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A new type of swaddling clothing improved development of preterm infants in neonatal intensive care units

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ABSTRACT

Background: Preterm infants undergo stress owing to essential treatments and exposure to the extrauterine environment in neonatal intensive care units.
Aims: The aim of this study was to enable preterm infants to maintain adequate positioning with a newly developed swaddling clothing, in order to improve low muscle tone and sleep quality, and to confirm the safety of the clothing.
Study design: This prospective clinical trial included an intervention group (preterm infants wearing bag-shaped clothing, allowing only exposure of the head, n = 27), and a control group (preterm infants managed only with conventional swaddling, n = 12).
Outcome measures: We used the Dubowitz method to analyze behavior, recorded the frequency of vomiting and apnea in both groups, and assessed the sleep state in the intervention group.
Results: Muscle tone and total score for the Dubowitz method significantly improved in the intervention group, compared with those in the control group. We evaluated the sleep state before and after the introduction of the device in the intervention group, and State 1 increased from 53.5% to 69.2% after introduction. No significant difference was seen in the frequency of vomiting and apnea between the groups.
Conclusions: The new swaddling clothing with enhanced stretch capacity improved the muscle tone and increased sleep time by decreasing the state level of preterm infants. This is an effective tool to assist in infant development in neonatal intensive care units.

1. Introduction

Preterm infants undergo stress because of essential treatments and exposure to the extrauterine environment. It is difficult for the infants to maintain a prolonged appropriate position and behave naturally, as they did in the uterus, due to behavioral changes induced by treatments and the effects of gravity. Therefore, to improve the development of preterm infants, hospital healthcare workers are making efforts to arrange environments to simulate the uterus, and to provide "developmental care." Maintaining appropriate positioning is a common approach, and is effective for the improvement of posture, rest, and relaxation. In our hospital, we used a cotton swaddling cloth to wrap preterm infants to maintain appropriate positioning. However, we encountered several problems. The swaddling made it difficult to retain stable positioning for a prolonged period, and there were differences among the staff in positioning skills. Infants needed to be awakened to adjust their position; therefore, we developed a new type of clothing to address these problems. The clothing we developed is bag-shaped and extends in both longitudinal and transverse directions. Infants are wrapped neck to feet with this clothing, and can maintain appropriate position and move their limbs to some extent.

The purpose of this study was to evaluate whether the newly developed clothing can be used safely on preterm infants enabling them to maintain appropriate positioning, thus improving their muscle tone and sleep quality.

2. Methods

We selected a fabric consisting of 85% nylon and 15% polyurethane; this fabric provides heat retention and is hygroscopic, and stretches in both longitudinal and transverse directions. We sewed the cloth into a bag shape, cut vertically down the middle on the ventral side, and

Abbreviations: NBAS, neonatal behavioral assessment scale; REM, rapid eye movement

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Fig. 1. Representative image of an infant wrapped in our newly developed swaddling clothing.

Fig. 2. From the left, size S, size M, and size L. The shape resembles a bag, with the front side opening in the middle with three buttons.

attached three buttons. After dressing an infant in the new clothing, the entire body is wrapped from the neck down (Fig. 1). The features of this clothing allow body movement to some degree, and simultaneously maintain appropriate positioning for a long period. We designed three sizes of clothing. The S size is intended for infants > 1000 g and < 1300 g, the M size for > 1300 g and < 1700 g, and the L size for > 1700 g (Fig. 2).

Our group studied 39 infants, born at a gestational age of < 36 weeks, between May 2012 and December 2012. We classified 27 cases in the intervention group from May to August, and 12 cases in the control group from September to December. The intervention group was introduced to this clothing after confirming stable status for breathing and circulation. After introduction, they were placed in the clothing continuously, except during treatment. When the intervention group reached 37 weeks 0 days of age, we discontinued use of the clothing. The control group was managed with conventional swaddling clothes until age 37 weeks 0 days.

We performed an electroencephalogram (EEG) within 2 days after birth and every two weeks thereafter. We evaluated acute abnormalities that showed a decrease in brainwave activity due to invasive events, and chronic abnormalities that showed a disorganized pattern (modification of the physiological brain wave component), a dysmature pattern (residual pattern of prematurity), and a dysmorphic pattern (an abnormal pattern that could not be recognized as typical) [1–3].

