THE EFFECT OF AN INCUBATOR COVER DESIGNED TO PREVENT NOISE AND LIGHT ON PHYSIOLOGICAL PARAMETERS OF PRETERM INFANTS IN A NEONATAL INTENSIVE CARE UNIT

WPŁYW OSŁONY INKUBATORA CHRONIĄCEJ PRZED HAŁASEM I ŚWIATŁEM NA PARAMETRY FIZJOLOGICZNE WCZEŚNIAKÓW NA NOWORODKOWYM ODDZIALE INTENSYWNEJ TERAPII

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Summary

Background. In order to support the physical and neurodevelopment of infants, they should be protected from intense light and noise in the neonatal intensive care unit (NICU). For this reason, specially designed incubator covers may be used to reduce noise and light in the NICU.

Material and methods. The study was conducted as a pretest-posttest quasi-experimental study, on a single group between February and May of 2015, in the NICU of a training and research hospital. The study sample consisted of 30 preterm infants selected randomly and according to inclusion criteria. Written and verbal consent was obtained from the family before starting the study. Data were collected using an information form, registration form, and sound level meter and a vital sign monitor.

Results. The mean heart rate at 30 minutes was 134.93±14.63 beats per minute (bpm) in preterm infants in the incubator without a cover, and 131.63±11.95 bpm for preterm infants in the covered incubator. There was a statistically significant difference between the means. The mean respiratory rate at 30 minutes was 45.16±10.48 in preterms in the incubator without a cover and 41.95±9.86 in preterms in the covered incubator, and the difference between the means was significant. **Conclusions.** Incubator covers were effective at decreasing noise levels, and had a positive impact on

Conclusions. Incubator covers were effective at decreasing noise levels, and had a positive impact on the physiological parameters of preterms.

Keywords: incubator cover, preterm infants, NICU, noise, light

Streszczenie

Wprowadzenie. Aby wspierać fizyczny i nerwowy rozwój niemowląt, należy je chronić przed intensywnym światłem i hałasem na noworodkowym oddziale intensywnej terapii (NOIT). Z tego powodu w celu ograniczenia hałasu i światła na NOIT można stosować specjalnie zaprojektowane osłony inkubatorów.

Materiał i metody. Badanie zostało przeprowadzone jako quasi-eksperyment z badaniem pretestposttest na jednej grupie w okresie od lutego do maja 2015 r. na NOIT szpitala szkoleniowobadawczego. Próba badawcza składała się z 30 wcześniaków wybranych losowo i zgodnie z kryteriami włączenia. Przed rozpoczęciem badania uzyskano pisemną i ustną zgodę rodziny. Dane zebrano za pomocą formularza informacyjnego, formularza rejestracyjnego i miernika poziomu dźwięku oraz monitora funkcji życiowych.

Wyniki. Średnia częstość akcji serca w 30-stej minucie wynosiła 134,93±14,63 uderzeń na minutę u wcześniaków w inkubatorze bez przykrycia i 131,63±11,95 uderzeń na minutę u wcześniaków w inkubatorze z przykryciem. Różnica między tymi wartościami była istotna statystycznie. Średnia częstość oddechów w 30-stej minucie wynosiła 45,16±10,48 u wcześniaków w inkubatorze bez przykrycia i 41,95±9,86 u wcześniaków w inkubatorze z przykryciem; różnica między średnimi była istotna statystycznie.

Wnioski. Osłony inkubatorów skutecznie obniżyły poziom hałasu i miały pozytywny wpływ na parametry fizjologiczne wcześniaków.

Słowa kluczowe: osłona inkubatora, wcześniaki, noworodkowy oddział intensywnej terapii, hałas, światło

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Introduction

Neonatal intensive care units (NICU) are specialized facilities where infants that are born preterm and/ or have medical and surgical problems receive intensive treatment and care [1,2]. Preterm infants leave the intrauterine environment at an early and critical period for thier physical and neurodevelopment. After leaving the safe intrauterine environment, they continue their development in the NICU where there are various environmental stimuli such as noise and intense light [3]. To support the physical and neurodevelopment of preterm newborns, these stimuli must be regulated by the healthcare professionals [4].

