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# Reduction of Environmental Noise Impact on Preterm Babies in NICU by Using Ear Plugs

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**Abstract**

**Objective** – To determine if using ear plugs reduce the impact of noise on preterm babies admitted to neonatal intensive care units in terms of changes in their vital parameters and their discomfort level, assessed using the Neonatal Infant Pain Scale (NIPS) score. **Materials and Methods** – This is an interventional study conducted in a tertiary level neonatal intensive care unit (NICU) (Bangalore, India) over a period of 3 months, ranging from June 2022 to September 2022. This study included 20 preterm babies with different gestational ages and birth weights who were admitted to the NICU during that period. The babies' response to noise, in terms of changes in heart rate, respiratory rate, blood pressure, oxygen saturation and discomfort level, were assessed with ear plugs and without ear plugs on alternate days and the results were recorded. Descriptive statistics were used for statistical analysis. **Results** – On days 1 and 3, mean heart rate and systolic blood pressure were lower in babies wearing ear plugs (141.55±2.42 SD and 60.1±11.58, respectively) than in the same babies without ear plugs (157.55±2.52 SD and 61.85±1.6 SD, respectively) on days 2 and 4. The mean oxygen saturation was higher in babies wearing ear plugs (96.7%±0.80 SD) than in the same babies without the intervention (93.75%±1.29 SD). The mean NIPS score was lower with the intervention (2.05±0.22) than without ear plugs (5.05±0.22 SD). **Conclusion** – Ear plugs were an effective alternative in situations where noise in the NICU cannot be consistently maintained at a lower level than the standard recommendation by the AAP of 45 decibels.

**Key Word:** Preterm ▪ Tertiary NICU ▪ Noise Reduction ▪ Ear Plugs.

## Introduction

In preterm babies especially excessive noise is known to cause instability in heart rate, blood pressure and saturation in the short term, and hearing loss, abnormal sensory development, and speech and language issues in the long term (1, 2). The recommended noise levels for preterm babies, according to the American Academy of Paediatrics (AAP), is 45 decibels or less (3). The usual noise level in neonatal intensive care units ranges anywhere from 25 to 90 decibels (4). Preterm babies lack protective hearing mechanisms, such as the Stapedial reflex, background noise masking, frequency ceilings, unlike adults, hence they are vulnerable to noise-induced hearing damage. Functionally, the cochlear amplification process is higher in newborns, especially in preterms, when compared to adults, so most sounds are amplified and heard by these babies.

There is no frequency ceiling in neonates, so they hear higher frequency sounds than adults. Background noise masking, which is seen in adults, is also absent in babies so a preterm baby's brain hears all sounds equally, thus constantly responding to background noise as well. The stapedial reflex, which is a protective reflex in adults, is not well formed in neonates, making them vulnerable to noise induced hearing damage. Preterm babies are unable to self-regulate their autonomic responses and stress responses to environmental stimulation, which can result in apnoea, desaturation,



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hypoxemia, reduced weight gain, an increase in intra cranial pressure, and behavioural effects in babies, such as altered sleep patterns, neuro endocrine effects and reduced immunity (5, 6, 7).

Since controlling environmental noise without breaching the set level of 45 decibels standard is difficult, individual hearing protection from noise may be a more feasible option. Although exposure to noise is harmful to preterm babies, exposure to meaningful sounds is essential for the development of hearing and understanding of language later in life, so completely blocking all sound will interfere with the baby's development (8). Individual noise protection devices are promising, and include earmuffs and ear plugs which are placed in the babies' ears constantly and reduce noise levels by at least fifteen to thirty decibels compared to the environment.

Since earmuffs are difficult to use in babies who are being ventilated or on continuous positive airway pressure (CPAP) support with CPAP caps and prongs, and attachments, due to their large size, and the chance of displacement is very high, ear plugs were chosen. There is already one major study by Abou Turk et al. that was performe**d** using ear plugs which showed better results in preterm babies wearing ear plugs, and this research project was devised on this basis (9).

Our study aimed to explore the effect of ear plugs in reducing the impact of environmental noise in preterm babies admitted to the neonatal intensive care unit (NICU) in a developing country, without modification of the background environment.

