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Comparison of Outcome Between Hypothermia Alert Device and Conventional Temperature Recording in Babies Getting Kangaroo Mother Care

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ABSTRACT

Background: Hypothermia is a significant risk factor for newborn morbidity and mortality. Thus, thermoregulation is one of the central components of newborn care. Continuous temperature monitoring can prevent prolonged hypothermia and, subsequently, adverse outcomes.

Aims: To see the performance of the BEMPU hypothermia alert device over the conventional touch method among babies getting kangaroo mother care (KMC).

Materials and Methods: A randomized controlled trial was conducted in the Department of Neonatology in two tertiary care hospitals, Bangabandhu Sheikh Mujib Medical University (BSMMU) and Bangladesh Institute of Research and Rehabilitation in Diabetes, Endocrine and Metabolic Disorders (BIRDEM) at Shahbag, Dhaka, from June, 2019- September, 2020. Stable preterm low birth weight newborns (≤ 2000 g) eligible for KMC were enroled and monitored for 28 days.

Results: The mean detection of hypothermic episodes was significantly higher in the BEMPU group than in the conventional group (6.73 vs. 2.87, $p = 0.001$) over 28 days. The average duration of ensuring KMC per day was significantly more in the BEMPU group (mean $\pm$ SD, 7.19 ± 3.2 vs. 3.04 ± 1.69 h); $p = 0.001$). Weight gain over 28 days after discharge was more in the BEMPU group (20.96 ± 7.9) than in the conventional group (16.2 ± 7.6), which was statistically significant (p value 0.007). A significant daily weight gain was observed in the BEMPU group (20.96 ± 7.9vs 16.2 ± 7.6; $p = 0.007$).

Conclusions: The performance of the hypothermia alert device was found to be significantly higher than the conventional touch method.

1 | Introduction

Newborns are prone to develop hypothermia due to their large body surface area per unit of body weight, deficient thermal insulation, limited subcutaneous fat, and sometimes sudden exposure to changes in the temperature in their surrounding environment [1]. The World Health Organization (WHO) recognizes neonatal hypothermia as one of the major risk factors for various morbidity and even mortality in newborns [2]. A thermoneutral environment

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ensures their minimal basal metabolic rate (BMR), ensuring maximum energy is used for their growth and maintaining optimal temperature [2].

The risk of such hypothermia is higher in premature newborns than in babies with term deliveries and normal birth weight [1]. Preterm infants have a greater need for an environment with a neutral temperature due to their ineffective thermoregulation [3].

Monitoring temperature in the neonatal care units (NICUs) has always been considered an essential component of newborn care. The World Health Organization considers a newborn to be normothermic when its temperature is between 36.5°C and 37.5°C. To maintain a thermo-neutral environment (36.5–37.5°C) for a newborn, the WHO suggests ensuring a warm delivery room, immediate drying after birth with skin-to-skin contact, warm resuscitation when necessary, an early initiation of breastfeeding within 1 h of birth, appropriate clothing and bedding, warm transportation, and appropriate training of the relevant health care workers [4]. Despite vigilance on its prevention, neonatal hypothermia is still a common neonatal adverse event and has been associated with newborn morbidity and mortality, both in low- and high-income countries [5, 6].

Hypothermia is a significant contributing factor to newborn morbidity, mortality and subsequent admissions in NICUs. Hypothermia in newborns can have multiorgan involvement, such as cardiopulmonary (bradycardia, tachypnea, apnoea), the neural (lethargy, distress, poor feeding) and the vascular system (cold extremities, peripheral vasoconstriction). Metabolic derangements can result in hypoglycemia, hypoxia and eventually metabolic acidosis [3].

Their risk of mortality is five times more than newborns with normal body temperatures [7]. Hypothermia also predisposes an infant to an 11% increase in sepsis for each 1°C drop in temperature below 36°C [8]. Newborns who were found hypothermic on admission were 59% more likely to die compared to those who were normothermic [1]. However, preventing hypothermia is an essential part of newborn care recommended by the WHO [7].

Regular temperature monitoring enables caregivers to start early intervention to prevent aftereffects. Thus, a simple, intuitive tool for continuous temperature monitoring is necessary both in hospitals and in homes [8].

