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A Randomized Clinical Trial Evaluating Silicone Earplugs for Very Low Birth Weight Newborns in Intensive Care

Chirine A. Abou Turk, MD[1], **Amber L. Williams, MS**[2], and **Robert E. Lasky, PhD**[2]

[1] Pediatric Group of Acadiana, New Iberia, LA, USA

[2] University of Texas Medical School at Houston, Center for Clinical Research and Evidence-Based Medicine, Houston, TX, USA

Abstract

Objective—Determine whether very low birth weight (VLBW) newborns (<1500 g) wearing silicone earplugs grow larger and perform better on developmental exams than controls.

Study Design—VLBW newborns (n=34) were randomized to wearing earplugs or not. Hospital outcomes were abstracted from medical charts by research staff masked to intervention status. Fourteen extremely low birth weight (ELBW) newborns (<1000 g) were also evaluated at 18−22 months.

Result—After adjusting for birth weight, 11 surviving newborns in the earplug group were 225 g (95% CI: 45, 405) heavier at 34 weeks post-menstrual age than the 13 controls. Six ELBW earplug infants scored 15.53 points (95% CI: 3.03, 28.02) higher than 6 controls on the Bayley Mental Development Index. Their head circumferences were 2.59 cms (95% CI: 0.97, 4.21) larger.

Conclusion—Earplugs may facilitate weight gain in VLBW newborns. Better outcomes may persist at 18−22 months at least in ELBW infants.

Keywords

Noise reduction; growth and developmental outcomes

Introduction

For decades health care providers have been concerned that noise levels in neonatal intensive care units (NICUs) may contribute to poor outcomes for high-risk newborns.[1,2] Nevertheless, with the addition of cellular phones, monitor alarms, and new medical technologies, the noise levels in contemporary NICUs over the past 40 years have increased.[3,4] The American Academy of Pediatrics' recommendation limiting noise levels in NICUs to 45 dB (A) [5] is rarely achieved.[6,7]

Corresponding Author: Robert E. Lasky, PhD University of Texas Medical School at Houston Center for Clinical Research and Evidence-Based Medicine 6431 Fannin, MSB. 2.106, Houston, TX, 77030 Robert.E.Lasky@uth.tmc.edu Phone: 713 500 5651 Fax: 713 500 0519.

The few studies evaluating noise reduction in the NICU as an isolated intervention involved brief interventions and assessed only the immediate physiologic responses of the newborn.[8,9] The effects of more extended noise reduction on clinical outcomes such as growth and development have not been evaluated.

Individual protection from excessive noise exposures such as ear muffs or plugs are relatively inexpensive and have immediate clinical application. There have been no studies evaluating earplugs to reduce noise levels in the NICU.

Methods

Participants

Thirty-four very low birth weight (VLBW) newborns (< 1500 g birth weight) were enrolled in this study from June 2002 to March 2003 at Children's Memorial Hermann NICU in Houston, TX. Inclusion criteria for the study were birth weight between 401 and 1500 g, < 1 week of age, and parental informed consent. Exclusion criteria included terminal illness, congenital anomalies, and syndromes associated with hearing loss.

Follow-up assessments for the subsample of 15 surviving extremely low birth weight (ELBW) newborns (< 1000 g birth weight) were conducted between the ages of 18 and 22 months from April 2004 to August 2005 at a follow-up clinic in the University of Texas-Houston Professional Building adjacent to Children's Memorial Hermann Hospital. The follow-up assessments were performed by professionals masked to earplug intervention status. They were trained and certified by the NICHD Neonatal Network. Only the newborns in this study that met the eligibility criteria for Neonatal Network studies (<1000 g birth weight) were evaluated at 18−22 months.

Twenty-three nurses who had primary responsibility for the care of the newborns in the earplug condition were given a survey concerning their evaluation of the earplugs.

Intervention

Earplugs were positioned at the time of randomization and worn continuously until the newborns were 35 weeks postmenstrual age or discharged (whichever came first). Earplugs were removed for medical or social reasons (e.g., parental visits). Newborns in the control group received standard care.

The NICU nurses were given in-service-training concerning the intervention. Nurses were instructed how to shape the plugs and insert them into the concha of the newborn in order to maintain a tight acoustic seal. If earplugs were properly positioned when spot random checks were made, nurses were given tokens. Four tokens were rewarded by a $20 gift certificate.

