RESEARCH PAPER

Effect of Earmuffs on Physiological Parameters of Preterm Neonates Nursed in Incubators: *A Before-and-After Study*

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Received: January 04, 2021;
Initial review: February 22, 2021;
Accepted: May 15, 2021.

Objective: To determine the effect of earmuffs on stability of physiological parameters i.e. heart rate, respiratory rate, and oximeter saturation (SpO_2) in preterm neonates. **Methods:** Non-randomized, cross-over study. 60 stable preterm neonates observed without and with earmuffs for 2 hours each (control and intervention periods, respectively). The above parameters were recorded every 60 seconds. Spikes of parameters and fluctuation [by coefficient of variation (CoV)] were compared between periods. **Results**: Spikes of all parameters as a proportion of observations, were significantly less in intervention period. Median (IQR) spikes per subject were lower in intervention vs control: tachycardia [2.5 (2.5, 18) vs. 20.5 (2.2, 37.7); *P*<0.01]; tachypnea [11.5 (11.5, 25) vs. 18 (2, 40) vs; *P*=0.01] and hypoxia [0 (0, 0) vs. 0 (0, 1.75); *P*<0.01]. There was significantly less fluctuation of heart rate and SpO_2 with earmuffs. **Conclusion**: Earmuffs improve physiological stability of preterms.

Keywords: *Heart rate*, *NICU, Noise, Respiratory rate*.

***Published online*:** June 28, 2021; ***PII*:**S097475591600343

The American Academy of Pediatrics recommends noise levels of less than 45 A-weighted decibels (dBA) in neonatal intensive care units (NICU) [1]. High noise level adversely affects the physiological parameters, behavior, and sleeping patterns of neonate. In a pilot study, we found that the mean (SD) noise level in our NICU was 57.60 (3.95) dBA. There is a paucity of well-conducted studies evaluating the effect of earmuffs on noise reduction and stabilization of physiological parameters, such as heart rate (HR), respiratory rate (RR), pulse oximeter saturation (SpO_2), and blood pressure in preterm neonates, and the available studies have shown conflicting results [2-4].

A Cochrane review on the effect of noise reduction on very low birth weight infants could find only one single-center randomized controlled trial on 34 newborns [5]. The authors reported better weight gain and neuro-development among infants who were randomized to wearing silicone earplugs [6]. Some RCTs have included a reduction in both light and noise levels, making it difficult to assess the effect of noise reduction alone [7,8]. Previous studies have compared only the average values of the physiological parameters [2-4,7-11]. Relying solely on averages could be misleading because averages do not adequately reflect transient but harmful spikes nor do they capture fluctuation of the physiological parameters. We hypothesized that the application of earmuffs on preterm neonates, nursed in incubators in a NICU, would reduce spikes and fluctuations in their physiological parameters.

METHODS

We conducted a prospective, cross-over study in a level III NICU in a tertiary care institute in Northwest India. The institute ethics committee approved the study protocol. The study was done in accordance with the Helsinki declaration and with the Indian Council of Medical Research (ICMR) national ethical guidelines. We included preterm neonates (<37 weeks gestation) who required incubator care, but were otherwise clinically stable. Kangaroo mother care was intermittently provided but they were unable to consistently maintain body temperature outside an incubator. Infants who were ill, sedated, encephalopathic, had scalp electrodes, or had syndromes associated with deafness were excluded. Written informed consent was obtained from either parent. Baseline data included the demographic and clinical profile of enrolled neonates.

In the 'control' period, we recorded HR, RR, and SpO_2 at 60-second intervals for 2-hour duration by a multichannel monitor (IntelliVue MX800, Philips) without the application of earmuffs, thus providing 120 data points for each parameter. This was followd by a two-hour washout period. Following this, in the 'intervention' period, we recorded data on the same neonates for 2-hour

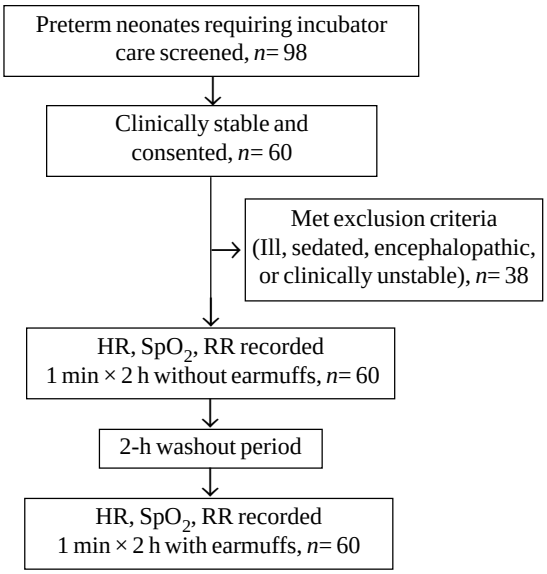

Fig. 1 Flow diagram of the study population.

duration with the application of earmuffs (Minimuffs, Natus Medical Inc.), which reduce noise by 7 dBA, as per manufacturer. Each subject acted as its own control.