Kangaroo Mother Care (KMC), a widely used intervention, consists of skin-to-skin contact, exclusive breastfeeding, early discharge from the hospital and continuous support for infants and caregivers at home. KMC has demonstrated efficacy in reducing hypothermia, neonatal infections and neonatal mortality in both facility and community settings, while promoting weight gain and parent-infant bonding [2, 9]. Moreover, universal adoption of KMC for premature infants could avert up to 450,000 neonatal deaths annually [10]. Infants receiving kangaroo mother care after stabilization were found to show 40% less mortality than those who received conventional care in an incubator or a radiant warmer [11]. Despite its benefits, widespread implementation of KMC has been hindered by structural, economic, logistic and social barriers [2, 9].

When cared for at home, a newborn's temperature is usually monitored by a thermometer or by touching the newborn [2]. If the feet are cold to the touch, it indicates the baby is in cold stress. If feet and abdomen are cold to touch, it means the baby is hypothermic. Other serious symptoms, like lethargy, poor feeding, weak crying, respiratory distress, and bleeding manifestations, can appear subsequently [12]. Continuous temperature monitoring is impossible with this method, and there is a chance of missing hypothermic episodes. There is also a chance of subjective variation in the touch assessment method, and thus, hypothermia may go undetected, and ultimately, severe consequences may happen to the baby.

Early detection of hypothermia is crucial in promptly implementing interventions to prevent or minimize the life-threatening consequences linked to neonatal hypothermia [12]. Advances in technology have provided us with opportunities for the early detection of neonatal hypothermia, facilitating timely interventions to prevent associated adverse outcomes. One of them is the BEMPU TempWatch. Developed by BEMPU Health (Bangalore, India). The BEMPU TempWatch provides real-time continuous monitoring of the temperature of newborns. The device has a silicone band with an added audio alarm and an orange light-emitting thermistor metal cup. The device gets activated when the newborn's temperature drops below 36.5°C, helping identify the onset of hypothermia. The device has been constructed based on the physiological phenomenon where peripheries cool before the central core temperature drops, indicating heat loss and impending hypothermia. A noninvasive continuous temperature monitor is possible with this hypothermia alert device. This simple, innovative bracelet detects and alerts the caregiver regarding the newborn's hypothermia, aids in immediate thermal care, and promotes further KMC. Actually, timely alerts to the caregiver about hypothermia can save lives. This device continuously monitors a newborn for over 4 weeks. The device is tied to the infant's wrist, and it shows a blue light every 30 s and confirms the newborn's temperature is above 36.5°C. When a baby is hypothermic, the device flashes an orange light and beeps, drawing caregivers' attention. A validation study conducted in Pondicherry, India, demonstrated high diagnostic accuracy of the BEMPU TempWatch in detecting neonatal hypothermia among neonates weighing less than 2000 g, with a sensitivity of 98.6% and a specificity of 95.0%. In addition, the device has been found to enhance caregivers' confidence in caring for premature newborns [13].

Several studies have been conducted in different facilities using the BEMPU TempWatch device, but in Bangladesh, this was the first study to evaluate its efficacy in premature newborn care.

For the above consideration, this study was conducted to compare the performance of this hypothermia alert device over the conventional touch method among premature newborns getting KMC at home after being discharged from the hospital.

2 | Materials and Methods

The randomized control trial was conducted over 15 months in the Department of Neonatology, BSMMU and BIRDEM, Dhaka.

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2.1 | Study Procedure

Preterm low birth weight neonates eligible for getting KMC (Kangaroo mother care) from NICU and postnatal ward, BSMMU and BIRDEM after satisfying the inclusion and exclusion criteria were enroled for the study. The sample size was calculated by using the following statistical formula [14]:

$$n = \frac{(Z_\alpha + Z_\beta)^2 \times (\alpha_1^2 + \alpha_2^2)}{(\mu_1 - \mu_2)^2}$$

where, n = estimated sample size

$Z_\alpha = 1.96$ at 5% level, $Z_\beta = 0.85$ at 80% power

From a previous study [15],

$\mu 1 = 28.3$ (mean from BEMPU group), $\mu 2 = 22.9$ (mean from control group)

$\alpha 1 = 11.4$ (Standard deviation of BEMPU group), $\alpha 2 = 20.7$ (Standard deviation of control group)

So, $n = (1.96 + 0.85)2x\ (11.42 + 20.72)/(28.3-22.9)2 = 148$,

So, $n = 148$

In total, 148 eligible newborns were randomized in each group.