Objectives

There were 3 objectives, 1) conduct a randomized clinical trial to evaluate the benefits and harm of using silicone earplugs (Insta-Putty Silicone Earplugs®, Insta-Mold, West Boulder, CO), 2) evaluate the feasibility of using silicone earplugs in the NICU, and 3) measure the sound attenuation of silicone earplugs in high risk newborns.

Outcomes

The primary outcome measure was weight at 34 weeks post-menstrual age (PMA), the oldest age all newborns enrolled were likely to be in the hospital. We hypothesized that newborns wearing earplugs during their NICU stay would weigh more than control newborns at 34 weeks PMA. Secondary outcome measures included death before discharge from the NICU, length of stay in the NICU, time on a ventilator, irritation to the ear, and passing a hearing screen. We hypothesized that newborns wearing earplugs during their NICU stay would have more favorable outcomes through hospital discharge than control newborns that did not wear earplugs. We also hypothesized that the earplugs would not irritate the newborns' ears.

A subsample of ELBW newborns were assessed at 18−22 months of age to evaluate growth (weight, length, and frontal-occipital circumference, FOC) and neurodevelopmental (cerebral palsy, the Bayley Mental Developmental Index, MDI, and the Psychomotor Developmental Index, PDI) differences associated with wearing earplugs in the NICU. We hypothesized that the benefits from wearing earplugs as assessed by growth and neurodevelopmental outcomes would be evident at 18−22 months in the ELBW newborns in the study sample.

Nurses who had primary responsibility for the care of the newborns in the earplug group were surveyed concerning the use of silicone earplugs. We hypothesized that the nurses would accept the earplugs and be able to use them with undue burden on their care giving responsibilities.

The sound attenuation of the silicone earplugs was measured by the difference in newborn auditory evoked response (ABR) thresholds to 100 μs clicks with and without earplugs in place. We used standard recording parameters and determined ABR thresholds to within 5 dB by the lowest click level evoking a reliable, averaged response to 1500 clicks. We hypothesized that the silicone earplugs would achieve greater sound attenuation than 7 dB reported for circumaural ear protection (Natus ear muffs™) for preterm newborns.

Sample size

This study was designed to provide information to plan and conduct a larger, definitive trial evaluating the efficacy of silicone earplugs to reduce noise exposure in high risk, preterm newborns. Given the available resources, 34 newborns (18 in the earplug and 16 in the control condition) were enrolled with 24 surviving to be discharged from the NICU. Fifteen survivors were <1000 g birth weight, qualifying for a comprehensive 18−22 month follow-up assessment. With 80% power and alpha = 0.05, we could expect to detect effect sizes of 1.2 standard deviations (SDs) for the continuous outcomes in the 24 newborns evaluated at discharge, 1.6 SDs in the 14 newborns evaluated at follow-up for growth, and 1.8 SDs for the 12 newborns evaluated for Bayley II performance.

Randomization and blinding

The University of Texas-Houston Medical School Internal Review Board approved the study protocol. Parental consent was obtained from all participating families by the first author as soon after birth as feasible. Randomization occurred immediately after enrollment. Randomization was accomplished by a random number generator. Group assignment was indicated in sequentially numbered opaque sealed envelopes.

The subjects' health care providers and families were not blinded to intervention status because the earplugs were clearly visible. The research staff that collected medical record data and assessed the participants at 18−22 months follow-up were blinded to intervention status.

Statistical methods

Although the newborns were randomly assigned to the treatment groups, differences between the groups in the outcome variables may be explained by baseline differences between the groups. Unadjusted regressions and regressions adjusted for birth weight (as an indicator of baseline differences) were calculated with earplug condition as the independent variable. Linear regressions were calculated for the continuous outcomes and logistic regressions for the categorical outcomes.

An alpha level of 0.05 was accepted to evaluate the statistical significance of the primary outcome, weight at 34 weeks. The alpha level for the secondary outcomes was not adjusted for multiple comparisons because false negatives were a greater concern than false positives. The analyses were conducted using STATA (Intercooled STATA version 9.2, College Station, TX 77845) and NCSS (2007, NCSS, Kaysville, Utah) software.

