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Hypothermia detection in low birth weight neonates using a novel bracelet device

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ABSTRACT

Objective: The objective of this study is to assess the diagnostic accuracy of a novel hypothermia monitoring and alert bracelet device (BEMPU Bracelet) in low birth weight (LBW) neonates weighing less than 2000 g.

Design: This was a controlled prospective study.

Setting: This study was done in the step-down nursery of a tertiary level newborn unit of a major teaching hospital in India.

Methods: Eligible cases fulfilling inclusion criteria were given BEMPU Bracelets for a period of 24 h. A comparison was made between skin temperatures taken at the axilla by a mercury thermometer and skin temperatures taken at the wrist by the BEMPU Bracelet. Temperatures were taken every 6 h and every time the BEMPU Bracelet alarmed. Trained nurses obtained temperature measurements on newborns during their 24-h stay in the hospital step-down nursery.

Results: A total of 461 neonates were screened for hypothermia, giving 2428 temperature readings. Three hundred and eleven of 461 babies experienced hypothermia at some point. The 461 babies studied experienced 495 episodes of hypothermia in total. The sensitivity and the specificity of the bracelet in diagnosing hypothermia were 98.6% and 95% respectively. The positive and negative predictive values of the bracelet were 83.6% and 99.6%, respectively. The accuracy of the bracelet in diagnosing hypothermia was 95.8%.

Conclusion: The BEMPU Bracelet is an accurate screening tool to detect and alert for neonatal hypothermia, thereby facilitating prompt management, which could prevent complications.

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KEYWORDS

Bempu; diagnostic accuracy; hypothermia; low birth weight neonates

Introduction

The World Health Organization recognizes hypothermia as one of the most important risk factors for morbidity and mortality in newborn infants of all birth weights and gestational ages. Neonates are particularly prone to hypothermia as their temperature regulation mechanism is immature. Preterm and low birth weight (LBW) neonates specifically are more susceptible to hypothermia, and the consequences may be disastrous leading to apnea, hypoglycemia and poor weight gain [1].

Normal temperature in neonates should be maintained between 36.5 and 37.5 °C, a thermoneutral environment at which basal metabolic rate is minimal and the neonate thrives [2]. Maintaining this temperature range is crucial. In developed settings, this is ensured by warmers and incubators, which maintain

neonates in thermoneutral environments. But in low-resource settings, and especially in homes, the facilities for thermal monitoring and thermal protection of neonates are limited. There is a high risk of neonates especially those who are LBW or preterm becoming hypothermic, which may go undetected and result in suboptimal management [3].

The majority of infant deaths occur during the neonatal period. Hypothermia is a major risk factor for neonatal deaths, even though it is entirely preventable [4]. Hypothermia also predisposes an infant to an 11% increase in late onset sepsis for every 1 °C drop in temperature below 36 °C [5].

There is a great need for a simple, intuitive tool that aids caregivers in continuous temperature monitoring in low-resource hospitals and in homes. The BEMPU Bracelet (Figure 1) is a silicone band with a thermistor metal cup to detect a neonate's



Figure 1. The BEMPU hypothermia alert device (BEMPU Bracelet).

temperature. The device blinks with a blue light when the neonate is not hypothermic ($\geq 36.5^{\circ}\text{C}$) and an orange light when the neonate is hypothermic ($< 36.5^{\circ}\text{C}$). The BEMPU Bracelet remains active during the entire neonatal period (4 weeks) with continuous monitoring ability [6].

This study aims to detect the sensitivity and specificity of the BEMPU Bracelet in detecting and alerting for hypothermia.

Materials and methods

This study was done in the step-down nursery of the Level III NICU (Neonatal Intensive Care Unit) at Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), in Pondicherry, India from January to June 2016. The Institute Ethics Committee (JIPMER) approved this study. The step-down nursery is the part of the NICU resembling the home environment, where mothers are encouraged to breastfeed their babies and to provide kangaroo mother care (KMC), where the neonate is held skin-to-skin on the caretaker's chest.

