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PREVENTING EXCESSIVE POSTNATAL WEIGHT LOSS IN HEALTHY NEW-BORNS. WILL CONTINUOUS TEMPERATURE MONITORING HELP?

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Abstract
Objective: To study if continuous temperature monitoring helps to prevent excessive postnatal weight loss in healthy newborns during hospital stay.
Design: Prospective randomised controlled trial
Setting: Postnatal ward of a tertiary level hospital in south-west India, between July 2018 and October 2018.
Participants: 515 healthy newborns born in the hospital during the study.
Intervention: Mothers were given the BEMPU device within 24 hours of delivery and taught to recognize alarms and take measures to treat hypothermia when the device alarmed till the baby was discharged from the hospital. All healthy newborns born in the hospital were included in the study and random allocation was done to either the intervention or control group. Babies who were sick and admitted in NICU and babies with congenital anomalies were excluded.
IEC approval was obtained prior to the study.
Outcome measures: postnatal weight loss.
Results: 515 babies were included in the analysis. For vaginal deliveries; 163 babies were in the intervention group and 168 were in the control group. The mean lowest weight was higher and the mean weight loss was lower for the intervention group. For caesarean deliveries, 91 babies were in the intervention and 93 were in the control groups. The mean lowest weight was higher and the mean weight loss was lower for the intervention group for cesarean deliveries as well.
Conclusions: Continuous monitoring of the temperature helps to prevent excessive postnatal weight loss in healthy babies born by spontaneous vaginal deliveries.
Keywords: Hypothermia, Newborn, Temperature, Weight loss

Introduction:

It is well known that some degree of early neonatal weight loss is normal. On the first 2-3 days of life, neonates that are exclusively breastfed lose on average between 5% and 7% of their birth weight. The maximum physiological limits of weight loss for newborns that are exclusively breastfed are controversial. A weight loss of 10% may be considered normal or acceptable, although there have been references of about 7% values [1].

There are some well-documented factors that are correlated with increased weight loss after birth. These factors include higher weight at birth, female sex, advanced maternal age and education, caesarean delivery, and jaundice [2]. For a small percentage of infants, excessive weight loss may indicate a problem including poor breastfeeding management, undiagnosed metabolic disorders, neurological disorders, or other infant morbidities that cause poor feeding [3]. A serious consequence of persistent feeding problems and excessive weight loss can be hypernatremic dehydration, complications of which may include renal and liver failure, disseminated intravascular coagulation, intracranial hemorrhage, seizure, and death [4]. Apart from these there are other influential factors of hypothermia in new-borns that include inadequate clothing, unregulated environmental temperature and delayed breastfeeding. [17]

Neonatal hypothermia is widely recognized as an important contributing factor to neonatal morbidity, especially in low and middle income countries. Neonates are particularly prone to hypothermia as their temperature regulation mechanism is immature. Consequences may be disastrous leading to apnea, hypoglycaemia and poor weight gain [5].Prolonged, unrecognized cold stress may divert calories to produce heat, impairing growth [6].

Hypothermia is a common occurrence in postnatal wards and step-down nurseries of resource-restricted health care systems [7].In community-based studies in Nepal and India, hypothermia prevalence ranged from 11% to 92% [8]. The risk of hypothermia and related morbidities is the highest in the first week of life [9]. The term infant may experience temperature instability for several reasons. The infant may become cold with prolonged exposure to the environment during diaper changes, weighing, physical exams, or resuscitative measures [10]. The World Health Organization (WHO) has included thermal care and prevention of neonatal hypothermiaas a component of essential care for the newborn[11].