Results

Participant flow

Figure 1 illustrates the flow of subjects through each stage of the study from randomization to follow-up assessment. The 1 newborn that did not return for the follow-up assessments was allocated to the control condition. One control and 1 earplug newborn were not administered a Bayley II assessment because of fatigue.

Baseline characteristics

The newborns in the earplug condition weighed less at birth and were slightly more premature than the controls (see Table 1). Their 1 and 5 minute Apgars were slightly better than the controls. None of these baseline differences were statistically significant.

Primary outcome

Despite being smaller at birth, the earplug newborns that survived until discharge weighed on average 111 g more (95% C.I. = −149, 371 g) than the controls at 34 weeks PMA. After adjusting for birth weight, weight at 34 weeks PMA significantly differed (p=0.017) between the two groups (adjusted difference in weight at 34 weeks = 225 g, 95% C.I. = 45, 405 g).

Group differences were not as pronounced in the subsample of ELBW newborns that were later evaluated at 18−22 months. Despite being 84 g (95% C.I. = −109, 276 g) lighter at birth, ELBW newborns wearing earplugs weighed as much as ELBW newborns not wearing earplugs by 34 weeks of age (they were 0.1 g heavier, 95% C.I. = −259, 259 g). After adjusting for birth weight differences, the ELBW newborns wearing earplugs were 56 g heavier at 34 weeks (95% C.I. = −189, 302). None of these group differences in weight were significant although the trend in these data was the same as for the total sample.

Secondary outcomes

The earplug newborns and the controls did not significantly differ on any of the secondary outcomes assessed by the time they were discharged from the NICU (death before discharge from the NICU, length of stay in the NICU, time on a ventilator, irritation to the ear, and passing a hearing screen). However, all adjusted outcomes with the exception of survival were more favorable for the earplug newborns albeit non-significantly so.

Anthropometric and Bayley II outcomes for the ELBW newborns at 18−22 months are presented in Table 2. Those outcomes were corrected for age at testing. The earplug group tended to be heavier, taller, and have larger heads than the controls. The newborns in the earplug condition outperformed the controls on the MDI. PDI performance was similar in the 2 groups. One child was diagnosed with cerebral palsy (diplegia) in the earplug condition.

Sound attenuation

The sound levels in the study NICU are described in detail elsewhere6,7. A typical ELBW neonate in our NICU was exposed to noise levels averaging 56.4 dB(A) from 26−42 weeks PMA7. During that time, noise levels were rarely (5.5% of the time) below 45 dB(A), the maximum level recommended by the American Academy of Pediatrics5. The average difference in the newborn ABR thresholds with the earplugs inserted compared to the ABR thresholds without the earplugs was 17.7 dB (95% C.I. = 11.3, 24.2).

Adverse events

Irritation to the ear and any other adverse reactions to the earplugs were evaluated regularly at the bedside. No irritation was recorded. Figure 2 presents the nurses' responses to the survey questions. Nurses felt earplugs were of benefit to the newborns and did not interfere with nursing care. However, almost half the nurses also felt the earplugs were potentially a hazard. In addition to the short answers, an open-ended question solicited "any concerns/ comments about the earplugs". Of the 13 (57%) responses to that open-ended question, 10 concerned keeping the plugs in place. Another open-ended question asked the nurses to elaborate on their concerns that the earplugs were hazards. Eleven nurses (48%) expressed concern about the earplugs falling out, and 8 (35%) were concerned the plugs could be swallowed, aspirated, or lodged in the nares.

Discussion

Despite much speculation about the potentially adverse consequences of noisy NICUs, there have been few trials evaluating interventions to reduce noise levels in NICUs.10 The Newborn Individualized Developmental Care and Intervention Program is reported to decrease the need for respiratory support, duration of tube feeding, the length and cost of hospital stay, and increase brain size although Ariagno et al's study of this intervention showed no effect on developmental outcomes.11 Similar individualized developmental interventions have reported a reduction in ventilation days 12 and enhanced neurodevelopmental outcomes at 1 and 2 years corrected age.13,14 A trial of 41 infants randomized to reduced light and noise at night just prior to discharge or routine care showed long lasting effects on weight gain, feeding, and sleeping.15 The above interventions all involved other components (especially changes in light and caregiver behavior) that make it impossible to isolate the contribution of reduced noise levels. These mixed intervention programs have not been widely adopted because some are very elaborate and expensive to implement and benefits are not consistently reported.