All LBW neonates weighing less than 2000 g were enrolled in this study after parental written informed consent. Once neonates were enrolled, they were given a BEMPU Bracelet. The device showed a blue light when the neonate was not hypothermic (core temperature greater than or equal to 36.5°C), and an orange light with an alarm when they were hypothermic (core temperature less than 36.5°C). The device was used for 24 h on each neonate.

BEMPU staff trained nurses on proper use of the device to ensure uniformity. Nurses trained mothers

on proper use of the device, and told mothers to alert a nurse if the bracelet blinked orange and beeped. Nurses recorded axillary temperatures every sixth hour using mercury thermometers and at that time, noted the color of the bracelet indication. They also recorded temperatures every time the bracelet alarmed, to cross-check temperatures, and to confirm or deny hypothermia. Thus both hypothermia alerts (orange light) and sixth hourly routine thermometer readings were crosschecked with each other. In case of hypothermia (as per thermometer reading), corrective measures (KMC, incubator care) were undertaken immediately until the bracelet returned to blue light and a normal temperature was confirmed by axillary measurement and recorded.

Data on gestational age, weight, and gender were recorded for each neonate at the time of enrollment. Occurrence of hypothermia and any subsequent complications during the study period were also recorded.

Sample size was calculated with an expected sensitivity/specificity of wrist temperature in diagnosing the hypothermia as 90% at 5% level of significance with 5% absolute precision.

Statistical analysis was done using SPSS version 19.0 (SPSS Inc., Chicago, IL). Data were analyzed using both descriptive and inferential statistics. The continuous variables were expressed as mean with standard deviation, while categorical data were expressed as frequencies and percentages.

Results

The STROBE chart (Figure 2) shows the enrollment process of neonates in this study. The baseline parameters are shown in Table 1. The majority of study participants were neonates of 33–36 weeks gestational age with birth weights ranging from 1500 to 2000 g. Table 2 shows the total number of hypothermia events detected by the device was 584, out of which 488 were true positive events. The total number of normal temperature events detected by the device was 1844, out of which seven were false negatives. The sensitivity and the specificity of the device were 98.6% and 95% respectively, and positive and negative predictive values were 83.6% and 99.6% respectively. Three hundred and eleven of 461 babies, or 67.5% of study participants, experienced at least one episode of hypothermia. Thirty-five babies each experienced three episodes of hypothermia; 114 babies each experienced two episodes; 162 babies each only experienced one episode of hypothermia.

