# Will Earmuffs Improve Neonate Behavior in The Neonatal Intensive Care Unit?

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## Abstract

**Background** Modern advanced technologies in the neonatal intensive care unit (NICU) have created more noise sources of varying frequencies and intensities, increasing the risk of hearing loss in infants. This study aimed to determine the effect of earmuffs on neonatal behavior.

**Materials and Methods** This study was conducted in the 13-bed level III-A NICU of a 1,000-bed tertiary care teaching hospital. Preexperimental, one-group pretest, posttest design was adopted in the study. Twenty-seven neonates were selected using nonprobability and purposive sampling techniques. The noise level was checked using a dosimeter (sound level meter SL-4030), the baseline variables were collected, and earmuffs were applied to the neonates for 2 hours in the morning and 2 hours in the evening for 3 consecutive days. An observational checklist was used to assess neonatal behavior.

**Results** The mean age in days was $2.19 \pm 0.96$, the mean weight in kilograms was $2.92 \pm 0.43$, and the mean gestational week was $37.56 \pm 1.50$. The mean sound level in the NICU was $56.7 + 14$, which was higher than the NICU's recommended noise level. The most noise-generating events and equipment found in NICU were human-made noise and ventilator bubbling sounds. There was a significant difference in the mean behavioral score among neonates using earmuffs, as the "$p$-value was $< 0.05$." However, there was no association between pretest neonatal behavior with baseline data ($p > 0.05$).

**Conclusion** This study revealed that wearing earmuffs had a beneficial impact on enhancing newborn behavior.

**Keywords**
- newborn
- ear protective devices
- intensive care units
- neonatal
- neonatal behavior

## Introduction

The neonatal period is well-defined as the time between birth and 4 weeks after delivery. The risk of illness and mortality is highest during this stage of life. According to the United Nations International Children's Emergency Fund, there were 2.4 million neonatal deaths worldwide in 2019. Neonatal mortality is 21.7% in India as of 2019.[1] Neonatal intensive care units (NICUs) are commonly used to care for newborns requiring extraordinary medical assistance.

The contemporary NICU is a sophisticated facility with a wide range of advanced life-saving technology. Consequently, these enhanced technologies have resulted in additional sound and noise sources in the NICU, with various frequencies and intensities. A sudden, loud sound from outside sources commonly appears in the NICU. Noise pollution has raised the incidence of hearing loss in newborns.[2]

Several studies have shown that newborn exposure to extreme noise during this growing stage affects their auditory development and physiological instabilities, such as heart rate,

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blood pressure, oxygen saturation, an increase in intracranial pressure, and changes in corticosterogenesis.[3,4]

The American Academy of Pediatrics (AAP) environmental health committee has found that the newborn's hearing capacity has been harmed. The newborn's exposure to high levels of noise in the NICU influences his or her hearing issues and central nervous system development. The AAP advises that the noise level in the NICU be controlled below 35 decibels at night and 45 decibels during the day. However, several studies have found that the noise level in the NICU frequently surpasses the acceptable threshold.[5–8]

Intensive care aims to have intact survival with a normal brain, not just to survive or escape severe impairment. Noise has physiological effects on newborns, with both short- and long-term implications. NICU sound levels are considerably higher than recommended. [9]

Using earmuffs to reduce noise benefits preterm babies by increasing sleep efficiency and encouraging quiet sleep.[10] Hearing loss was found to be 7.69% in research, due to specific risk factors such as birth weight of <1,500 grams, hyperbilirubinemia, and APGAR scores of <4 at 1 minute or <6 at 5 minutes, as well as newborns who required mechanical breathing for more than 5 days.[11] A study recommended regular use of earmuffs to protect newborns from excessive noise, as the results indicated improvements in both physiological and motor responses.[12] This study aimed to explore the effectiveness of earmuffs to see changes in neonatal behavior and to measure the sources of sound and noise in the NICU.

## Materials and Methods

The study design was based on a preexperimental design (one group pretest and posttest design) conducted at a Mangalore hospital's NICU. The neonates admitted to the NICU were chosen using nonprobability and purposive sampling methods. The sample size for the present study was calculated by comparing the mean formulas. The sample size calculation was made manually and also by nMaster software. Using the nMaster software, the required sample size was 27 for a two-sided test at α 5%, the effect size was 0.5581, and the power was 80%.

Neonates with normal hearing ability, certified by neonatologists, gestational ages of 33 to 40 weeks, preterm neonates, and neonates under phototherapy were included in this study. This study excluded extremely low birth weight babies, neonates with congenital anomalies, congenital infections, and those on a ventilator/continuous positive airway pressure. An earmuff is a commercially available device (Iwinna safety earmuffs) that covers a neonate's ears and protects them from the harmful effects of sounds produced in the NICU environment. Single Number Rating (SNR) noise reduction for Iwinna safety earmuffs is 31 dB, while Noise Reduction Rating (NRR) is 26 dB. It has a low-profile design with two layers of professional noise-dampening foam ear cups, an over-the-head, separately packed, adjustable headband to fit a broader range of sizes, is lightweight and easy to store, and is durable and comfortable.