## Methods

This was a research project conducted in a tertiary level neonatal intensive care unit (Bangalore, India) over a period of 3 months, ranging from June 2022 to September 2022. We opted for a Quasi-Experimental study design. The Patient Intervention Comparison Outcome (PICO) model was used in the study. Inclusion criteria for study were Preterm (<37 weeks) babies of different gestational ages and birth weight. Exclusion criteria included preterm babies with congenital anomalies, birth asphyxia, NEC, seizures and babies who were on mechanical ventilation (Ventilators, CPAP, HHFNC), in incubators, sedation, drugs which affect hearing such as amino glycosides, and those on ionotropic support and term babies (defined as babies born after completion of 37 weeks) were excluded from the study. Those babies whose parents did not give consent for the study were also excluded.

Twenty-four preterm babies were included in the study after obtaining informed and written consent from the parents, but of these two babies dropped out as they were moved to their mother's side before completion of the four-day study period. Two more babies were excluded as the parents did not want to remove the ear plugs and wanted their babies to continue wearing the ear plugs all through their stay in the NICU. Hence, a total of 20 preterm (<37 weeks) babies of different gestational ages and birth weight completed the study (Fig. 1). Out of the twenty babies studied the genders were equally distributed as 10 babies were females and 10 babies were males (Table 1).

Twenty preterm babies, with varying gestational ages and birth weights, completed the study, Genders were equally distributed as 10 male and 10 female babies.

Our NICU is an open NICU with cradles and open warmers for stable preterm babies on one side, and unstable and sick babies on the opposite side. The walls are concrete with no sound proofing and with wooden doors. Only stable preterm babies who were feeding and growing were included in the study, and any babies who required acute NICU care were excluded.

These babies had ear plugs placed on them one hour before admission to the unit. The ear plugs used were made of silicone, and were mouldable and hypoallergenic, with strings attached to them. The strings were taped with a sticky tape (micropore) to the caps the babies were wearing. The noise reduction offered by the ear plugs used in this project, as mentioned by the manufacturer, is 32 decibels and the minimum noise reduction was 16 decibels less than the environmental noise. Thus,

