were given either a placebo bracelet or a BEMPU Bracelet. Bracelets were identical and both monitored for hypothermia, however only the BEMPU Bracelet gave an alarm when the newborn was hypothermic.

Results: Statistically 44 neonates completed the 4-week trial; 23 were in the control group and 21 were in the BEMPU group; of these, 19 participants in the control group completed KMC diaries and 19 BEMPU group completed KMC diaries. The results of the clinical trial reveal that parents of neonates in the BEMPU group demonstrated better compliance to KMC. In the BEMPU group, the average daily time spent doing KMC was significantly higher in first (3.02 v 1.96 h, p=0.016) and fourth (3.04 v 2.38 h, p=0.094) week of discharge. There was an increase of weight gain in the BEMPU group after the first (25.7 v 20.7 g, p=0.1.85) and fourth (28.3 v 22.9 g, p=0.057) week of discharge.

Conclusions: The hypothermia alert device was found to be an effective intervention to promote parent adherence to Kangaroo Care and weight gain.

Keywords: Hypothermia, Kangaroo mother care, Low birth weight, Neonatal weight gain

INTRODUCTION

Lack of thermal protection is one of the major challenges faced by developing nations for newborn survival.¹ In India, the prevalence of hypothermia varies widely but

recent estimates in normal newborns in community settings are around 31% and about 32% in hospital settings, but these included mostly normal weight newborns.^{2,3} The prevalence can be estimated to be even higher for low birth weight newborns. Approximately 27

million babies are born in India every year and out of those 8 million are LBW.⁴ Newborns with hypothermia are likely to face issues of poor weight gain, hypoxia, hypoglycemia, sepsis and death.

Preventing hypothermia is recognized as an essential part of care for all newborns by the WHO. Regular temperature monitoring can enable early intervention and is one of the most effective ways to ensure babies grow healthy. Up to 42% of neonatal death can be prevented through hypothermia prevention.⁵ However, hypothermia is often missed especially in clinics where nurses are few and in homes where parents are uneducated or unaware.

The Hypothermia Alert Device (Made by Bempu Health) is a simple neonatal bracelet which continuously monitors the infant day and night for 4 weeks in the hospital and home setting. If the infant is hypothermic, the device sounds an alarm alerting the mother to perform kangaroo care to warm the infant well before injury or death can occur. Should the baby continue to be hypothermic despite warming actions, the device continues to alarm nudging the mother to seek skilled care since hypothermia is a sign of sepsis. To further investigate, authors designed a randomized control trial to test the effects of the Bracelet on newborn weight gain and parent compliance to Kangaroo Mother Care (KMC). Currently there is no published literature showing the efficacy of the Bracelet in reducing the incidence rate of hypothermia or promoting healthier weight-gain, thereby warranting this study.

METHODS

Study design

The study was conducted from April 2016 to December 2016. The trial was a double blinded randomized control trial performed in Indira Gandhi Institute of Child Health (IGICH). The trial was designed and conducted by the authors, and the protocol was approved by the institutional review board at IGICH. The authors vouch for the accuracy and completeness of the data and all analyses, and for the fidelity of this report to the protocol. The BEMPU Bracelets were donated by BEMPU Health.

Participant selection and randomization

Eligible participants were LBW newborns (less than 2500 grams) who were stable at the time of discharge and willing to return to the hospital for weekly follow-ups for next four weeks. All participants provided written informed consent.

Beginning on April 21st, 2016 participants were randomly assigned, in a 1:1 ratio, to the BEMPU group or the control group. Neonates were given either a placebo bracelet or a BEMPU Bracelet by IGICH staff to be worn for four full weeks. All bracelets monitored for hypothermia, however only the BEMPU Bracelet gave an

audiovisual alarm when the newborn became hypothermic. Parents were informed of study design and potential for a placebo. Bracelets were block randomized by the BEMPU engineers and given to IGICH health staff in groups of ten. All bracelets were identical, and only the BEMPU engineers knew which bracelet number corresponded to which group; IGICH staff and parents were blinded.

Interventions and measurements

Intervention was the BEMPU Bracelet, a hypothermia monitoring and alert device which works continuously for four full weeks. The bracelet shows a blue light every 30 seconds to communicate the newborn's temperature is above 36.5 C. When a newborn becomes hypothermic (core temperature of <36.5C) the bracelet sounds an alarm and display an orange light. Once the newborn's body is warmed and returns to a temperature above 36.5C, the bracelet will return to a blue light every 30 seconds. Parents were instructed to provide KMC every time the bracelet alarmed and if the bracelet alarmed for over 2 hours to seek medical intervention.