There are few studies of noise reduction as an isolated intervention. Reduced room noise has been reported to be associated with decreased heart rate, less fussiness and crying, and more sleep.16,17 Two trials used individualized noise reduction approaches. D'Agati et al reported significantly more sleep when wearing ear muffs in the 6 infants tested.8 In the second trial, none of the physiological measures and only 1 of the 10 measured behavioral states (awake quiet) differed in the 9 infants randomized to ear muffs compared to the 8 controls.9 A second group tested in Zahr and Traversay's study acted as their own controls. When wearing earmuffs, the newborns had higher oxygen saturation rates, spent more time in regular quiet sleep, and demonstrated fewer changes in behavioral state.9 These small sample size studies involved short duration, modest interventions and focused on immediate outcomes. It is plausible that changes in sleep cycles and oxygen saturation have important long-term benefits, but these studies were neither designed nor powered to demonstrate long-term effects that have important public health implications. Our study is also limited in sample size and the length and extent of the follow-up evaluations, but it does suggest that noise reduction may have short and long term benefits.

Nurses perceived the need for noise reduction and felt using ear plugs on the newborns they cared for could be easily integrated into their routine. However, they expressed concerns about ear plugs falling out and posing a safety hazard. Using earplugs in conjunction with circumaural ear protection may add additional noise attenuation while reducing the likelihood that loose earplugs will fall out of the ear.

Limitations of the study include the small sample size, multiple comparisons, unbalanced baseline characteristics and adjusted outcomes, use of an unmasked intervention, and incentives for nursing compliance that may have promoted additional care. Because the intervention was unmasked to the caregivers, they could have consciously or unconsciously provided better care to newborns wearing earplugs. Methods to mask the caregivers are probably impractical (e.g., the research team could assume responsibility for placing and maintaining the earplugs and also an acoustically neutral, opaque cover over the ear to be worn by all study newborns). Reducing noise levels may be detrimental to development if necessary social stimulation is inhibited. Future research should measure and evaluate verbal interactions with study newborns.

Despite the limitations of our study, noise reduction alone may have promoted the growth and development of sick, very preterm and low birth weight newborns cared for in NICUs. Weight gain was better at 34 weeks of age in VLBW newborns wearing earplugs. The weight gain associated with wearing earplugs at 34 weeks was greater in newborns >1000 g birth weight than in ELBW newborns. There are several possible explanations. Reducing one of many factors affecting growth in ELBW newborns may have less effect than reducing noise levels for larger, healthier newborns. Alternatively, because ELBW infants grow more slowly than their larger healthier peers, the benefits of reduced noise levels on weight gain may not be as apparent at 34 weeks of age in ELBW compared to VLBW newborns. The vagaries of small sample sizes are also a plausible explanation of these results.

Only ELBW infants were evaluated at 18−22 months of age because of limited resources. We recorded persisting benefits of wearing earplugs in ELBW infants. ELBW infants that wore earplugs as newborns had larger heads and scored more highly on a mental developmental assessment. We do not know whether the long-term effects we recorded in ELBW newborns would also be recorded in heavier and older newborns as well.

The magnitude of the reported effects was larger than expected. Traditional frequentist statistics do not account for prior expectation concerning plausible effect sizes. A benefit of a Bayesian analytic approach is formally incorporating prior expectations to interpret results that seem “too good to be true”18. A Bayesian approach would seem to be a reasonable way to analyze the results of small studies such as this study. Nevertheless, these provocative results warrant addressing the practical limitations of using silicone earplugs to reduce noise, conducting a much larger study to replicate the results and trends from this study, including larger and older newborns, and extending the outcomes measured to childhood and adulthood to evaluate long-term effects.