Normal temperature in neonates should be maintained between 36.5° C and 37.5° C [12]. In low-resource settings, the facilities for thermal monitoring and thermal protection of neonates are limited. The BEMPU Bracelet is an accurate device that can be used in low-resource settings to detect and alert for neonatal hypothermia with significant sensitivity and specificity [7]. The BEMPU Bracelet is a silicone band with a thermistor metal cup to detect a neonate's temperature. The device blinks with a blue light when the neonate is not hypothermic (≥36.5°C) and an orange light when the neonate is hypothermic (<36.5°C). The BEMPU Bracelet remains active during the entire neonatal period (4weeks) with continuous monitoring ability [13].

Moreover BEMPU device has its advantages over conventional temperature monitoring methods. BEMPU Bracelet works on its own in detecting low temperatures continuously. While conventional methods like hand touch or thermometers cannot be used continuously. The conventional methods also require at least a minimal technical training for efficient detection of low temperature. Use of BEMPU bracelet, on the other hand, does not require any prior technical knowledge or training. The device was developed keeping in mind the rural population on India, where literacy rate is very low. The device uses a very basic audio visual method to alarm the parents, about babies' temperature.

There is lack of literature about the association between hypothermia and excessive neonatal weight loss. We conducted this study to assess whether continuous monitoring of temperature to detect hypothermia and taking adequate measures to treat it would prevent excessive weight loss among healthy babies who were cared for in the postnatal wards.

Methods:

This was a prospective randomised controlled trial conducted in the postnatal ward of a tertiary level hospital in south-west India. The study was conducted over a period of 4 months from July 2018 to October 2018. IEC approval was obtained prior to the study. The study was not registered under CTRI, All healthy (the babies admitted in the postnatal wards by the mother's side) newborns born in the hospital were included in the study after parental consent. This was intended to occur in a 1:1 ratio but after allocation some babies were excluded (Figure 1). As this study was time-limited, all eligible babies born during the study period whose parents provided consent were enrolled. Simple Randomization process was followed using odd-even procedure. Every live birth during the period of the study, 752 births, was evaluated for eligibility then alternately allocated to the intervention or control group by the principal investigator of the study. 528 babies were included in the study in total.

Inclusion Criteria

- Babies admitted in the postnatal ward
- New-borns without congenital anomalies
- Babies haemo-dynamically stable
- Babies accepting breast feeds well
- Parents willing to give written informed consent

Exclusion Criteria

- Infants readmitted to NICU for serious illness.
- New-born is not clinically stable
- Baby is discharged with a condition known to impact its ability to gain weight, such as down's syndrome, metabolic or genetic disorder

No changes to methodology occurred after trial commencement, but babies who were sick and admitted in the NICU and those with congenital anomalies were excluded. Neonates who were enrolled in the intervention group were given the BEMPU bracelet within 24 hours of delivery. Mothers

were taught to recognize alarms and take measures to treat cold stress when the device alarmed. The device was used on the baby until discharge.

The investigator was trained by the BEMPU staff to use the device. The same investigator trained all the mothers whose babies were allocated to the intervention group. The number of times the bracelet alarmed during the day and subsequent measures taken by the mother were recorded. Simple treatment measures such as Kangaroo Mother Care, covering the baby with woollen clothes, and changing soiled clothes were advised to the mother. She was also advised to inform the nurse if the bracelet did not return to blue light.

In the control group, babies received routine neonatal care as per the hospital protocol including: initiation of breastfeeding within one hour of birth for vaginal deliveries or as soon as the mother was conscious for a Cesarean, assistance by lactation counselors and provision of breastfeeding counseling, and daily weight checking.

A Performa with maternal and neonatal details including the birth weight, gestation, parity, mode of delivery was filled. The baby's weight was checked every day using a standardized digital weighing machine (Essae BS 256) until the baby was discharged. The difference between birth weight and the lowest weight of the baby in the hospital was calculated. Weight loss was quantified as a percentage of the birth weight. Weight loss more than or equal to 10% was considered excessive. Any other morbidity in the babies of both groups, such as hyperbilirubinemia or sepsis, was also recorded. Statistical analysis was done by calculating the association of weight change and the two groups using Chi square test. A P value of <0.05 was considered significant. SPSS version 24 was used for analysis. No changes to outcomes occurred after the trial commenced. Funding for the study was provided by BEMPU Health.

