

Original Research Article

Randomized control trial evaluating the effectiveness of ear plugs in hearing loss in NICU preterm babies

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ABSTRACT

Background: The prevalence of hearing loss is higher in neonates admitted to NICU compared to the general population. Preterm babies are more vulnerable to the hearing damage due to their immature inner ear exposing them to various high frequency noises in the NICU to which they were not accustomed. Most NICU in India exceed the recommended sound levels. In order to reduce damage to the ears, foam-based earplugs are used to reduce the sound intensity reaching the ears of these premature babies.

Methods: Babies admitted to NICU are allocated alternatively to receive earplugs or not. Cases are preterm babies with earplugs and controls are the ones without earplugs. The incidence of hearing loss is found by OAE testing of the ears at the end of NICU stay.

Results: Out of 40 in each group, 6 babies in control group failed the OAE compared the 3 in the earplug group. Babies who did wear earplugs had longer period of NICU stay.

Conclusions: Use of earplugs in babies admitted to NICU reduced the incidence of hearing loss and also length of NICU stay.

Keywords: Hearing loss, Neonatal intensive care unit, Preterm babies, Otoacoustic emissions

INTRODUCTION

The sensory neurons of a preterm baby is not fully developed, hence they are highly sensitive to sound levels in the neonatal intensive care units. Most of the NICUs exceed the sound levels recommended by the American academy of Pediatrics (45 dB).^{1,2} In India, noise levels in NICU ranges from 60 to 90 Db.³ Hence the prevalence of hearing loss is found to be 10 times higher in those neonates who were admitted to NICU compared to the neonates in the general population.⁴

Foetus is only exposed to low intensity sounds in the uterus of the mother.⁵ When they are born prematurely, the fragile cochlea of the baby gets exposed to high frequency sounds in the NICU. Louder the noise, more

the number of cochlear hair cells are stimulated causing vigorous vibrations of the basilar membrane of the outer hair cells resulting in structural damage.⁶ Sound level of 68 dB can adversely impact the hypothalamic pituitary axis of the newborn which leads to disturbances in the vital parameters of the baby.⁵ High intensity sounds release stress hormones, cortisol in the newborn which further deteriorates the vital parameters of the sick infant in NICU.⁶

Cochrane Database Systemic Review compared the effect of earplugs on the growth and neuro developmental outcome for the NICU babies. There were no studies that compared the use of earplugs on the hearing loss of NICU graduates.^{7,8}

Aim of the study is to evaluate whether the use of earplugs in the preterm babies admitted to NICU reduces the incidence of hearing loss and length of NICU stay.

METHODS

Single centered, pilot randomized control study was done in AJ institute of Medical Science, Mangalore in the department of Pediatrics. Data was collected from January 2019 to December 2019. Preterm babies with birth weight between 1.5 kgs to 2.5 kgs admitted to NICU for 4 or more days were included in the study.

A detailed systemic examination: relevant investigations and treatment for their disease will be instituted and monitored. After initial stabilization of the baby received into the NICU and recording their birth weight, the babies were selected alternately to receive earplugs. The external ears of the cases were inspected. Depending on the size of the external auditory meatus, foam-based ear plugs were cut with the help of sterile scissors. They were moulded in order to insert into the auditory meatus of the preterm baby. Those babies who stayed for more than 4 days were included in the study Cases and control were randomized alternately and grouped into cases (preterm babies with earplugs) and controls (preterm babies without earplugs). 40 cases versus 40 controls were compared statistically.



Figure 1: Foam based earplugs.

Inclusion criteria

- Preterm babies who are admitted to NICU of AJIMS for 4 or more days were included in the study to compare the effectiveness of earplugs on OAE tests.
- Only preterm (<38 weeks) babies with birth weight less than 2.5 kgs were included.

Exclusion criteria

- Those with congenital infections associated with hearing loss and those with cranio- facial or otological abnormalities.

Earplugs were worn continuously except for medical or social reasons (parental visits). Nursing staff were taught

to mould and insert the earplugs into the babies’ ear canal.

Ear plugs used are uncorded foam-based ear plugs which has NRR (noise reduction rate) of 29 dB and SNR (signal to noise ratio) of 37 dB.

Demographic details were taken and compared. Hearing was tested by oto- acoustic emission test done on the day the newborn was discharged from the NICU.

Data was entered into excel sheet and cases and controls were compared statistically using IBM SPSS version 25. p value less than 0.05 was considered statistically significant.

RESULTS

Out of 80 babies included in the study conducted in the NICU, there were 40 cases (neonates who wore the foam earplugs) and 40 did not wear earplugs. 44 were males and 36 were females.

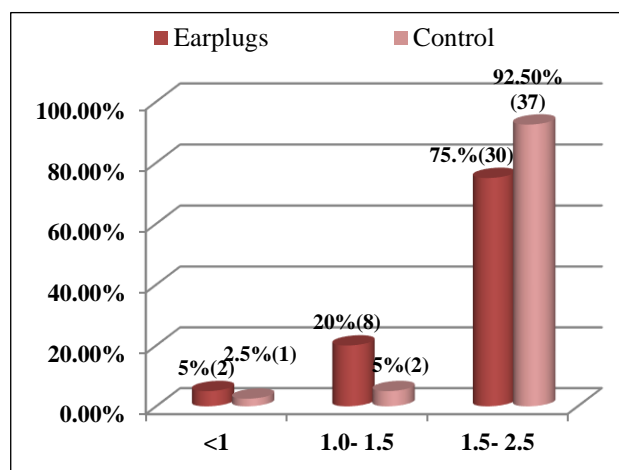


Figure 2: Distribution based on birth weight.