Neonatal behavior refers to the subsystem's changes according to the Synactive Theory of Infant Development. It includes physiological changes, motor changes, state behavior, and self-regulatory behaviors.[13]

This study was conducted in the 13-bed level III- NICU of a 1,000-bed multispecialty teaching hospital located approximately 16 kilometers from Mangaluru. The most common causes of neonatal NICU admission are low birth weight, birth asphyxia, neonatal sepsis, and jaundice. Every month, 20 to 30 neonates are admitted to the NICU.

### Description of the Tool

The six baseline variables were age in days, gender, weight, gestational age (in weeks), admission, and hospitalization stay. A dosimeter (sound level meter SL-4030) was used to record the sound levels, and the device was autocalibrated to traceable international standards. Every event and equipment were monitored for a week, and the Leq (the integrated mean sound level) was measured in decibels.

Earmuffs were applied over the newborns' ears to protect them from the harmful effects of NICU noise. An observational checklist was used to evaluate newborn behavior. A Synactive Theory was proposed for newborn development, which was utilized to create the study's observational checklist.[13] The newborn behavior checklist includes physiological parameters, motor behavior, state behavior, and self-regulatory behaviors. Physiological changes were measured by heart rate, respiratory rate, temperature, O2 saturation, and color changes. Motor changes were measured by flexed relaxed posture or arm salute, smooth movements or squirm, flaccid or limp, sitting on air, and toe slay. State behavior was measured by calm, alert and focused, deep sleep, active sleep or hypo-alert, gaze aversion, fussing and crying, upward gaze, and grimace. Self-regulatory behavior was measured by grasping, holding, sucking, foot clasping, tucking, looking, and attending. The observational checklist comprises 20 criteria that characterize newborn behavior, classified as organized or disorganized, under various subsystems. A newborn who displays organized behavior received a score of 1, whereas a neonate who exhibits disorganized behavior received 0. Based on neonatal behavior, the total maximum projected score was 20, and the median score of pre-test neonatal behavior was calculated from the newborn behavioral score. A score less than the median indicates disorganized newborn behavior, whereas a score more than the median indicates organized neonatal behavior.

It was sent to 13 specialists for review to ensure the tool's content validity. The baseline variables had a content validation index of 0.94. In contrast, Tool 1—NICU sound level had a content validation index of 1, and Tool 2—observation checklist on newborn behavior had a content validation index of 0.95. The internal consistency of the observational checklist was estimated using Cronbach's alpha and found to be reliable with a "*r*" value of 0.86. The stability of the observational checklist was assessed using the test–retest method with five samples, where the tool was administered on two consecutive mornings. The stability was assessed using Karl

Pearson's correlation coefficient and found reliable with an "*r*" value of 0.87.

The researcher filled in the baseline variables from the case file. Each neonate was observed for a half hour, and the researcher completed a pretest by filling out an observation checklist. Following the pretest, the neonates donned the earmuffs for 3 days, 2 hours in the morning and 2 hours in the evening. After 30 minutes of therapy, a posttest was conducted. The investigator conducted the pretest, whereas the follow-up assessment was administered by a nurse employed in the NICU. SPSS software version 20 was used for statistical analysis.

### Ethical Considerations

The scientific and institutional review boards have granted endorsement of this study proposal. The approval number of IRB is grant N/RG/NUFR2/NUINS/02002. The hospital granted formal permission to undertake the study. The study's objective was communicated to the 27 neonatal parents, and their anonymity and agreement to participate in the data collection procedure were ensured.

## Results

### Baseline Characteristics

The neonates in the research were all between the ages of 1 and 7 days, according to their baseline characteristics (100%). Males comprised 66.7% of the newborns, while females constituted 33.3%. In total, 95.2% of the neonates weigh between 2.5 and 4 kilograms, whereas 3.7% weigh between 1.5 and 2 kilograms. With gestational ages ranging from 37 to 40 weeks, 74.1% of the neonates were hospitalized owing to jaundice (74.1%). In total, 81.5% of newborns were admitted to the hospital within 4 to 6 days. The mean age in days was $2.19 \pm .96$, the mean weight in kilogram was $2.92 \pm .43$, and the average gestational week was $37.56 \pm 1.5$.

### Sound/Noise Level and Sources of Noise in the Neonatal Intensive Care Unit

The mean sound level in the NICU was $56.7 \pm 14$ dB, which was higher than the NICU's recommended noise level. The NICU's main noise-producing activities and devices were human-made noise and ventilator bubbling (►**Table 1**).