Discharge instructions, KMC education, follow-up schedule, and data collection methods were identical between groups. Weekly follow-ups were held with parents and doctors every Tuesday to record measurements of growth and daily sessions of KMC. All weights were measured on the same electronic scale. Additionally, parents were given a KMC diary to track daily sessions of KMC .

End Points

The primary end point was the weight increase between discharge and the 4th follow-up appointment. The secondary end point was number of hours of KMC performed per day. In instances where participants came infrequently, data was gathered at follow-up appointments from the first through fifth week after discharge. At the final follow-up appointment, KMC diaries were collected and parents were interviewed on their experience.

Statistical analysis

It was estimated that a sample of 210 would be required to provide statistical power of 80% to detect an increase of 3 gm per day in BEMPU group during a 4-week follow-up period, assuming a 20% dropout rate in both groups. In July, after reviewing midpoint data, we discovered three important pieces of information: the difference between the groups was closer to 6 gm per day; the dropout rate was closer to 60%; and very few newborns were eligible for this study, reducing available population. On the basis of lower-than-expected sample population and follow-up rates and larger than expected difference between the groups, the sample size was recalculated to 50 (25 per group).

All data was collected on a pre-designed data collection form filled by doctors and parents and later transferred to excel. Primary analyses were performed on Minitab. A comparison of means was run using a 1-sided two sample Student's t-test.

RESULTS

Baseline characteristics of the study participants

From April 2016 to December 2016, a total of 104 newborns were screened for eligibility, enrolled, and assigned to one of the two study groups. Of the 104 enrolled: 51 were lost after discharge, 4 were readmitted, and 2 died. The baseline characteristics according to study group are shown in (Table 1).

Compliance with the intervention and follow-up schedule

Participants were followed for an average of 30 days. Participants in the two groups reported similar adherence to bracelet use and KMC diary completion. The significant difference between these two groups was the average hours of KMC hours per day; the BEMPU group reported higher averages of KMC sessions per day (See Figure 1).

End points

The mean follow-up period was 30 days. A total of 44 neonates completed the 4-week trial; 23 were in the control group and 21 were in the BEMPU group; of these, 19 participants in the control group completed

KMC diaries and 19 BEMPU group completed KMC diaries.

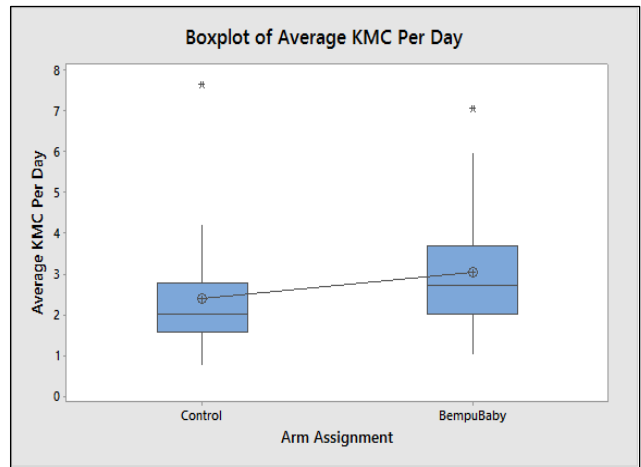


Figure 1: Average number of hours of KMC performed by the mother in each group.

No relevant adverse effects of wearing the BEMPU bracelet were reported.

The results of the clinical trial reveal that parents of neonates in the BEMPU group demonstrated better compliance to KMC. In the BEMPU group, the average daily time spent doing KMC was significantly higher in first (3.02 v 1.96 h, p=0.016) and fourth (3.04 v 2.38 h, p=0.094) week of discharge. There was an increase of weight gain in the BEMPU group after the first (25.7 v 20.7 g, p=0.185) and fourth (28.3 v 22.9 g, p=0.057) week of discharge (Table 2).

Table 1: Baseline characteristics of the subjects.

Measurement	N	Control		BEMPU		
		Mean	SD	N	Mean	SD
Gestational age (weeks)	23.00	32.70	1.79	19.00	34.32	3.02
Birth weight (kgs)	16.00	1.42	0.41	14.00	1.58	0.32
Discharge weight (kgs)	23.00	1.65	0.28	21.00	1.69	0.28
Days in study (days)	23.00	30.40	5.14	21.00	29.80	6.15

Table 2: Results of weight gain and KMC compliance.