Babies got KMC according to NICU protocol [16], and 2 days before discharge, babies were randomized to the BEMPU hypothermia alert device group and the conventional touch method group. The conventional touch method group was taken as a comparison group. Written informed consent was obtained from the parents, and confidentiality was assured. The eligible neonates were randomly assigned with computer-generated random number tables via the "Random Allocation Software" software to receive a BEMPU hypothermia alert device. The weight of newborns was taken by a digital weighing machine (Salter baby weighing scale and Beurer baby scale, Germany) with errors of ±10 g and ±5 g in BSMMU and BIRDEM, respectively. Gestational age was assessed by LMP, first-trimester ultrasonography and New Ballard scoring. Details of maternal and perinatal medical history and anthropometry were recorded for each neonate. Both groups received routine care and KMC.

The BEMPU hypothermia alert device was used for the first time in Bangladesh. The principal author provided the device to each of the caregivers free of cost. She also counselled them regarding the use of the device, troubleshooting, complications while using the device, like local rashes, itching, sweating, etc., and details on KMC. Each counselling session was done in the presence of at least two co-authors.

In KMC with a conventional touch group, caregivers were trained on how to monitor temperature manually by keeping in touch with the soles of the foot and abdomen according to the NICU discharge protocol. If the baby becomes hypothermic, instruction was given for extra rewarming care and ensured further home KMC and continued other routine care, and to document it (number of detections of hypothermia and hours of KMC given daily) in the supplied home diary.

BEMPU hypothermia alert device was used in another group, in addition to routine care, which continuously monitored baby's temperature. BEMPU gave audiovisual alert to the caregiver about hypothermia, beeped with an orange light, which encouraged the caregivers to ensure further corrective care, thus enhancing prolonged duration KMC. Thereafter, when temperature returns to normal hypothermia, alert device flashes a blue light again.

Both groups were counselled about action to be taken for hypothermia and alerted about danger signs like lethargy, unable to feed, breathlessness, convulsions, hypothermia and hyperthermia. Any family members could give KMC. When the baby becomes hypothermic, the caregiver is advised to manage at home, ensuring extra warmth and knowledge of referral if hypothermia persists for more than 2 h. They were also asked to make a phone call to the researchers to seek medical attention if any of the danger signs were noticed. A home KMC monitoring diary containing a KMC chart to keep notes regarding the detection of hypothermia and hours of KMC was given to each infant every day. Guardians were requested to return for follow-up weekly for up to 4 weeks after hospital discharge. In addition, researchers gave three follow-up phone calls weekly to learn about the health status of newborns regarding KMC compliance, episodes of hypothermia events and the status of the hypothermia alert device. A reminder was also given for follow-up appointments weekly.

In each follow-up, researchers measured weight, length and OFC and also observed the KMC compliance, hypothermia episodes and device-related complications like skin rash and device troubleshooting. If any newborn showed static or declining weight on a subsequent follow-up, it was planned to scrutinize exclusive breastfeeding, compliance with KMC regarding anaemia of prematurity, or evaluate any underlying pathology, like urinary tract infection, etc. At the final follow-up appointment, the parents submitted their KMC diary, and the researcher analysed KMC adherence and feedback about the device.

Weight gain was calculated by

$$\frac{\text{Final weight} - \text{weight at the time of discharge from hospital}}{\text{Total number of days between discharge and final follow up}}$$

Survival of each enroled baby is documented at 4th week follow-up. Finally, comparison was made to see KMC outcomes between hypothermia alert device group and conventional touch method group.

2.2 | Statistical Consideration and Data Analysis

Data entry and analysis were carried out by using the Statistical Package for Social Sciences Software program (SPSS), version 20. Quantitative data is expressed as mean values ± SD.

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Qualitative or categorical data is presented as numbers and percentages. All quantitative variables were compared by an independent *t*-test, and categorical variables were compared by the Chi-square test and Fisher's exact test. *P*-value less than 0.05 is considered statistically significant.

3 | Results

3.1 | Flow Chart of Patient Enrolment and Outcome

A total of 117 newborns were screened for eligibility; four were excluded, and the rest were randomized into two groups (Figure 1).

The baseline characteristics of the studied neonates are presented in Table 1. The mean gestational age (GA) was 33.01 ± 1.82 weeks in the BEMPU group and 33.40 ± 1.83 weeks in the conventional touch method group.

Most of the newborns randomized in the BEMPU group had gestational age < 32 weeks (50.9% vs 37.7%), and the conventional touch group had GA > 32 weeks (62.2% vs 47.2%).