Results:

During the period of study, there were 752 live births in the institute. 528 babies were included in the study and 515 babies were analysed. The babies who were excluded from analysis either left against medical advice or were shifted to the neonatal intensive care unit (Fig 1).

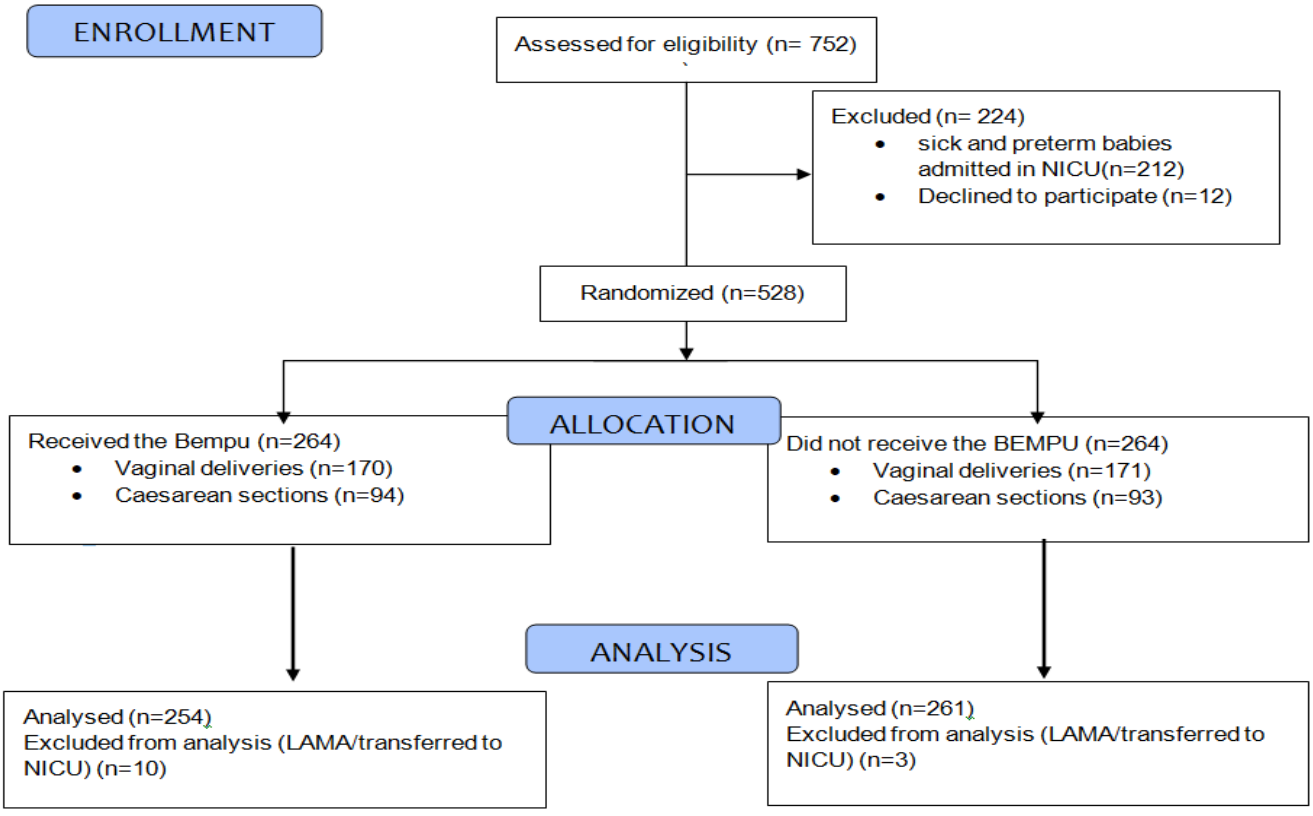

Figure 1: (CONSORT Flow Diagram)