Head magnetic resonance imaging (MRI), with T1-weighted images (WI), T2WI, and fluid attenuated inversion recovery (FLAIR) examinations were performed prior to hospital discharge. We recorded the frequency of vomiting and apnea as adverse events during the introduction period, and compared this frequency in the control and intervention groups.

To evaluate the sleep stage of infants, we adopted the state-based neonatal behavioral assessment scale (NBAS); in the intervention group, we introduced the swaddling process to all cases following the same protocol: start the swaddling after feeding, and evaluate sleep state every 10 s for 15 min. We analyzed the distribution of sleep states 90 times in each infant. The assessment was performed by one physical therapist. The states are defined as follows: State 6 is characterized by crying, State 5 is a conscious state with strong reactions and optimal body function, State 4 is alacrity with attention to surroundings (i.e., shiny eyes state), State 3 is a semi-conscious state, State 2 shows irregular activity and primitive reaction in light sleep (rapid eye movement [REM]) with irregular breathing, and State 1 is deep sleep with regular breathing and REM without physical exercise [4,5].

One physical therapist performed the evaluation using the Dubowitz method at 37 weeks gestational age before hospital discharge [6,7]. The Dubowitz method includes evaluation of muscle tone, pattern of muscle tone, reflection, movement, abnormal signs, and a 5-point score for items on behavioral evaluation.

We also investigated chronic lung disease, defined by respiratory distress symptoms such as need for oxygen administration beyond 28 days after birth.

For statistical analysis, we used Chi-square test for categorical data and the Wilcoxon rank-sum test for the numerical data. The numerical data are expressed as median (interquartile range).

This research was approved by the Hospital Ethics Committee.

3. Results

The intervention and control groups included 27 and 12 infants, respectively. The gestational age of the intervention group was 32.3 weeks (interquartile range, 30.7–33.9 weeks), and that of the control group was 32.6 weeks (31.6–34.4 weeks) ($p = 0.20$). The median birth weight of the intervention group was 1668 g (1262–1860 g), and that of the control group was 1647 g (1382–1962 g) ($p = 0.49$). The 1-minute Apgar score in the intervention group and control group was 7 (5–8), and 6 (2.5–8), respectively, and the 5-minute Apgar score of the intervention group and control group was 9 (7–9) and 8.5 (7.25–9), respectively. There was no significant difference in the Apgar score at either 1 ($p = 0.75$) or 5 min ($p = 0.96$).

No infants in the intervention group had acute abnormalities on the EEG, while 1 patient in the control group had an acute abnormality ($p = 0.13$). Chronic abnormalities on EEG were observed in 3 and 2 patients ($p = 0.63$) in the intervention and control groups, respectively. Two patients in the intervention group had chronic lung disease while none did in the control group ($p = 0.10$). One case in the intervention group had an abnormality on head MRI, while the control group had no patients with a head abnormality ($p = 0.08$). No obvious significant differences were noted between the two groups with regard to chronic lung disease or abnormalities on MRI (Table 1).

The new clothing was introduced at 14.9 days after birth and corrected gestational age of 33.9 weeks on average. The introduction period was 19.1 days in the intervention group. We evaluated infant sleep state before and after introduction of the clothing in the intervention group. The results were as follows: State 1 increased from 53.5% to 69.2%, State 2 decreased from 42.0% to 22.9%, State 3 decreased from 9.4% to 3.0%, State 4 increased from 1.0% to 4.0%, and State 5 increased from 0.1% to 0.9% (Fig. 3). The rank sum of state significantly decreased after the intervention ($p < 0.0001$).

A comparative evaluation was performed using the Dubowitz method, with scores as follows: for tone, the intervention and control groups scored 9 and 6, respectively ($p = 0.03$); for movement, the intervention and control groups scored 2 and 1.5, respectively ($p = 0.05$); for behavior, the intervention and control groups scored 6.5 and 7, respectively ($p = 0.06$); and the total score for the intervention and control groups was 27.5 and 29.5, respectively ($p = 0.02$) (Table 2). The score for muscle tone improved significantly, leading to an increase in the total score of the intervention group, although the total scores of both groups were within the normal range.

The vomiting frequency per day in the intervention and control groups was 0.14 and 0.13, respectively ($p = 0.99$). The frequency of