Mean birth weight was more in conventional touch group (mean ± SD 1622.45 ± 276.15 g) than BEMPU group (mean ± SD 1531.698 ± 216.52 g), $p = 0.072$.

Most of the newborns (62.2%) in the conventional touch method group had birth weight (BW) ranging from 1500 to 2000 g, and most in the BEMPU group (56.6%) had BW ranging from 1000 to 1500 g. Almost 30% of newborns in the BEMPU group had a BW appropriate for their gestational age, which was 24% in the conventional touch method group. Male babies were predominant in the conventional touch group (62.2% vs 52.8%).

Mean discharge weight was higher in the conventional touch method group (mean ± SD1598 ± 271.248-gram vs 1505.47 ±

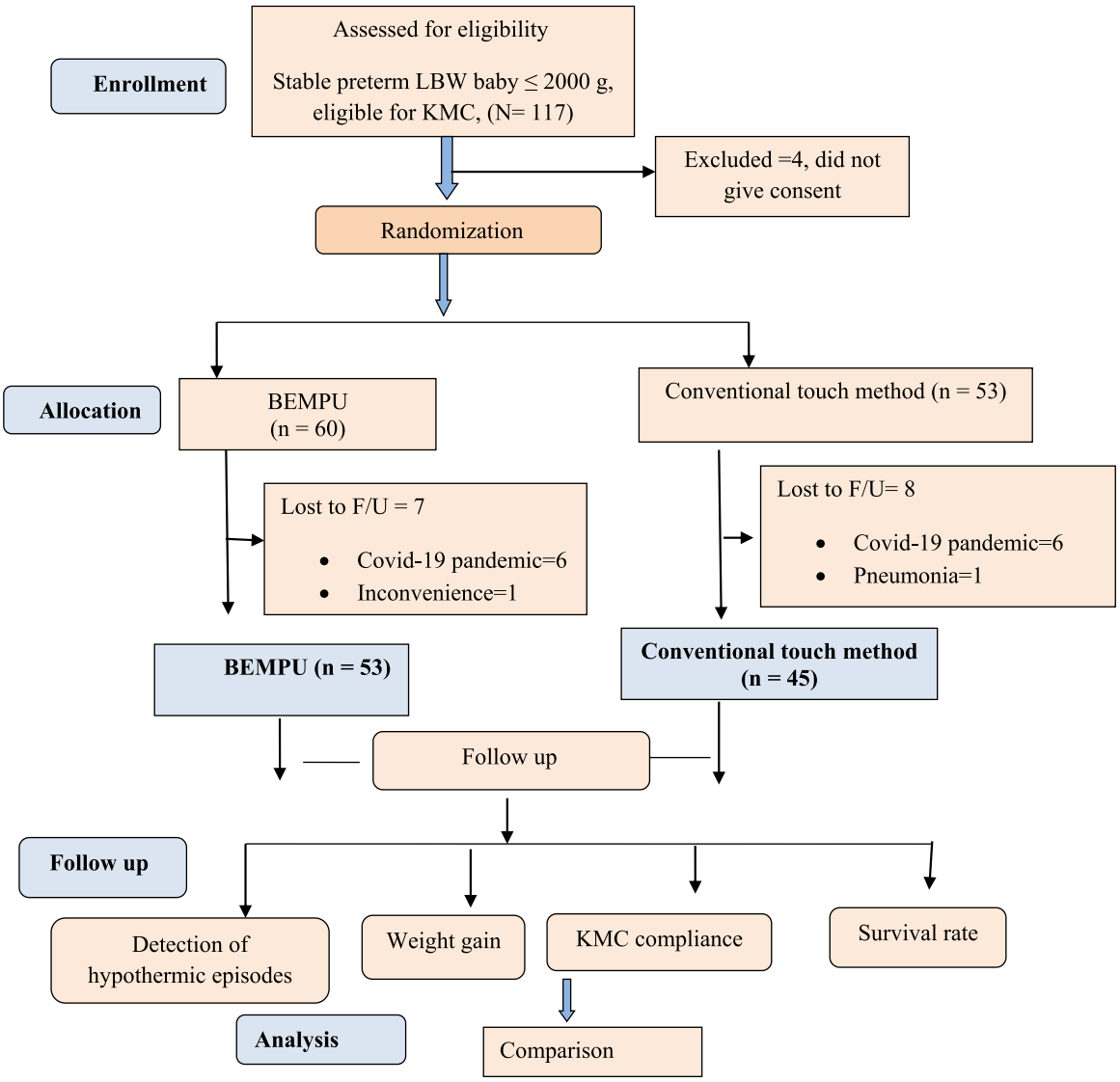

FIGURE 1 | Flow chart of patient enrolment and their outcome.