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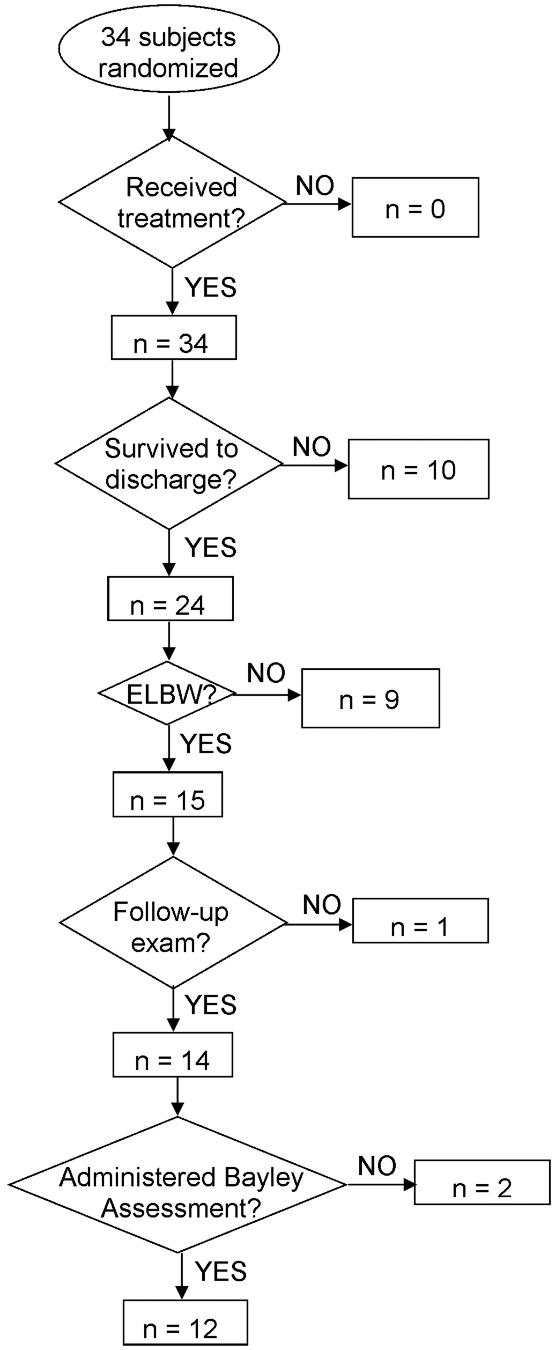