Intense light in the NICU has a direct effect on the physiological stabilization and central nervous system of preterm infants [5]. Preterm infants are directly affected by intense light levels because incubators are mostly transparent [6]. Providing near-dark light cycling, similar to the intrauterine environment, supports the development of infants [5,6]. The American Academy of Pediatrics (AAP) recommends a minimum of 10 lux and a maximum of 600 lux of NICU lighting [7]. Physiological changes such as desaturation, tachycardia, bradycardia, apnea, irritability, sleep disturbance, and weight loss occur in preterm infants exposed to intense light [6,8]. Although incubators provide some sound insulation, preterm infants in incubators are still affected by noise in the NICU [9]. The AAP recommends that the noise level for NICUs should not exceed 45 dB during the day and 35 dB at night [7]. It has been reported that noise causes hearing loss, changes in heart and respiratory rhythm, apnea, hypoxia, bradycardia, and increased intracranial pressure in preterm infants [10-12]. To avoid neurodevelopmental problems, preterm infants need to be protected against intense light and noise. Studies have indicated that special incubator covers designed to reduce noise and light in the NICU should be used [5,13-15]. It was reported that, although the incubator covers used were not standard, they reduced the amount of light and noise [14,16,17].

Controlling noise and light levels in the NICU by health professionals will contribute to the reduction of neurodevelopmental problems and increase the quality of care given to preterm infants. The aim of this study was to determine the effect of an incubator cover with improved insulation properties on the physiological parameters (heart rate, oxygen saturation, and respiratory rate) of preterm infants.

Material and methods

Design

The population of the study consisted of preterm infants staying in a 2^{nd} level NICU between February and May of 2015. As a result of the power analysis (G*Power 3.1.9.2) conducted to determine the sample, the delta value (δ) was found to be 2.80 when it was accepted that the probability of type 1 errors (α) was 0.05 (at 95% confidence level) and the probability of type 2 errors (β) was 0.80 (at 80% power level). Accordingly, the minimum sample size required was at least 25 preterm infants. By considering possible participant losses, 32 preterm infants who met the inclusion criteria were randomly selected and included in the study. A preterm infant was withdrawn from the study due to septic shock, and another preterm infant was withdrawn due to an allergic reaction to a vaccination. Therefore, the sample of the study consisted of 30 preterm infants selected according to the inclusion criteria. Written and verbal consent was obtained from the family before starting the study.

The inclusion criteria for the study group were as follows: the family voluntarily accepted to participate in the study and their written consent was obtained. All preterm infants were aged less than 37 gestational weeks according to the New Ballard scoring criteria [18]. The exclusion criteria for the study group were: the presence of congenital anomalies, intubation or continuous oxygen therapy, and hyperbilirubinemia.

Participants

Most of the preterm infants included in the study were male (63%). The mean gestational age of the preterm infants was 33.45 ± 5.84 weeks, the mean chronologic age was 18.40 ± 22.66 days, the mean birth weight was 1623.90 ± 513.79 g, the mean birth height was 41.20 ± 4.64 cm, and the mean birth head circumference was 29.60 ± 3.55 cm.

Procedures

The study was conducted as a pretest-posttest quasi-experimental study on a single group between February and May of 2015 in the NICU of a training and research hospital. Noise levels inside the incubator and NICU were measured with a sound level meter just before the incubator cover was used. The sound level in the incubator was measured immediately after the incubator cover was placed. After that, physiological parameters of preterm infants were monitored for 30 minutes with the incubator cover in use. Health professionals in the NICU were opening the incubator frequently for important reasons such as treatment or care. For this reason, the follow-up of the infants was limited to 30 minutes without any interruption or intervention. After the incubator was covered, oxygen saturation, heart rate and respiratory rate of the preterm infants were recorded on the monitor at 1 and 30 minutes. Data were collected approximately 30 minutes after feeding and routine care. All data was collected and evaluated between 13:00 and 15:00. No assessments were made at the time points of the highest noise levels (e.g. nutrition, care, visits). There were two windows near the ceiling of the room. There was daylight in the room, but it was arranged in such a way that it would not come into direct contact with the incubators.

Outcome measures

Information form

The two-part information form was developed by the researchers and consisted of 16 questions. The first part included the preterm infants's sex, weight, height, head circumference, gestational week, and nutrition. The second part included socio-demographic characteristics such as parental age, family type, and education.

Intervention registration form

This form was used to register oxygen saturation, heart rate, and respiratory rate of the preterm infants at 1 and 30 minutes, with and without an incubator cover, as well as noise levels inside and outside of the incubator.

Incubator cover with improved insulation properties

The cover was designed and prepared by the researchers and a national patent application has been filed (Figure 1). The cover consists of a thick, dark blue, 100% cotton fabric, in order to reduce the penetrating light, with acoustic foam placed into the cover to reduce noise (Figure 2). The measurements of the cover were sewn with consideration of the dimensions of incubators used in the NICU. The acoustic sponge has antibacterial properties but contains no chemical substances harmful to health. A pocket that could be opened and closed with a zipper, in the interior part of the cover, housed the acoustic sponge. The acoustic sponge can be washed easily because it can be attached and detached from the incubator cover. The cover was made in a "T" shape such that it would cover the back, side, and top surface of the incubator. However, the front surface of the incubator was left open to allow interventions to be made and to observe the infant comfortably. In addition, the cover was designed so that it would not inhibit life support units that were attached to the incubator.