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TABLE 1 | Baseline characteristics of the studied newborn ($N = 98$).

Variable	BEMPU group Frequency, $n = 53$ (%)	Conventional touch method group Frequency, $n = 45$ (%)	p value
Gestational age (weeks) (Mean ± SD)	33.01 ± 1.82	33.40 ± 1.83	0.307[ns]
Gestational age category (weeks)			
< 28	1 (1.9)	1 (2.2)	0.246[ns]
> 28–32	27 (50.9)	17 (37.7)	
> 32–< 37	25 (47.2)	28 (62.2)	
Birth weight (g) (Mean ± SD)	1531.698 ± 216.52	1622.45 ± 276.15	0.072[ns]
Birth weight category (≤ 2000 g)			0.833[ns]
< 1000 g	1(1.9)	1 (2.2)	
> 1000–< 1500 g	22 (41.5)	16 (35.6)	
> 1500–≤ 2000 g	30 (56.6)	28 (62.2)	
Gender			0.136[ns]
Male	25 (47.2)	28 (62.2)	
Female	28 (52.8)	17 (37.8)	
Mode of delivery			0.236[ns]
LUCS	41 (77.4)	39 (86.7)	
NVD	12 (22.6)	6 (13.3)	
Foetal growth at birth			0.526[ns]
SGA	16 (30.2)	11 (24.4)	
AGA	37 (69.8)	34 (75.6)	
Discharge weight (g) (Mean ± SD)	1505.47 ± 209.14	1598 ± 271.248	0.060[ns]
Discharge length (cm) (Mean ± SD)	41.5 ± 2.65	42.12 ± 2.55	0.241[ns]
Discharge OFC (cm) (Mean ± SD)	29.08 ± 1.75	29.6 ± 1.66	0.144[ns]

Note: Quantitative data are presented as mean ± SD and qualitative data are presented as number (percentage). Statistical test: Independent sample *t*-test and Chi-square test.

TABLE 2 | Hypothermia detection was done using the studied methods in each group ($N = 98$).

Variable	BEMPU group (mean ± SD), $n = 53$	Conventional touch method group (mean ± SD), $n = 45$	p value
Hypothermia detection (in 28 days)	6.73 ± 1.97	2.87 ± 1.04	0.001[s]

Note: All values were given as mean ± SD. Statistical test: Independent Sample *t* test. s: significant

209.14gram), $p = 0.060$. Discharge mean length and OFC were slightly higher in the conventional touch group (41.5 ± 2.65 vs 42.12 ± 2.55 cm, $p = 0.241$ and 29.08 ± 1.75 vs 29.6 ± 1.66 cm, $p = 0.144$.

Table 2 shows the mean detection of hypothermia episodes in both groups over the total period of study. The detection of hypothermic episodes was significantly higher by the BEMPU hypothermia alert device than by the conventional touch method group ($p = 0.001$).

Anthropometric measurement of enroled newborn (weight, length and OFC) at 4th week after discharge is presented in Table 3. Measurements in all three parameters were higher in the BEMPU group, though they were not statistically significant.

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TABLE 3 | Anthropometric measurements of enroled newborn at 4th week after discharge.

Variables (at 4th week after discharge)	BEMPU group (mean ± SD), $n = 53$	Conventional touch group (mean ± SD), $n = 45$	p value
Weight (g)	2095.56 ± 380.027	1971.89 + 364.347	0.139[ns]
Length (cm)	44.63 ± 2.72	44.52 ± 2.41	0.856[ns]
OFC (cm)	31.38 ± 1.90	31.15 ± 1.56	0.629[ns]

Note: All values were given as mean ± SD. Statistical test: Independent Sample t test. ns: not significant.

TABLE 4 | Weight gain among enroled newborns in both groups ($N = 98$).

Variable	BEMPU group (Mean ± SD) ($n = 53$)	Conventional touch method group (Mean ± SD) ($n = 45$)	p value
Average weight gain per day over 28 days (g/day)	20.96 ± 7.9	16.17 ± 7.6	0.007[s]

Note: All values were given as mean ± SD. Statistical test: Independent Sample t test. s: significant.