At the start of the control and the intervention periods, we measured the sound level inside the incubator using the Bruel and Kjaer precision integrating sound level meter type 2230, fitted with microphone type 4155. We collected data at a time when we anticipated the least number of nursing/clinical activities so that other stressful conditions could be avoided.

We defined a 'spike of tachycardia' in two ways- either as any data point of HR ≥160 beats per minute (bpm) or any data point of HR ≥180 bpm; a 'spike of tachypnea' as RR ≥60 breaths per minute; and a 'spike of hypoxemia' as SpO_2<90%. We recruited a sample size of convenience of 60 consecutive eligible subjects.

Statistical analysis: Normality of distribution was determined by Shapiro-Wilk test and the QQ plot. We compared proportions between the periods by the McNemar test and distributions by the Wilcoxon signed rank-sum test for skewed distributions. Using the data point as the unit of observation, we compared the proportion of spikes between the two periods. Using the subject as a unit of observation, we compared the median number of spikes. We calculated the coefficient of variation (CoV) of each parameter for each subject and compared the median CoV. Using 120 data points for a given parameter, we calculated the area under the curve (AUC) using a differential function for each subject in each period, and compared the median AUC between the groups.

RESULTS

We enrolled 60 eligible subjects (31 males) (**Fig. 1**). The study population had a mean (SD) gestation of 31 (2.5) weeks, birthweight of 1348 (408.3) grams and current weight of 1239 (404.9) grams. Median (range) Apgar scores at 5 minutes was 9 (8, 9) and postnatal age was 7 (4, 10) days. Twenty five (41.7%) subjects were small for gestational age and the remainder were appropriate for gestational age and 25 (41.7%) were delivered vaginally. The mean (SD) noise level inside the incubator during the control and intervention periods was 57.6 (3.9) and 57.3 (3.5) dBA, respectively (P=0.27).

The number of spikes as a proportion of all individual observations was significantly higher in the control period compared to the intervention period for all three parameters (P<0.01) (**Table I**). There were statistically significant reductions in the median number of spikes of tachycardia, tachypnea and hypoxia in the intervention period compared to the control period (P values of <0.01, 0.01 and <0.01, respectively) (**Table II**).

We compared the median CoV of each parameter between the two periods (**Web Table I**). There was a significantly higher variability of HR (P=0.03) and SpO_2 in the control vs intervention periods (<0.01). There were significantly higher median AUC for HR (P=0.01) and RR, whereas, for SpO_2, there was almost no difference (P=0.97).

Table I Spikes of Physiological Parameters Among Individual Observations in Preterm Neonates With and Without Earmuffs (*N*=60)

Physiological parameters (number of spikes)	*Without earmuffs (n= 7200 observations)*	*With earmuffs (n= 7200 observations)*
Heart rate ≥160 bpm	1769 (24.5)	1037 (14.4)
Heart ratee ≥180 bpm[a]	168 (2.3)	70 (0.97)
Respiratory rate ≥60 per min	1491 (20.7)	1162 (16.1)
Oxygen saturation <90%	117 (1.6)	41 (0.5)

Values in no. (%). Bpm-beats per minute. All P<0.01; [a]P<0.001.

Table II Spikes of Physiological Parameters per Subject in Preterm Neonates With and Without Earmuffs (*N*=60)

Physiological parameters (no. of spikes per subject)	*Without earmuffs (n=60)*	*With earmuffs (n= 60)*
Tachycardia (rate ≥160 bpm)[a]	20.5 (2.25, 37.75)	2.5 (2.5, 18)
Tachycardia (rate ≥180 bpm)[b]	0 (0, 4)	0 (0,0)
Tachypnea[c]	18 (2, 40)	11.5 (11.5, 25)
Hypoxemia[a]	0 (0, 1.75)	0 (0, 0)

Values in median (IQR). [a]P<0.01; [b]P<0.001; [c]P=0.01.

WHAT THIS STUDY ADDS?

- This study shows that application of earmuffs among stable preterm neonates nursed in incubators results in significantly less spikes and less variability of physiological parameters.