Measurement	N	Control			BEMPU			P (1-sided)
		N	Mean	SD	N	Mean	SD	
Average Weight Gain per Day Over 4 weeks	23	22.9	20.7	21	28.3	11.4	0.057	
Average Number of Hours of KMC Given per day Over 4 weeks	19	2.38	1.58	19	3.04	1.45	0.094	
Average Weight Gain per Day Over 1 week	22	20.7	14.6	20	25.7	20.1	0.185	
Average Number of Hours of KMC Given per day Over 1 week	18	1.96	1.28	20	3.02	1.61	0.016	

DISCUSSION

Newborn hypothermia remains one of the most important contributors to neonatal mortality and morbidity in both facilities and communities of low-resource settings. Since neonatal deaths account for more than 40% of under-5 mortalities, reaching Millennium Development Goal (MDG) 4 will require a substantial reduction in newborn mortality.⁶ Although addressing neonatal hypothermia might facilitate this goal, it has so far been a neglected challenge. Maintaining a normal body temperature is a critical function for newborn survival. The Hypothermia Alert Device intuitively alerts caregivers in case their infant goes into cold stress thus timely intervention can be attempted.

The hypothermia alert device previously underwent validation in a n=460 baby study at JIPMER, Pondicherry. The Bracelet was found to have the follow values: sensitivity of 98.57; specificity of 99.62; positive predictive value of 83.45%, and negative predictive value of 99.62%. Case studies of the device have shown plausible evidence of increased weight gain in newborns and behavior changes in parents. Although published literature on the benefits of the device is not available, the fact that it has a relatively large number of users within a short period of time is an indicator of the need for a product to prevent neonatal hypothermia. The results indicate that these healthcare workers are comfortable with using The hypothermia alert device suggesting that the design of the product is simplistic in nature and does not require extensive training and there were no adverse event reported due to the device.

In this single centered, single-blinded, placebo-controlled RCT we found that parents were alerted by the device which led to early intervention in terms of kangaroo mother care. In the BEMPU group, the average daily time spent doing KMC was significantly higher in first (3.02 v 1.96 h, p=0.016) and fourth (3.04 v 2.38 h, p=0.094) week of discharge. There was an increase of weight gain in the BEMPU group after the first (25.7 v 20.7 g, p=0.1.85) and fourth (28.3 v 22.9 g, p=0.057) week of discharge. These findings agree with those of Suman, Udani, [HYPERLINK](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4010854/) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4010854/> and [HYPERLINK](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4010854/) ["https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4010854/"](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4010854/) Nanavati whose research at a Level III NICU of a teaching institution in Western India reported an average weight gain per day in the KMC babies of 23.99 g versus 15.58 g in the conventional methods of care.⁷

Kangaroo mother care has shown to prevent hypothermia along with other benefits to the child which include increased breast feeding and better weight gain.⁸ An estimated 4,50,000 babies can be saved worldwide every year if supportive care in the form of kangaroo mother care is provided.⁹ The most recent systematic review on kangaroo mother care in low birth weight infants has shown a

reduction in the risk of mortality (risk ratio of 0.60, 95% Confidence Interval (CI) 0.39 to 0.92) as well as reduction in the risk of hypothermia (risk ratio of 0.34, 95% CI 0.17 to 0.67) and reduction of nosocomial infection/sepsis (risk ratio of 0.45, 95% CI 0.27 to 0.76) when evaluated at discharge or 40-41 weeks postmenstrual age. Even at the latest follow-up the KMC was associated with reduction of mortality and sepsis.¹⁰ Improved survival rates and reduced readmission rates were comparable. As authors institution is the highest referral centre in the government sector neonates belonging to poor socioeconomic status from all over state and neighboring states were recruited, large number of babies were lost to follow up owing to distance and financial constraints involved in attending weekly follow up.

CONCLUSION

In areas where there are fewer healthcare providers and even lesser resources a simple technique to prevent and manage hypothermia is required. The Hypothermia Alert Device was found to be an effective intervention to promote newborn weight gain and parent adherence to Kangaroo Care, and it should be considered an effective intervention for LBW neonates discharged early in the home setting. Author propose that understanding, managing, and significantly mitigating the global burden of hypothermia, a largely understudied risk factor for neonatal survival, might be relatively simple and contribute substantially towards reaching MDG 4.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Jagadish AS, Benakappa A, Benakappa N, Morgan G. A randomized control trial of hypothermia alert device in low birth weight newborns and the effect on kangaroo mother care and weight gain. *Int J Contemp Pediatr* 2020;7:52-6.