Figure 1. Incubator cover with improved insulation properties



Figure 2. Acoustic sponge

Digital Sound Level Meter

A calibrated Cadrim Digital Sound Level Meter was used to measure the noise levels inside and outside of the incubator, before and after the procedure. This sound level meter can record the current maximum or minimum decibel value, and a hold function freezes the reading on the screen.

Analysis

For statistical analysis, the Number Cruncher Statistical System (NCSS) 2007 (Utah, USA) programme was used. To assess the data, descriptive statistical methods (mean, standard deviation, median, frequency, ratio, minimum, maximum) were applied. The distribution of data was assessed by the Kolmogorov-Smirnov test. Paired-sample t-test was used for within-group comparisons of variables showing normal distribution among quantitative data, and Wilcoxon's signed-rank test was used for within-group comparisons of variables that were non-parametric. A significance threshold of $p \le 0.05$ was used throughout this study.

Ethics

Before starting the study, the necessary approval was obtained from the clinical trials ethics committee of the Istanbul University (number 74311748-302). The families were informed about the purpose, plan, and duration of the study, and their verbal and written consents were obtained. In addition, families were informed that they could withdraw from the study at any stage and that the health service they received from the hospital would not be affected by the study.

Results

As shown in Table 1, the difference in the noise level inside the covered incubator was 2.20 ± 3.55 dB compared with the uncovered incubator, and this difference was found to be statistically significant (*p*=0.002).

Noise level (dB)	Measurement place	Incubator without cover	Incubator with cover	Difference	Test Value	
		Mean ± SD	Mean ± SD	Mean + SD	t	р
		(min-max)	(min-max)	Mean ± 5D		
	Outside the incubator	60.18±3.77	60.04±2.80	0 20+2 24	0.46	5 0.650
		(53.10-65.60)	(55.60-64.30)	0.2013.24	0.40	
	Inside the incubator	58.28±3.66	56.29±2.89	2 20+2 55	2 2 2	0.002*
		(52.20-63.80)	(51.40-60.40)	2.20±3.33 3.33		0.002

Table 1. Comparison of mean noise levels inside and outside of the incubators with and without the cover (N=30)

Notes: Paired samples t-test; *p<0.001.

As shown in Table 2, the mean heart rate at 1 and 30 minutes was 134.93 ± 14.63 bpm in preterm infants in the incubator without the cover and 131.63 ± 11.95 bpm for the preterm infants in the covered incubator. There was a statistically significant difference between the means (p=0.029). In addition, there was a difference between the mean heart rate of preterm infants in the covered incubator at 1 (135.50 ± 13.37 bpm) and 30 minutes (131.63 ± 11.95 bpm), and this difference was significant in favour of the covered group (p=0.006).

Table 2. Comparison of mean heart rate, respiratory rate, and oxygen saturation of preterms in covered and uncoveredincubators (N=30)

	Maasuramant	Incubator without cover Incubator with cover		Test Value	
	time	Mean ± SD (min - max)	Mean ± SD (min - max)	t	р
	1 st minute	135.10±13.62 (106-159)	135.50±13.37 (112-161)	0.191	0.850
Heart Rate (min)¤	30 th minute	134.93±14.63 (111-161)	131.63±11.95 (111-159)	2.430	0.029*
	Т	0.078	2.937		
	Р	0.939	0.006**		
				t	р
	1 st minute	43.73±10.06 (29-68)	44.17±10.80 (24-66)	0.313	0.756
Respiratory rate (min) ¤	30 th minute	45.16±10.48 (30-62)	41.95±9.86 (26-64)	3.733	0.001**
	Т	1.586	2.264		
	Р	0.124	0.031*		
				Z	р

	1 st minute	96.83±2.48 (91-100)	96.50±3.34 (86-100)	0.097	0.923
Oxygen saturation (%)¤¤	30 th minute	97.31±2.06 (91-100)	97.73±1.77 (91-100)	1.967	0.059
	Z	1.540	2.491		
	Р	0.123	0.013*		

Notes: "Paired samples t-test: *p<0.05, **p<0.001; ""Wilcoxon signed-rank test: *p>0.05

It was found that the mean respiratory rate was 45.16 ± 10.48 in preterm infants in the incubator without a cover, and 41.95 ± 9.86 in preterm infants in the covered incubator, at 30 minutes. The difference between the means was significant (*p*=0.001). It was also found that there was a difference between the preterm infants's mean respiratory rates at 1 (44.17 ± 10.80) and 30 minutes (41.95 ± 9.86) in the incubator with the cover. This difference was significant in favour of the covered group (*p*=0.031) (Table 2).