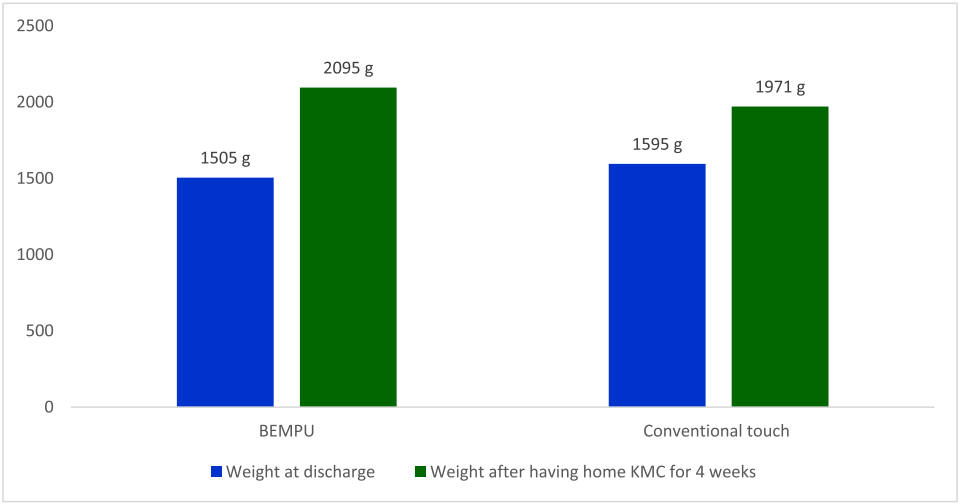

FIGURE 2 | Mean weight difference at discharge and 4th week after having home KMC.

Table 4 shows a significant daily weight gain over 28 days after discharge in the BEMPU group ($p = 0.007$).

The mean weight of discharge and mean weight at 4th week after discharge in each group is shown in Figure 2. The babies who were monitored via the BEMPU hypothermia-detecting device showed more weight gain than the other group.

The mean length of discharge and length 4th week after having home KMC in each group are shown in Figure 3. The findings were almost similar in both groups.

The mean OFC at discharge and length 4th week after having home KMC in each group are shown in Figure 4. The findings were almost similar in both groups.

Box and Whisker Plot chart of average duration of home KMC in both BEMPU and conventional touch method group is shown in Figure 5. The average KMC duration was higher in BEMPU than in the conventional touch method group.

The infants who were under the observation of a BEMPU hypothermia monitoring device could ensure a longer duration of KMC per day.

Table 5 shows average hours of KMC given per day over 28 days. Mean average duration was more in BEMPU group (mean ± SD7.19 ± 3.2) than conventional group (mean ± SD 3.04 ± 1.69), $p = 0.001$.

4 | Discussion

This study aimed to explore the effect of the BEMPU hypothermia detecting device on detecting neonatal hypothermia among neonates receiving KMC at home. To our knowledge, this is the first study in Bangladesh to evaluate the BEMPU hypothermia detecting device for detecting neonatal hypothermia.

Hypothermia alert devices can aid caregivers in identifying cold stress, and thus, timely intervention can be attempted to prevent

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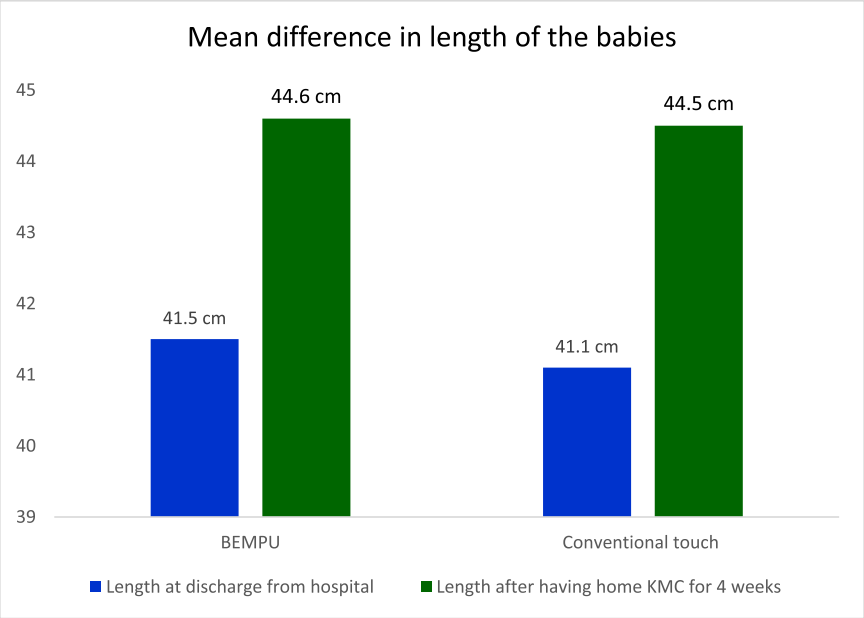

FIGURE 3 | Mean length difference at discharge and 4th week after having home KMC.