DISCUSSION

We evaluated earmuffs for their effect on three critical physiological parameters. One of the study's challenges was that the data was collected at 1-minute intervals for two hours during each period. Hence, we examined the data from various perspectives – observations above a pre-defined threshold, the variability of the observations per subject, and an integral of all the observations for each subject. The application of earmuffs resulted in lower HR and RR and higher SpO_2; less abnormal spikes, and less variability of these parameters. Although SpO_2 showed higher fluctuation in the control compared to the intervention period, its AUC was similar in both periods because the dips from baseline were compensated for by the peaks, thus maintaining AUC constant.

Our results are concordant with some previous studies. In a non-RCT, Abujarir, et al. [10] applied earmuffs, identical to ours, to neonates admitted in one area of the NICU and did not apply in another area. HR, systolic blood pressure (BP), RR, SpO_2 significantly improved among neonates wearing earmuffs, but mean BP, diastolic BP, and temperature did not. In the RCT by Abdeyazdan, et al. [2], environmental sound levels were higher than in our unit, and there was a significant difference in mean SpO_2, RR and HR between the groups with and without earmuff. Other authors also report that infants with earmuffs have greater mean SpO_2 values, less fluctuation in SpO_2, and sleep more [11].

A few research groups did not find a benefit of earmuffs [3,4]. Duran, et al. [4] evaluated earmuffs, identical to those in our study, in a prospective cross-over study on 20 clinically stable preterm VLBW neonates older than 7 days and nursed in incubators [4]. They reported no significant differences in body temperature, HR, RR, SpO_2, and BP. Bott, et al. [3] found no effect of earmuffs on intermittent hypoxia [3].

There are studies that looked at outcomes other than immediate physiological outcomes. Li, et al. [12] reported 100 preterm ventilated neonates randomly allocated to earmuffs and no earmuffs groups. The group wearing earmuffs had significantly lower incidence of hearing loss, periventricular hemorrhage and leukomalacia, and better developmental indices on follow-up. The only study included in the Cochrane meta-analysis reported better weight gain and neurodevelopmental outcomes, but no effect on physiological parameters [5,6].

A limitation of our study was that the sequence of cross-over was not randomly allocated. We did not perform a formal sample size calculation. Also, we did not maintain a record of the handlings and procedures done on preterm neonates during data collection, as we had chosen a period of the day expected to have minimal interventions. We did not measure non-invasive BP, because frequent non-invasive BP (NIBP) recording was not clinically indicated in our stable population and would have itself been stressful. Intermittent NIBP recording serves a limited purpose as it is unable to capture the BP record continuously.

We conclude that applying earmuffs protects premature infants from noise-induced adverse changes in physiological parameters. The application of earmuffs decreases the number of spikes of tachycardia, tachypnea and hypoxemia; and decreases the variability of HR and SpO_2. Routine use of earmuffs may be considered to improve the physiological stability of preterm infants nursed in incubators in the NICU.

Note: Additional material related to this study is available with the online version at www.indianpediatrics.net.

Ethics clearance: PGIMER Institute Ethics Committee; No. 41520/14/910, dated March 24, 2014.

Contributors: AK: substantial contributions to the design of the work, acquisition and analysis of data, and drafted the work; SK: substantial contributions to the conception of the work, interpretation of the data for the work, and revised the manuscript critically for important intellectual content; SM: substantial contributions to the design of the work, and revised it critically for important intellectual content; SD: substantial contributions to the concept and design of the work, analysis and interpretation of the data, and drafted and revised the work for important intellectual content. All authors approved the final version of manuscript, and are accountable for all aspects related to the study.

Funding: None; *Competing interest*: None stated.

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Web Table I Coefficients of Variation and the Area Under Curve of Physiological Parameters Per Subject Among Preterm Neonates With and Without Earmuffs (*N*=60)

Physiological parameters	*Without earmuffs*	*With earmuffs*
Heart rate (beats/min)[a]	0.059 (0.041,0.077)	0.050 (0.041,0.061)
Coefficient of variation		
Respiratory rate (per min)	0.221 (0.175,0.284)	0.208 (0.158,0.263)
Oxygen saturation[b]	0.014 (0.010,0.022)	0.0117 (0.008,0.015)
Area under curve		
Heart rate (beat-min)[c]	17604 (16735.7, 18764.6)	17318.75 (16319.2, 18190.2)
Respiratory rate (breath-min)[b]	5507.5 (4927, 6454.2)	5467.25 (4681.4, 6089.9)
Oxygen saturation (% -min)	11565.2 (11406.9, 11662.9)	11566.5 (11390.2, 11679)

Values are median (IQR). [a]P=0.03, [b]P<0.01, [c]P=0.01.