The events and equipment in the NICU produce noises over the recommended threshold. The combined noise produced by human actions, such as cleaning crew sound and conversation around the bedside, was determined to be the loudest ($77.4 + 65 = 142.4$ dB), followed by ventilator noise (74.8 dB).

### Assessment of Neonatal Behavior

The average mean and standard deviation of newborn activity in the subsystems before and after intervention indicates a continuous increase in mean + SD from pretest to posttest for all subsystems from day 1 to day 3 (►**Table 2**).

### Effects of Earmuff Application on Neonatal Behavior

The researcher used the Wilcoxon signed rank test to quantify the influence of earmuffs on neonate behaviors, as the normal distribution of data was determined with the Shapiro–Wilk test.

All of the "*p*" values are less than 0.05, indicating a significant difference in the newborn behavioral score before and after each session with the earmuff (►**Table 3**). So the study hypothesis H1 is accepted at a significance level of 5%.

Fisher's exact test was performed to determine a relationship between all baseline characteristics (gender, gestational week, weight in kilograms, and duration of hospitalization) and newborn behavior. No association was identified with "*p*" values $> 0.05$, indicating that the study hypothesis (H2) is not acceptable at the 5% significance level.

**Table 1** Difference of noise level from normal (dB) with the estimated sound levels from various events and equipment's in NICU

| Sl. No | Events/equipment | Sound level (dB) | Difference of noise level from normal (dB) |
|---|---|---|---|
| 1 | Cardiac monitor alarms | 65.7 | 20.7 |
| 2 | Bubbling sound of ventilator/CPAP circuit | 74.8 | 29.8 |
| 3 | Conversation around the bedside | 65 | 20 |
| 4 | Telephone ring | 53 | 8 |
| 5 | Closing of doors | 45.6 | 0.6 |
| 6 | Closing of incubators doors | 55 | 10 |
| 7 | Tasks of cleaning crews | 77.4 | 32.4 |
| 8 | Ambient noise | 65.9 | 20.9 |
| 9 | Opening of doors | 43.6 | Within the normal decibel |
| 10 | Suctioning | 40 | Within the normal decibel |
| 11 | SpO2 monitor | 37.2 | Within the normal decibel |
| NOTE** Mean sound level | | $56.65 \pm 14$ | |

Abbreviations: dB, decibel, CPAP, continuous positive airway pressure; NICU, neonatal intensive care unit.

**Table 2** Assessment of neonatal behavior before and after intervention

| Subsystem | | | Pretest Mean ± SD | Posttest Mean ± SD |
|---|---|---|---|---|
| **DAY1**<br>**DAY2**<br>DAY3 | Morning | Physiological parameters | 4.04 ± 1.43 | 4.70 ± 0.67 |
| | | Motor behaviors | 3.56 ± 0.89 | 3.85 ± 0.53 |
| | | State behaviors | 2.11 ± 1.31 | 2.48 ± 1.12 |
| | | Self-regulatory | 4.26 ± 2.31 | 6.37 ± 1.55 |
| | Evening | Physiological parameters | 4.52 ± 0.85 | 4.89 ± 0.42 |
| | | Motor behaviors | 3.48 ± 0.98 | 4 ± 0.00 |
| | | State behaviors | 1.85 ± 1.35 | 2.96 ± 0.19 |
| | | Self-regulatory | 3 ± 1.69 | 5.48 ± 2.41 |
| | Morning | Physiological parameters | 4.33 ± 1.14 | 4.93 ± 0.27 |
| | | Motor behaviors | 3 ± 1.64 | 3.96 ± 0.19 |
| | | State behaviors | 2.07 ± 1.33 | 2.89 ± 0.58 |
| | | Self-regulatory | 2.85 ± 2.54 | 4.74 ± 2.51 |
| | Evening | Physiological parameters | 4.52 ± 0.85 | 4.89 ± 0.32 |
| | | Motor behaviors | 3.19 ± 1.47 | 3.96 ± 0.19 |
| | | State behaviors | 2 ± 1.36 | 2.78 ± 0.80 |
| | | Self-regulatory | 3.44 ± 2.24 | 4.85 ± 2.23 |
| | Morning | Physiological parameters | 4.9 ± 0.32 | 4.96 ± .19 |
| | | Motor behaviors | 3.96 ± 0.19 | 3.96 ± .19 |
| | | State behaviors | 2.74 ± 0.81 | 2.89 ± .58 |
| | | Self-regulatory | 3.30 ± 2.73 | 4.52 ± 2.62 |
| | Evening | Physiological parameters | 4.74 ± 0.86 | 5 ± .00 |
| | | Motor behaviors | 3.85 ± 0.60 | 4 ± .00 |
| | | State behaviors | 2.39 ± 0.97 | 2.96 ± .19 |
| | | Self-regulatory | 2.62 ± 2.45 | 5.11 ± 2.15 |

Abbreviation: SD, standard deviation.