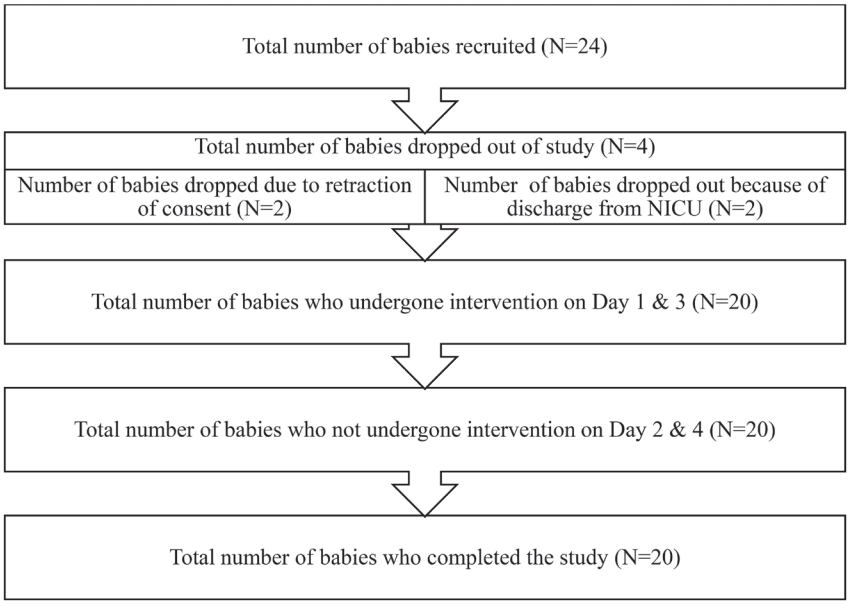


**Fig. 1.** *Flowchart of participants.*

Table 1. Demographic Characteristics of Preterms Included in the Study

| Number of preterm babies | Sex | Gestational age (weeks) | Birth weight (grams) |
|---|---|---|---|
| Baby 1 | Female | 29 | 980 |
| Baby 2 | Male | 29+5 | 1010 |
| Baby 3 | Male | 30+6 | 1240 |
| Baby 4 | Female | 31+3 | 1320 |
| Baby 5 | Male | 31+5 | 1460 |
| Baby 6 | Female | 32+4 | 1500 |
| Baby 7 | Female | 32+5 | 1580 |
| Baby 8 | Female | 32+6 | 1700 |
| Baby 9 | Male | 33 | 1690 |
| Baby 10 | Male | 33+2 | 1730 |
| Baby 11 | Male | 33+4 | 1810 |
| Baby 12 | Female | 33+5 | 1840 |
| Baby 13 | Male | 34 | 1860 |
| Baby 14 | Male | 34+1 | 1750 |
| Baby 15 | Male | 34+4 | 1900 |
| Baby 16 | Female | 31+6 | 1640 |
| Baby 17 | Female | 34+2 | 1720 |
| Baby 18 | Female | 30+4 | 1550 |
| Baby 19 | Male | 35+2 | 1980 |
| Baby 20 | Female | 36 | 2100 |

they did not completely block exposure to meaningful sounds which are essential for the development of hearing and understanding of language later in life.

The babies were studied over different times of the day and night at two hourly intervals for four days, and the data were recorded every two hours. The babies were studied on day 1 and day 3 with ear plugs inserted to reduce the noise impact, and the same babies were studied on day 2 and day 4 without the ear plugs. The data were considered as with intervention and without intervention. The total study period for each baby was 96 hours. There were no matched controls used as the same babies served both as test subjects and controls.

A Noise Dosimeter was used in this study, which was fixed to the wall. Every two hours before recording the babies' heart rate, SPO2, respiratory rate, blood pressure and Neonatal Infant Pain Scale (NIPS) scoring, the noise level in decibels as seen from the dosimeter was recorded and documented. NICU Nurses were trained by the authors in documenting vital parameters in Excel sheets, and also how to use the NIPS scoring chart. The vital parameters (heart rate, oxygen saturation, and systolic and diastolic blood pressure) were recorded by the nurse from the wall mounted cardiorespiratory monitors every two hours and recorded in an excel sheet. Discomfort level was also scored using the NIPS scoring, which is usually used in surgical babies to assess post operative pain. The recording was done at two hourly intervals as the babies were fed and cared for every two hours by the nurses, and the data collection coincided with the routine nursing care. The data were collected post feed as hunger may interfere with the NIPS score and confound the results.

### *Ethics Statement*

The procedures used in this research study were in accordance with the Declaration of Helsinki from 1975, and its amendments from 1983. This Research study was approved by the scientific research committee and ethics committee of the primary author's institution (Aster CMI Hospital) - Aster/IEC/001/2022-2023.

### *Statistical Analysis*

The data were entered into Microsoft Excel and analysed using SPSS software version 28. Descriptive statistics were used, results were expressed as percentages and the paired t-test was used for testing the significance differences in the interventions. A P-value of <0.05 was considered to be significant.

## Results

Out of the twenty babies studied the genders were equally distributed as 10 babies were females and 10 babies were males. The gestational age of the babies studied ranged between 29 weeks to 36 weeks. The mean gestational age of the babies studied was 32.62 weeks. The birth weight was measured in grams, and babies belonging to the study population ranged from 980 grams to 2100 grams, and the mean birth weight of the babies studied was 1618 grams.

### *Vital Parameters Studied*

The mean heart rate in the group of babies wearing the ear plugs and studied on days 1 and 3 was 141.55±2.42 SD, whereas the mean heart rate in the babies not wearing the ear plugs studied on days 2 and 4 was 157.55±2.52 SD. The t - statistic value was – 20.840 and the P-value was <0.001. The mean systolic blood pressure (60.1±11.58) in babies wearing ear plugs and studied on days 1 and 3 was lower than the mean systolic blood pressure (61.85±1.6 SD) in the babies when not wearing the ear plugs studied on days 2 and 4. The mean diastolic blood pressure on the days with ear plugs (days 1 and 3) was 35.55 mm Hg±3.41 SD. The mean diastolic blood pressure on the days without ear plugs (days 2 and 4) was 39.45 mmHg±2.86 SD. The t-statistical value was -9.518. The P-value for the systolic blood pressure was <0.001 and for the diastolic blood pressure the P-value was also <0.001. The mean oxygen saturation (96.7%±0.80 SD) in the group of babies wearing ear plugs and studied on days 1 and 3 was higher than the mean oxygen saturation (93.75%±1.29 SD) in the babies when not wearing the ear plugs studied on days 2 and 4. The t-statistic value was 15.98. The P-value was <0.001 (Table 2) (Fig. 2.)