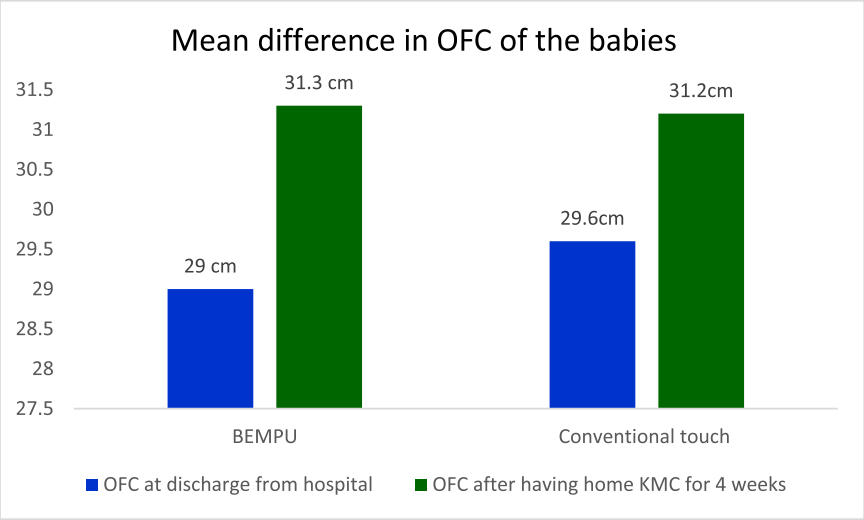

FIGURE 4 | Mean OFC difference at discharge and 4th week after having home KMC.

further serious consequences. Reddy MP et al. (2020) showed that the detection of hypothermic episodes was significantly higher in the BEMPU hypothermia alert device group [7].

Detection of mean hypothermic episodes was significantly higher in the BEMPU group than in the conventional touch group (6.73 vs 2.87, $p = 0.001$). Muppidi PR et al. (2020) mentioned similar findings of detecting more hypothermia episodes at home, with mean ± SD, 9.6 ± 8 in the BEMPU group and 0.20 ± 0.76 in the control group ($p = < 0.001$) [17].

The average duration of KMC ensured daily was longer in the BEMPU group than the other group (7.2 vs 3.04, p value 0.001). Joshi M et al. (2018) have also shown an increase in the duration of KMC from a baseline of 3 to 6 h in preterm infants through quality improvement measures [18].

A significant increase in weight gain 4 weeks after discharge from the hospital was found in BEMPU group than the conventional touch method group ($p = 0.007$). Jagadish AS et al. (2020) showed similar weight gain in the BEMPU group to the control group ($p = 0.057$) [19]. An early detection of hypothermia, immediate necessary intervention and prolonged duration KMC could contribute here.

Most of the enroled newborns survived at the end of 4 weeks after being discharged from the hospital, 98.1% and 97.7% in the BEMPU and conventional care groups, respectively (Table 6). Sharma M et al. (2020) also observed a significant survival of infants in the BEMPU group (6% and 14%, $p = 0.013$) [20].

Therefore, BEMPU devices can contribute to positive health outcomes and the baby's survival.