Using a type 1 error of 0.05, the power of the study was calculated as 96%. 254 babies received the intervention and 261 babies were controls. 24.8% babies had excessive weight loss among the intervention group compared to 37.5% in the control group. The Chi square value was 9.73 (p-value 0.001). The Odds ratio calculated was 1.823 (95% CI: 1.240 to 2.663). Out of the vaginal deliveries (n=331), 163 babies received the intervention and 168 were controls. Among the caesarean deliveries (n=184), 91 babies received the device and 93 were controls. The mean age of mother, parity, sex ratio of babies, mean gestation, and mean birth weight of all groups was similar as shown in Table 1.

Table 1:

	Total number		Vaginal deliveries		Caesarean section	
	Cases	Controls	Cases	Controls	Cases	Controls
n	254	261	163	168	91	93
mother's age	26.4 years	26.7 years	26.4 years	26.5 years	26.7 years	26.9 years
primiparous	101	103	69	68	32	35
multiparous	153	158	94	100	59	58
male	125	131	89	83	36	48
female	129	130	74	85	55	45
mean gestation	38 weeks	38 weeks	38 weeks	38.1 weeks	38.1 weeks	38.1 weeks
mean birth weight	2.775 kg	2.742 kg	2.742 kg	2.673 kg	2.809 kg	2.812 kg
mean lowest weight	2.5665 kg	2.51 kg	2.542 kg	2.443 kg	2.591 kg	2.577 kg
mean % weight loss	7.4%	8.55%	7.2%	8.5%	7.6 %	8.6%
LBW	58	74	39	51	19	23

In the vaginal delivery group, the mean lowest weight in the intervention babies was 2.542kg compared to 2.443 kg in the control group. The mean weight loss was 7.2% and 8.5% in the intervention and non intervention babies respectively. Among the intervention group, 132 babies (81%) did not have excessive weight loss and 31 babies (19%) had a weight loss of more than or equal to 10%. Whereas among the control group, 112 babies (66.7%) did not have excessive weight loss and 56 babies (33.3%) had a weight loss of more than or equal to 10%. The Pearsons Chi square values was 8.750 with a p value of 0.003. The Odds ratio was 2.129(95% CI:1.284-3.531). We also calculated the relative risk which was 0.5706 with a 95% CI of 0.3893 to 0.8362. The absolute risk reduction was 14.9% and the number needed to treat was 6.986.

In the caesarean section group, the mean lowest weight in the intervention babies was 2.591 kg compared to 2.577 kg in the control group. The mean weight loss was 7.6% and 8.6% in the intervention and non intervention babies respectively. 71 babies (78%) did not have excessive weight loss and 20 babies (22%) had a weight loss of more than or equal to 10% in the intervention group and among the babies who did not receive the intervention, 66 babies (74.5%) did not have excessive weight loss and 27 babies (25.5%) had excessive weight loss. The Pearsons Chi square values were 1.203 (p-value 0.273). The Odds ratio was 1.452(95% CI: 0.744-2.833).The relative risk was 0.7570 with 95%CI being 0.4588 to 1.2492, which was not significant.

There were 39 low birth weight babies born by vaginal deliveries in the intervention group and 51 in the non intervention group. In the sub group analysis of the low birth weight babies born by vaginal deliveries, only 6 babies (15.4%) among the intervention group had excessive weight loss compared to 18 babies (35.3%) in the non intervention group. The Pearsons Chi square value was 4.480 (p-value 0.034). The odds ratio was 3.000(95% CI: 1.058-8.508). Since being low birth weight increases the risk of hypothermia, we did an analysis of the normal weight babies who were born by vaginal deliveries. When compared, the Pearsons Chi square value was 5.270 (p-value of 0.021) for the normal weight babies. The Odds ratio was 1.910(95% CI: 1.100-3.330). Results are summarised in Table 2.No adverse events or unintended effects of using the device occurred. However, a few mothers found the device strap to be too tight and noticed it pinching the skin of the baby.