### *NIPS Score*

The mean NIPS score was 2.05±0.22 with the intervention and the mean NIPS score was 5.05±0.22 without the intervention. The t – statistical value was -41.352 and the P-value was <0.001.

Table showing the variations in vital parameters and NIPS scores of Preterm babies subject to the intervention (ear plugs) and with no intervention. The Chi-square test was used to obtain P-values

Variations in vital signs and NIPS scores in the preterm babies over the four-day study period, along with the corresponding environmental noise levels were depicted using a Bar diagram. Interventions (ear plugs) were implemented on Days 1 and 3, with no interventions on Day 2 and Day 4

Table 2. Vital Parameters and NIPS* Score with and without Intervention (Ear Plug).

| Vital parameter | With Ear Plugs ($\bar{x}$±SD) | Without Ear Plugs ($\bar{x}$±SD) | P-value† |
|---|---|---|---|
| Mean Heart rate | 141.55±2.42 | 157.55±2.52 | <0.001 |
| Mean Oxygen saturation | 96.7±0.80 | 93.75±1.29 | <0.001 |
| Mean Systolic Blood Pressure | 60.1±11.58 | 61.85±1.60 | <0.001 |
| Mean Diastolic Blood Pressure | 35.55±3.41 | 39.45±2.86 | <0.001 |
| NIPS score | 2.05± 0.22 | 5.05±0.22 | <0.001 |

*Neonatal Infant Pain Scale; †P values were obtained on the basis of Chi square test.