The mean oxygen saturation at 30 minutes was $97.31\pm2.06\%$ in preterm infants in the incubator without the cover and $97.73\pm1.77\%$ in preterm infants in the incubator with the cover; the difference between the means was not significant (*p*=0.059). However, the difference between the mean oxygen saturation values of the preterm infants in the covered incubator at 1 ($96.50\pm3.34\%$) and 30 ($97.73\pm1.77\%$) minutes was higher at 30 minutes, and this difference was significant (*p*=0.013) (Table 2).

Discussion

Failure to regulate the NICU to support the development of preterm infants, and controlling the noise and light in particular, might cause permanent neurodevelopmental and behavioural problems [1,19-21]. For this reason, the AAP recommend that noise levels in the NICU should not exceed 45 dB during the day and 35 dB at night [7]. However, it has been observed in many studies that noise levels in the NICU were significantly higher than the recommended levels. Noise levels were reported as 56 dB [9], 64 dB [22], and 64 dB [23]. In parallel with these results, the noise level in the present study was found to be higher than the recommended level (60 dB). This suggests that supportive approaches to reduce neurological and developmental problems that may occur in preterm infants must be applied [24,25]. One of these supportive approaches is the use of incubator covers to reduce noise levels [15-17]. In addition to incubator covers, acoustic sponges have been reported to be effective and can be used to reduce noise [9,26,27]. The acoustic incubator cover used in the present study reduced the noise by 2 dB, and this reduction was significant. We tried to keep the noise level, of the outside environment in particular, at a similar level in covered and uncovered applications as this was an important criterion for evaluating the effectiveness of the cover.

It was reported that incubator covers and acoustic sponges used in NICUs reduced noise levels significantly. In the study by Oliveira et al., noise levels in the incubator reduced when a cover that closed all surfaces of the incubator was used [22]. In their study, which investigated the effect of covering incubators and alarms with acoustic sponge on noise levels inside incubators, Altuncu et al. stated that the noise level of the outside environment was 56 dB before the application, and went down to 47 dB in the incubator when acoustic sponges were used [9]. In the present study, the noise level was reduced, but a smaller decrease was determined compared to the other studies. This could be associated with the fact that the front surface of the incubator cover was kept open and no material was used to reduce the noise of devices with alarms. Nevertheless, the results showed that the cover reduced noise.

In the literature, it has also been reported that noise and inappropriate light levels negatively effect the respiratory and cardiovascular system of preterm infants [6,28-30]. However, we found no studies on the effect of incubator covers on the physiological parameters of preterm infants. In the present study, it was determined that incubators, with or without covers, created a significant difference regarding the heart and respiratory rate of preterm infants after 30 minutes. This showed that the incubator cover had a positive effect on the physiological variables of infants by controlling noise and light. In addition, the difference between the oxygen saturations was not significant, but the values were stable. The absence of a difference in oxygen saturation levels may be associated with the fact that the infants received oxygen therapy during the time they were staying in the incubator. Moreover, their stable saturation levels are also important as they reveal that the cover had no negative effect. Indeed, when both interventions (covered/uncovered) were examined individually, in terms of heart rate, respiration rate, and oxygen saturation values at 1 and 30 minutes, it was determined that all physiologic parameters were affected positively within 30 minutes and the difference was significant (p<0.05).

Due to the routine practice of the unit, keeping the incubator cover time to 30 minutes shortened the follow-up duration of the infant. Nevertheless, the fact that the effectiveness of the incubator cover was positive, even in a short period of time, was an important result.

Conclusions

Noise levels inside the covered incubator were lower than when uncovered. Therefore, using incubator covers had a positive effect on physiological parameters of preterm infants including heart rate, oxygen saturation, and respiratory rate. Preterm infants are fragile and vulnerable. For this reason health professionals have to provide comprehensive care for the infant's health and development. Thus, environmental conditions that have an effect on growth and health need to be considered in the NICU. The use of incubator covers for preterm infants as a simple, safe, and supportive stimuli is recommended for the formation of positive effects.

In order to reduce noise and light, it may be recommended to expand the use of incubator covers to all neonatal units. Furthrmore, we recommend to use them repeatedly and to continue the intervention over longer periods, starting from one hour on the incubator. In order to determine the effect of the incubator cover on the vital parameters of infants, it will be much more meaningful to monitor them for more than 30 minutes. Studies on the use of the incubator cover during nursing care, feeding or painful procedures can be planned and compared with other developmental care interventions.

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