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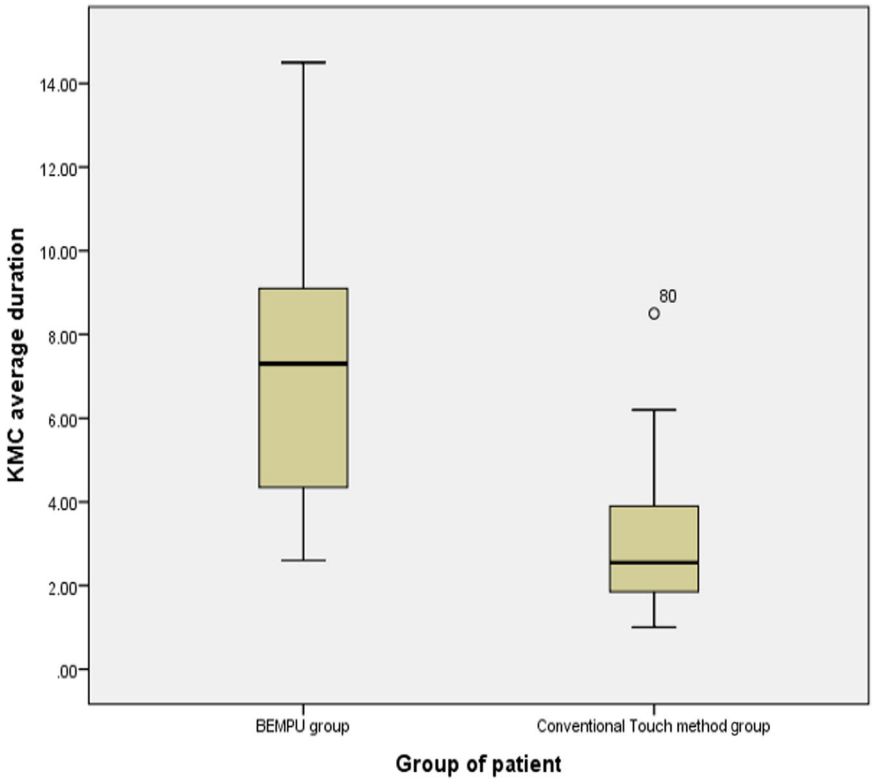

FIGURE 5 | Average duration of KMC per day in each group.

TABLE 5 | KMC compliance* among enroled newborn ($N = 98$).

Variable	BEMPU group (Mean ± SD) ($n = 53$)	Conventional care group (Mean ± SD) ($n = 45$)	p value
Average hours of KMC given per day over 4 weeks	7.19 ± 3.2	3.04 ± 1.69	0.001**

Note: Data was expressed as mean ± SD, Stastistical test: Independent sample t test.
*Duration of KMC per day.
**Highly significant.

TABLE 6 | Survival rate among enroled newborns after discharge ($N = 98$).

Variable	BEMPU group n (%)	Conventional group n (%)	p value
Survival	52/53 (98.1)	44/45 (97.7)	0.999^{ns}

Note: Statistical test: Fisher's exact test, ns: not significant.

Kangaroo mother care (KMC) prevents hypothermia, promotes breastfeeding, increases weight gain and improves mother–infant bonding. Global action report on preterm birth showed that, if supportive care in the form of KMC is provided, an estimated 450 000 babies can be saved worldwide in every year [10].

However, a device can never replace the necessity of adequate counselling of the caregivers regarding the routine care of a newborn, as well as the actions to be taken for hypothermia or any of the other danger signs like lethargy, inability to feed, breathlessness, convulsions and hyperthermia. The growth parameters of a newborn should be measured routinely, and if there is a lack of adequate weight gain, underlying pathologies like urinary tract infection or other condition needs to be ruled out.

4.1 | Limitations

Due to the COVID-19 pandemic and associated lockdown issue, patient admission was less than usual and also some participants were lost to follow up on due time. Baseline characteristics of the caregivers, like their age, educational status, past experience on newborn care, etc., were not evaluated in the study, which could have influence on the outcome.

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4.2 | Conclusion

Hypothermia alert device contributes in early detection of hypothermia, ensuring a better compliance to KMC and thus promotes growth of premature newborns. However, such a device does not replace the required strict and continuous monitoring of these fragile newborns getting KMC at home, rather it can be a useful addition for usual newborn care.

4.3 | Recommendation

Such a study on a larger population with further assessments of the impact of hypothermia devices during getting home KMC may contribute to ensuring longer duration KMC.

Neurodevelopment assessment, including cognitive, motor and language skills were not studied here, which may be assessed in further studies.

Author Contributions

Dr. Azmery Saima, Dr. Abdullahel Amaan, and Dr. Md. Ashraful Islam had conceptualized the study idea, gone through the literature reviews and constructed the study framework. Dr. Abdullahel Amaan, Dr. Md. Ashraful Islam, Dr. Mohtarama Mostari, and Dr. Afroza Islam Shuma verified the study procedure and analytical methods and actively participated in communicating with the caregivers. Dr. Ismat Jahan, Professor Dr. MA Mannan, and Professor Mohammad Shahidullah encouraged and supervised the study. All authors discussed the results and contributed to the final manuscript.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

All the data will be available for any query on request to the principal author Dr. Azmery Saima, email: azmerysaima@gmail.com.

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