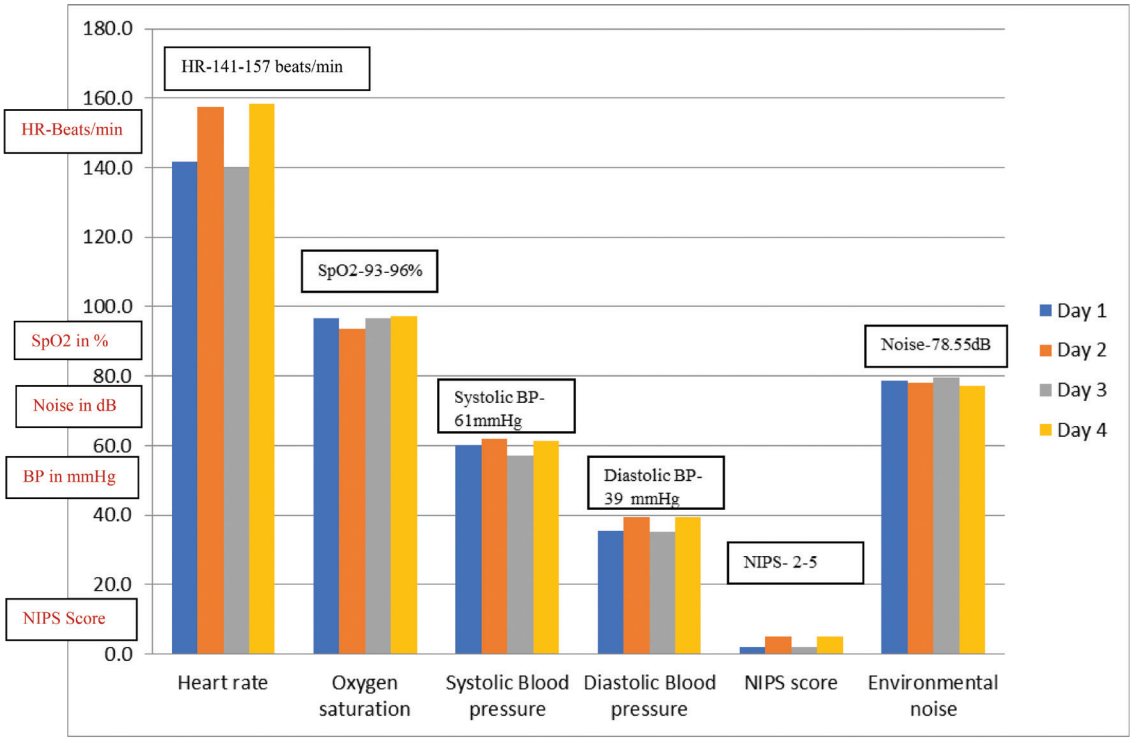


**Fig. 2.** *Variation of vital signs from Day 1 to Day 4.*

## Discussion

Our study aimed to examine whether the use of ear plugs could mitigate the detrimental effects of noise on preterm babies in NICUs, as measured by changes in their vital parameters, and to evaluate their comfort level using the NIPS score. Encouragingly, the findings revealed that the use of ear plugs could potentially be an effective strategy to reduce the negative impact of noise on preterm babies' vital parameters and comfort levels.

Only a limited number of studies have explored the impact of noise reduction in the NICU on neonates. Notably, Abdeyazdan et al. (10) and Abujarir et al. (11) employed earmuffs as a noise-reduction measure within the NICU setting. However, it is important to consider the practical challenges associated with using earmuffs in conjunction with interventions such as Continuous Positive Airway Pressure (CPAP) and various other ventilatory modalities. Furthermore, we observed the utilization of earplugs for noise reduction in the NICU, a method employed by Abuo Turk et al. Subsequently, concerns arose regarding safety hazards if earplugs were to fall off the baby's ear. To address this issue, we developed an effective method by securing the ear plug strings to the caps that the babies were wearing using micropore tape (9, 10, 11)

In this study, silicone ear plugs were used that were mouldable and hypoallergenic. According to the manufacturer, the ear plugs used in this study can achieve a sound attenuation of a maximum of 32 decibels and a minimum of 16 decibels. These standards are consistent with a pioneering study done by Abou Turk et al. in the United States, which used silicone ear plugs to achieve a sound attenuation of >7 decibels for preterm new-borns (9). The findings of our study indicated a significant decrease in the mean heart rate between the group of preterm babies who wore ear plugs, when compared to the group who did not. These results align with a similar study conducted by Abdeyazdan et al. in Iran using earmuffs for preterm babies, further supporting the potential effectiveness of ear plugs in reducing the impact of noise on preterm babies admitted to the NICU (10).

The results of our study showed a significant decrease in the mean systolic and diastolic blood pressure between the group of preterm babies who wore ear plugs, when compared to the group who did not. These findings are interesting because they differ from a similar study conducted by Rawia et al. in Qatar, which used earmuffs instead of ear plugs for preterm babies admitted to the NICU, where it showed improvement only in systolic BP but not diastolic BP. It is possible that the more targeted and precise protection provided by ear plugs was more effective in reducing blood pressure in preterm babies (11).

In the present study, it is evident that there was a significant increase in mean oxygen saturation levels and less fluctuation in preterm babies who had ear plugs compared to when they did not have ear plugs. These findings align with the results of the previous study conducted by Zahr et al. (2) which demonstrated a similar increase in oxygen saturation levels when ear muffs were used in preterms. It is noteworthy that there was a significant reduction in mean NIPS score in the preterm babies who wore ear plugs when compared to preterms who did not.

## Conclusion

The adverse effects of excessive noise on preterm newborn babies have been well documented, and it is essential to achieve noise control in all NICUs without blocking the normal sounds necessary for a baby's development. This study has shown that the use of ear plugs can significantly improve vital parameters, such as heart rate, oxygen saturation, blood pressure, and NIPS score in preterm babies with the use of ear plugs. Further research is needed to establish a comprehensive and widely applicable protocol for noise prevention in the neonatal intensive care setting for preterm babies.

**Authors' Contributions:** Conception and design: PT, MJ; Acquisition, analysis, and interpretation of data: PT, MJ; Drafting the article: PT, MJ; Revising it critically for important intellectual content: PT, MJ; Approved final version of the manuscript: PT, MJ.

**Conflict of Interest:** The authors declare that they have no conflict of interest.

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