Figure 1.
Flowchart of participants from randomization to follow-up assessment

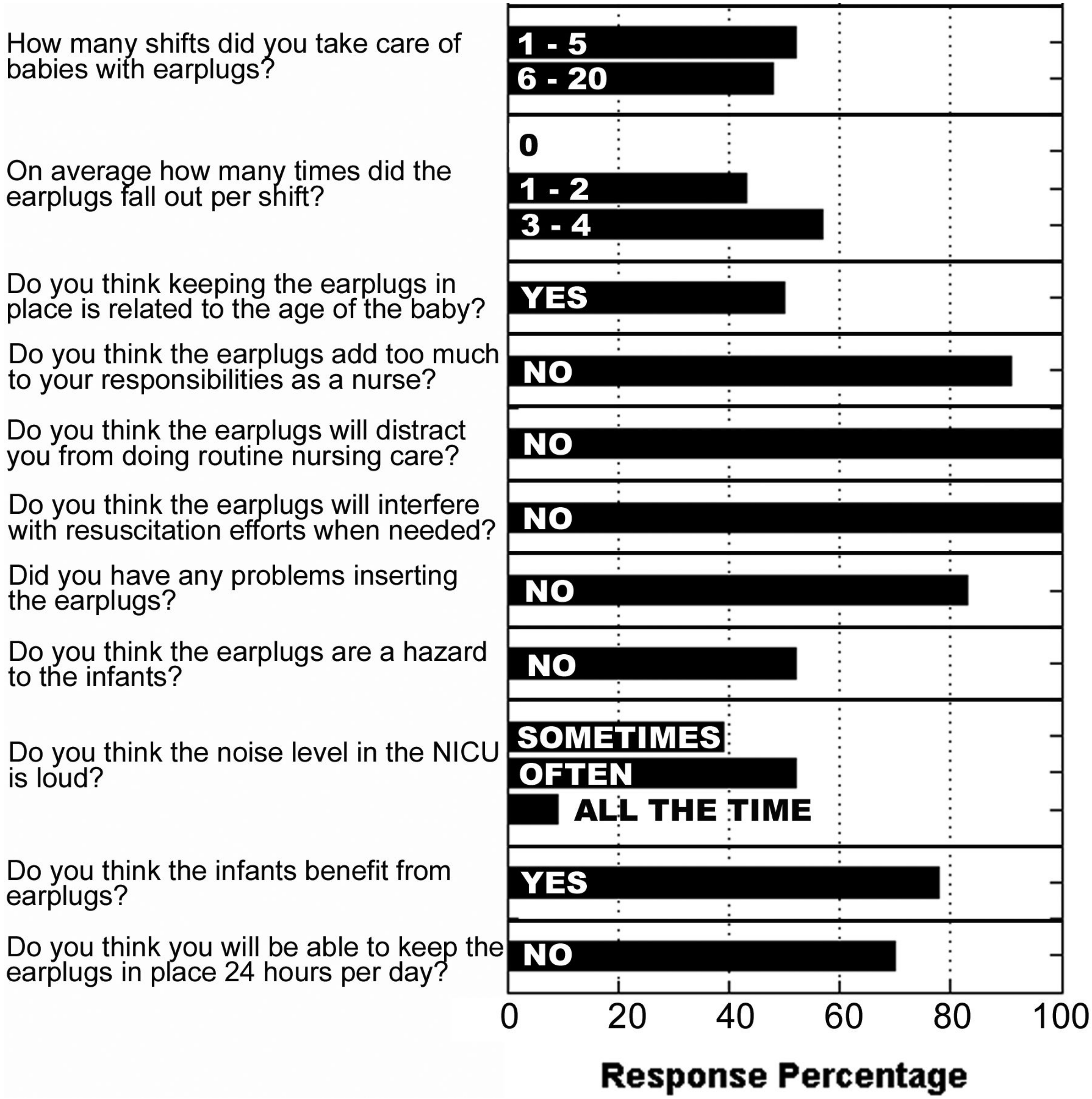

Figure 2.
The 23 NICU Nurses' Responses to the Short-Answer Study Survey Questions

Table 1

Baseline characteristics of the study sample

Variable	Entire sample (n=34)			Survivors (n=24)		
	Earplug (n=18)	Control (n=16)	p-value *	Earplug (n=11)	Control (n=13)	p-value *
Female	9 (50)[1]	7 (44)	0.744	6 (55)[1]	5 (38)	0.682
Race			0.396			0.315
Black	7 (39)	8 (50)		6 (55)	7 (54)	
Hispanic	4 (22)	5 (31)		1 (9)	4 (31)	
White	5 (28)	1 (6)		3(27)	1 (8)	
Other	2 (11)	2 12)		1 (9)	1 (8)	
Gestational Age at birth (weeks)	25.7 (SD=1.7)[2]	26.5 (SD=1.7)	0.191	26.0 (SD=1.7)	26.9 (SD=1.5)	0.183
Birth weight (g)	806 (SD=236)	924 (SD=216)	0.138	884 (SD=245)	971 (SD=212)	0.363
Apgar 1 minute	6.0 (IQR=3.5,7.0)[3]	4.5 (IQR=2.0,6.8)	0.274	6.0 (IQR=5.8,7.2)	6.0 (IQR=2.5,7.0)	0.885
Apgar 5 minute	7.0 (IQR=6.0,7.0)	6.0 (IQR=5.0,7.8)	0.286	7.0 (IQR=7.0,8.0)	6.0 (IQR=5.5,8.0)	0.933

[1] The number of newborns (the percentage of newborns).

[2] Mean (SD).

[3] Median (InterQuartile Range).

* Fisher's Exact or Chi-square Tests were calculated for the categorical variables, t-tests for the normally distributed continuous variables, and Wilcoxon Rank Sum Tests for ordinally scaled variables.

Table 2

Mean (95% C.I.) Differences in 18 to 22 Month Outcomes Favoring Infants Wearing Earplugs as Newborns in the NICU

Outcome	Mean unadjusted group differences (95% C.I.)	p-value	Mean adjusted group differences (95% C.I.)[1]	p-value
Weight (g)	408 (−1154,1970)	0.580	555 (−1112,2223)	0.479
Length (cms)	3.09 (−0.68,6.87)	0.100	2.81 (−1.26,6.89)	0.156
FOC (cms)	1.95 (−0.14,4.04)	0.065	2.59 (0.97,4.21)	0.005
MDI	14.00 (1.65,26.35)	0.030	15.53 (3.03,28.02)	0.020
PDI	−2.17 (−20.68,16.34)	0.800	−3.12 (−23.16,16.92)	0.733

[1] Adjusted by birth weight.