**Table 3** Effects of earmuff application on neonatal behavior within the group using the Wilcoxon signed-rank test

| | | | | | $n = 27$ |
|---|---|---|---|---|---|
| **Newborn behaviors** | | **Median** | **IQR** | **Z-value** | **"*p*"-Value** |
| Day 1 | Pretest 1 (M) | 15 | 12–17 | −3.29 | 0.001* |
| | Posttest1 (M) | 18 | 16–20 | | |
| | Pretest 2 (E) | 13 | 10–15 | −3.82 | 0.000* |
| | Posttest 2 (E) | 18 | 16–20 | | |
| Day 2 | Pretest 3 (M) | 13 | 9–14 | −4.05 | 0.000* |
| | Posttest 3 (M) | 17 | 13–18 | | |
| | Pretest 4 (E) | 13 | 10–16 | −3.35 | 0.001* |
| | Posttest 4 (E) | 18 | 13–18 | | |
| Day 3 | Pretest 5 (M) | 14 | 13–18 | −2.3 | 0.021* |
| | Posttest 5 (M) | 17 | 13–19 | | |
| | Pretest 6 (E) | 13 | 13–14 | −3.98 | 0.000* |
| | Posttest 6 (E) | 18 | 16–18 | | |

Abbreviations: E, evening; IQR, interquartile range; M, morning.
*$p < 0.05$.

## Discussion

This study aimed to see how earmuffs influenced neonates' behavior in the NICU. The neonates were between 1 and 7 days old (100%). More than half of the neonates (66.7%) were males. A similar study also reported that the majority (61%) of the neonates were male.[14]

Most neonates (95.2%) weigh 2.5–4 kilograms, while 3.7% weigh 1.5-2 kilograms. Many authors have expressed that India's average birth weight is 2.5–4 kg.[15,16]

### The Noise Level in the Neonatal Intensive Care Unit

The NICU's mean sound level is $56.7 \pm 14$ dB, higher than the NICU's prescribed noise level. The NICU's most noise-generating activities and devices were human-made noise and ventilator bubbling noises. A similar result in a study indicates that the sound level is higher than the AAP's recommended value. [17] This is consistent with a similar study that have reported that clinical conversations increased noise levels in the newborn intensive care unit. [8]

A study identified the noise level and sources in the NICU, which is congruent with the present results.[6] The findings of this analysis are comparable to those of a study conducted in the NICU to evaluate the sound intensity and identify the noise sources. The researchers also believe nurses in the NICU can control conversation noise (mean level 59–90 dB) and alarm devices (55–85 dB). [18] According to the findings of a study, the average hourly sound level (Leq) in the NICU was $60.66 + 2.99$ dBA.[19]

### Effect of Earmuff Application on Neonatal Behavior within the Group

The current study results revealed a significant change in the behavioral score of the newborn while using earmuffs, with a $p$-value of $< 0.05$. A study examined the influence of earmuffs on physiological parameters in newborns in an NICU and found similar results. The findings showed a significant change in mean temperature, heart rate, and sleep pattern ($p < 0.001$). [20]

Furthermore, a randomized trial study investigating the efficacy of earmuffs on preterm infants' physiologic and behavioral stability discovered a significant correlation between infants wearing earmuffs and lower heart and respiration rates ($p < 0.05$). [14] Clinical trial research done in Iran investigating the effect of earmuffs on neonates' physiologic and motor responses in the NICU corroborates the findings. [12]

The current study revealed that utilizing commercially available earmuffs is worthwhile, does not require any clinical expertise, and that no indication of organ damage has been identified due to wearing earmuffs.

### Limitation

It included a small sample size, no control group, data collected from only one NICU, and no attempt to follow up after 3 days to assess the effect of earmuffs.

### Recommendation

Health care workers should take the initiative to reduce noise levels during procedures, place monitor alarms with blinking lights, and cleaning crews should do their jobs quietly by carefully handling the devices. Professionals discuss neonatal conditions with experts and parents in separate rooms.

## Conclusion

The high level of noise exposure of the newborn in the NICU impacts the hearing problem and the development of the CNS. The study showed that earmuffs have a positive impact on the improvement of neonatal behavior. The mean sound level in the NICU is $56.7 \pm 14$, which is more than the NICU's recommended noise level. There was a significant difference in the mean behavioral score among neonates using earmuffs, as the $p$-value is $<0$ .05. There is, therefore, a greater commitment required for NICU professionals to use different strategies to improve overall neonatal health.

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Conflict of Interest
None declared.

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