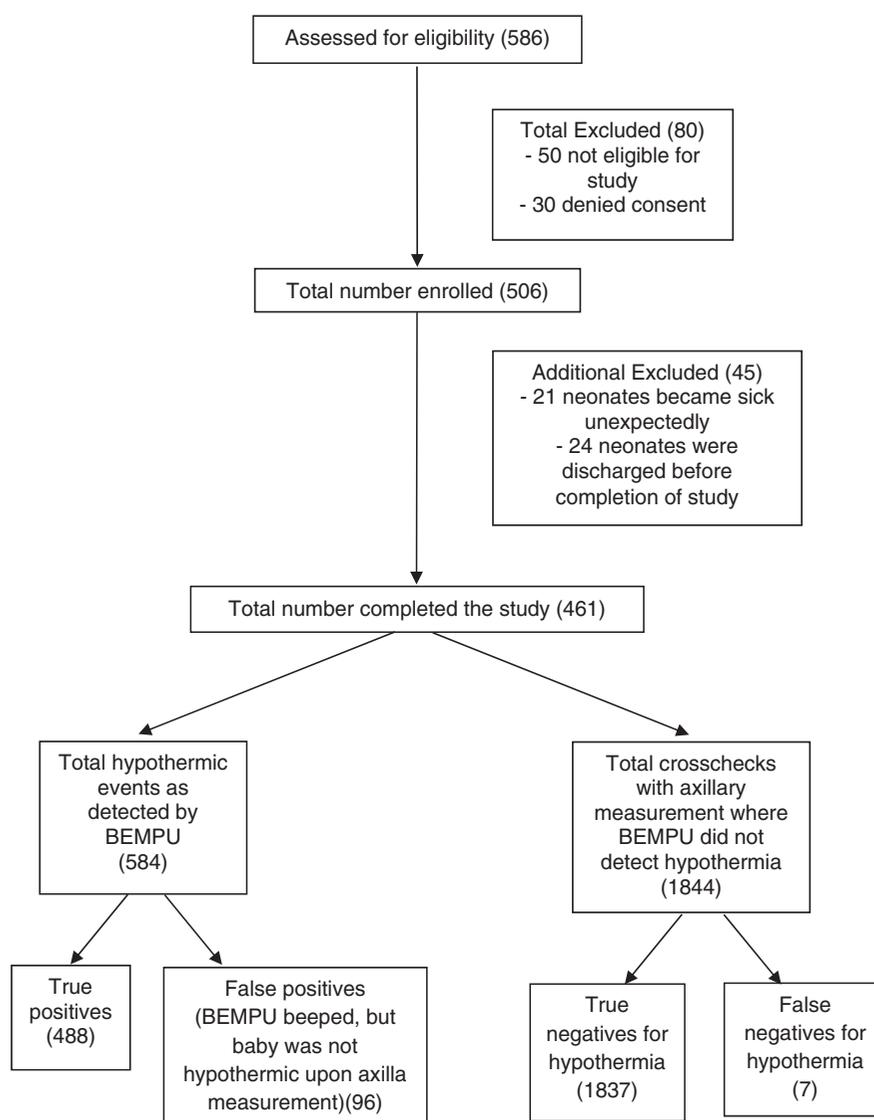


Figure 2. STROBE chart.

Table 1. Baseline characteristics of study group.

Characteristics	Distribution
1. Postmenstrual age	
29–32 weeks	139
33–36 weeks	277
>37 weeks	45
2. Weight at enrollment	
<999 g	15
1000–1499 g	210
1500–2000 g	236
3. Sex	
Male	261
Female	200

Table 2. Sensitivity and specificity of the device.

	Neonate truly hypothermic (Axilla < 36.5 °C)	Neonate truly non-hypothermic (Axilla ≥ 36.5 °C)
BEMPU showing hypothermia (positive alarm)	488 (true positive)	96 (false positive)
BEMPU showing non-hypothermia (negative/no alarm)	7 (false negative)	1837 (true negative)

Discussion

The BEMPU Bracelet is an accurate device to detect and alert for neonatal hypothermia with significant sensitivity and specificity. This is very relevant for newborns in low-resource settings, as maintenance of normothermia in low birth weight neonates is a great challenge to their survival. It is noteworthy that 311 out of 461 babies suffered hypothermia at least once during the study period. It once again confirms that hypothermia is a common occurrence in postnatal wards and step-down nurseries of resource-restricted health care systems. The BEMPU device continuously monitors temperature, in contrast to the periodic temperature checking every 6 h that is standard in step-down nurseries. Many of these detected events would have been missed in the 6-h window between temperature checks. These findings demonstrate the need for this device in detecting and alerting for hypothermia.

The high sensitivity and specificity establish that the BEMPU Bracelet is a reliable device to continuously screen for hypothermia.

It is well known that comorbid complications including sepsis, shock, hypoglycemia, and apnea are unmasked when hypothermia is diagnosed early. Hypothermia can lead to these comorbid conditions, or these comorbid conditions can present as hypothermia. Early detection of hypothermia can lead to caregivers intervening earlier and preventing complications. Community-based studies need to be conducted to assess the efficacy of the BEMPU Bracelet in hypothermia detection and caregiver response in home settings.

Disclosure statement

No potential conflict of interest was reported by the authors.

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