Out of 80 babies included in the study, majority 67% were low birth weight (1.5 to 2.5 kgs); 12.5% were very low birth weight (1 to 1.5 kgs) and 3.8% were extremely low birth weight (<1 kg).

In the group with earplugs, there were 30 babies who were LBW, 8 (5%) were VLBW and 2 were ELBW. Whereas, in the control group, there were 37 babies LBW, 2 were VLBW and 1 was ELBW. The data-based birth weight was similar in both groups. The earplugs group had a slightly higher incidence of VLBW (Figure 2).

According to the gestational age (Figure 3), only 16% (13) were less than 32 weeks of the total. Both earplugs and the control group had similar demography based on gestational age i.e. 6 vs. 7 babies were less than 32 weeks and 34 vs 33 babies were between 32- 38 weeks (Figure 3).

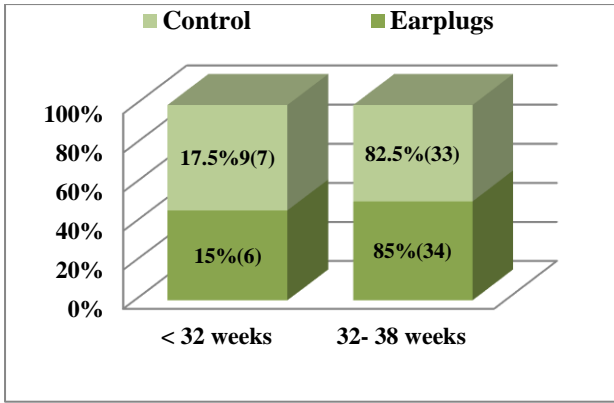


Figure 3: Distribution based on gestational age.

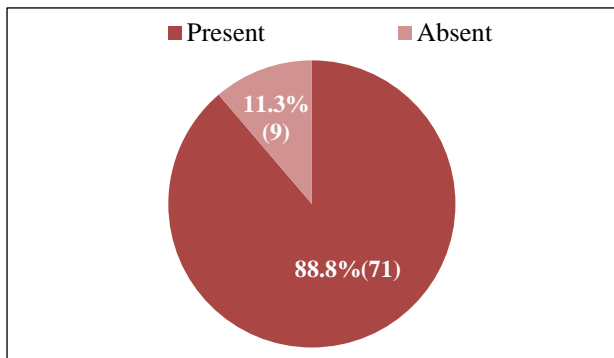


Figure 4: Based on OAE tests.

In figure 4, 11.3% that is 9 out of 80 babies failed the OAE screen.

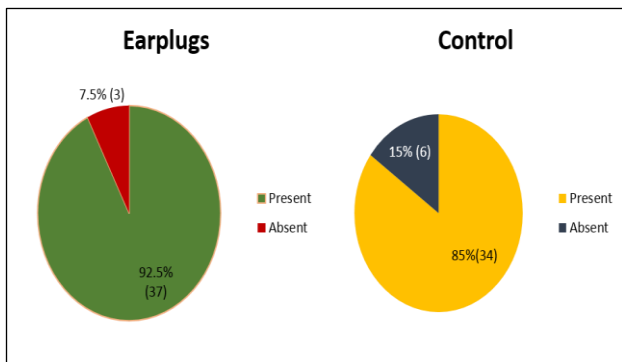


Figure 5: Distribution based on OAE tests.

Based on the figure 5, considering the group with earplugs, only 3 (7.5%) failed the OAE compared to 6 (15%) in the control group. Hence there was twice the incidence of hearing loss in the control group compared to earplug group. The earplugs could have protected the babies from extra noise causing hearing damage. p value was 0.28 which was not statistically significant due to the small sample size.

In Figure 6, it shows that the babies who did not wear earplugs had longer duration of stay in the NICU

compared to those babies who wore earplugs. 40% of the babies in the earplugs group stayed for 4-7 days and another 40% for 7-14 days. Only 2.5% in the earplugs group stayed for more than 22 days as compared to 27.5% in the control group. p value being 0.01 was statistically significant.

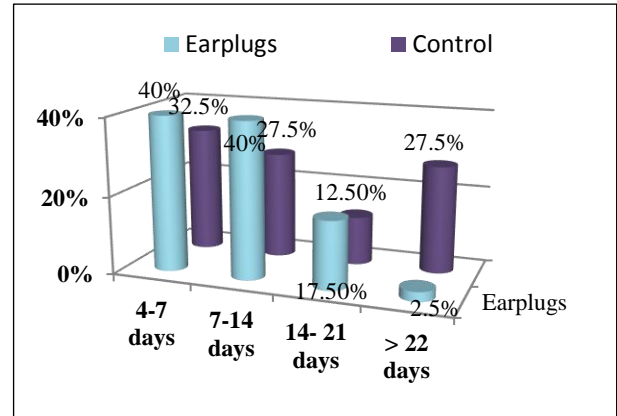


Figure 6: Correlation between use of earplugs and duration of NICU stay.

DISCUSSION

The incidence of hearing loss based on OAE testing was much lower in the group of neonates who wore the foam-based earplugs compared to the control. There was at least 50% reduction in the incidence of hearing loss with this intervention. Although statistically p value is 0.28 which was not significant, larger studies are required to compare the effectiveness of earplugs on the hearing of the preterm neonates.

Also, babies with earplugs had a shorter duration of stay in the NICU. As reduction in the sound levels reaching the neonates' ear, caused better stabilization of the vital parameters and noise induced stress in the babies. This is similar to the study done by Abujarir R et al, and Parmar et al, in Maharashtra, India where earmuffs were used to protect the hearing of the newborn babies in NICU.^{9,10}

Another study done by Litton E et al, concluded that newborns who wore earplugs had better quality of sleep.¹¹

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Ethical approval: The study was approved by the Institutional Ethics Committee

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