Table 2: Comparison of intervention and non intervention groups

		no	<10% weight loss	>=10% weight loss	Pearsons Chi square value	P value	Odds ratio	95% CI Lower limit	95% CI upper limit
Total number	Cases	254	191	63	9.73	0.001	1.823	1.240	2.663
	Controls	261	163	98					
Vaginal deliveries	Cases	163	132	31	8.750	0.003	2.129	1.284	3.531
	Controls	168	112	56					
C section	Cases	91	71	20	1.203	0.273	1.452	0.744	2.833
	controls	98	66	27					

Discussion:

Neonatal hypothermia has been recognized as a contributing cause of mortality and morbidity among both low-birthweight and normal-birth-weight babies, even in warm tropical environments [14]. Hypothermia management is increasingly gaining attention and significance as a critical intervention for newborn survival [5], andthe World Health Organization (WHO) has adopted thermal control among the essential components of newborn care [11].

Even though our study was not done with the objective of assessing the incidence of hypothermia, for babies who were in the intervention group and received the Bempu bracelet, the mothers reported that the device alarmed at least once every day. This shows that cold stress is common among babies who are apparently healthy and are kept by their mother's side.

In our study, the incidence of excessive weight loss was 31%, which was similar to the incidence of 25% found in a study by Mezzacappa et al [15]. Even after extensive research we did not find any study which showed the association between excessive weight loss and hypothermia in term healthy babies. Our study fills in that gap and also opens up avenues for more research in this aspect.

Babies whose temperature was continuously monitored using the Bempu device had significantly lower incidence of excessive weight loss compared to those who were not given the device. In the subgroup analysis, this difference was significant for the vaginal delivery group. Even though we found that the caesarean section babies had lower incidence of excessive weight loss among the intervention group, the difference was not significant. Caesarean sections is among the significant causes for excessive postnatal weight loss, especially sections without labour [16]. The number of babies in the Caesarean section group in our study was lower than vaginal delivery group so a bigger sample size may help to more thoroughly evaluate the effects of the temperature device in a better way in this subgroup.

One might argue that there are many other factors playing a role in excessive weight loss, the main one being poor breastfeeding. But our study was a randomised study and the lactational management was the same for both groups. In our setup, we evaluate every postnatal mother for feeding issues in the first 72 hours and do intensive lactational counselling and support for the mothers if a problem is detected. We had a small subset of low birth weight babies who also showed benefits of continuous temperature monitoring, but we need additional studies with bigger sample size to confirm these findings.

Our study therefore shows that cold stress may be an important factor in causing excessive postnatal weight loss in apparently healthy babies who are cared for by their mother's side. In spite of all measures taken to prevent hypothermia, it is still a common problem in the postnatal wards and seemingly healthy term babies are not routinely monitored for cold stress in many settings. A continuous temperature monitoring device may help the mother identify cold stress and take simple but effective measures to treat it and hence prevent excessive weight loss and related morbidities. The strengths of our study were a good sample size and a high power of the study. However, we need to evaluate the caesarean section babies and low birth weight babies with larger sample size to assess the use of temperature monitoring to prevent weight loss as both are independent risk factors for hypothermia and excessive weight loss. Another limitation is not having used a more objective method like breastfeeding assessment scores to show that the effectiveness of breastfeeding is the same in both groups.

Conclusion:

Continuous temperature monitoring helps prevent excessive postnatal weight loss in healthy newborns born by spontaneous vaginal deliveries.

WHAT IS ALREADY KNOWN?

Hypothermia and excessive postnatal weight loss are important causes of morbidity in newborns.

WHAT THIS STUDY ADDS?

Hypothermia is one of the reasons for excessive postnatal weight loss.

Continuous monitoring of temperature will help prevent excessive weight loss in otherwise healthy newborns.

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