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Effects of White Noise and Swaddling on Pain and Physiological Parameters During Eye Examination in Healthy Term Infants: A Randomized Controlled Trial

Sağlıklı Term Bebeklerde Göz Muayenesi Sırasında Beyaz Gürültü ve Kundaklamanın Ağrı ve Fizyolojik Parametreler Üzerindeki Etkileri: Randomize Kontrollü Bir Çalışma

Sultan GÜNER BAŞARA[1], Hüsniye ÇALIŞIR[2], Emel BAHADIR ARSU[3], Özdemir ÖZDEMİR[3]

[1]Tokat Gaziosmanpaşa University Erbaa Faculty of Health Sciences, Department of Child Health and Disease Nursing, Tokat, Türkiye
[2]Aydın Adnan Menderes University Faculty of Nursing, Department of Child Health and Diseases Nursing, Aydın, Türkiye
[3]Ankara Bilkent City Hospital, Clinic of Ophthalmology, Neonatal Outpatient Clinic, Ankara, Türkiye

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ABSTRACT

Objective: Eye examinations in infants for vision screening can cause pain and stress. The aim of this study was to evaluate the effect of white noise and swaddling on pain, heart rate, and oxygen saturation in healthy term infants undergoing post-discharge eye examinations.

Methods: The study was conducted from September 1, 2022, to March 1, 2023, in the neonatal eye outpatient clinic of a maternity hospital. This randomized controlled trial included 120 term infants randomized to four groups: white noise (n=30), swaddling (n=30), white noise plus swaddling (n=30), and control (n=30). Pain was assessed using the premature infant pain profile scale, and heart rate and peripheral capillary oxygen saturation (SpO_2) were measured by pulse oximetry before, 30 seconds after, and at the end of the examination.

Results: The groups showed comparable pain scores, heart rates, and SpO_2 levels, with no significant differences observed ($p>0.05$). However, all groups showed significant increases in pain scores and heart rates, and a decrease in SpO_2 during the examination compared with baseline ($p<0.001$).

Conclusion: White noise, swaddling, and their combination did not reduce pain or improve physiological parameters during eye examinations in term infants.

Keywords: Eye examination, pain management, swaddling, term infant, white noise

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Corresponding Author/ Sorumlu Yazar:
Sultan GÜNER BAŞARA, MD,
Tokat Gaziosmanpaşa University Erbaa Faculty of Health Sciences, Department of Child Health and Disease Nursing, Tokat, Türkiye
✉ sgune6377@hotmail.com
ORCID: 0000-0002-0665-5396

ÖZ

Amaç: Yenidoğanlarda görme taraması için yapılan göz muayeneleri ağrı ve stres oluşturabilir. Bu çalışmada, taburculuk sonrası göz muayenesi yapılan sağlıklı term yenidoğanlarda beyaz gürültü ve kundaklamanın ağrı, kalp hızı ve oksijen satürasyonu üzerine etkisi değerlendirildi.

Yöntem: Çalışma, 1 Eylül 2022-1 Mart 2023 tarihleri arasında bir doğum hastanesinin yenidoğan göz polikliniğinde yürütüldü. Randomize kontrollü bu çalışmaya 120 term yenidoğan dahil edildi ve dört gruba ayrıldı: beyaz gürültü (n=30), kundaklama (n=30), beyaz gürültü + kundaklama (n=30) ve kontrol (n=30). Ağrı, kalp hızı ve periferik kapiller oksijen satürasyonu (SpO_2), prematüre bebek ağrı profili ölçeği ve pulse oksimetre kullanılarak muayene öncesi, muayeneden 30 saniye sonra ve muayene sonunda ölçüldü.

Bulgular: Gruplar arasında ağrı skorları, kalp hızı ve SpO_2 seviyeleri açısından anlamlı bir fark gözlenmedi ($p>0,05$). Ancak, tüm gruplarda muayene sırasında bazal değerlere kıyasla ağrı skorları ve kalp hızında anlamlı artış, SpO_2'de ise anlamlı düşüş görüldü ($p<0,001$).

Sonuç: Beyaz gürültü, kundaklama ve bunların kombinasyonu, term yenidoğanlarda göz muayenesi sırasında ağrıyı azaltmadı ve fizyolojik parametreleri iyileştirmedi.

Anahtar Kelimeler: Ağrı yönetimi, beyaz grültü, göz muayenesi, kundaklama, term bebek

INTRODUCTION

Eye problems that arise during early childhood are of critical importance, as they can lead to permanent vision loss.[1] It is recommended that term infants be evaluated for congenital cataracts, congenital glaucoma, retinoblastoma, strabismus, amblyopia, and refractive errors.[2] An estimated 20,00-40,000 infants are born with bilateral cataracts globally each year, leading to blindness in over 14 million children. Congenital glaucoma, a developmental disorder that may be unilateral or bilateral, typically presents at birth or within the first few months of life and can damage the optic nerve, leading to vision loss.[3] Detecting risk factors that may hinder normal visual development through vision screening in infants and providing early treatment help prevent vision loss and blindness. In the country where the study was conducted, healthy term infants undergo detailed eye examinations for conditions such as congenital cataracts and glaucoma, using techniques similar to those employed in retinopathy of prematurity (ROP) screening.

Eye examinations for screening and early diagnosis can be painful and stressful for infants. Exposure to pain in infancy can lead, in the short term, to increased pain sensitivity and altered cortical development, and, in the long-term, to behavioral and learning problems.[4,5] Therefore, it is crucial to minimize pain and stress during these examinations.[6] Although analgesic agents are considered effective for pain control during eye examinations, the most effective and safest combination of interventions that does not increase adverse effects has yet to be determined.[7] Kinoshita et al.[8] Cochrane review indicated that topical anesthesia administered during ROP screenings is insufficient for complete pain relief. The evidence suggests that a single intervention is not sufficient to completely alleviate pain. Systemic pharmacological analgesics used to reduce pain in infants may adversely affect their early brain development, nutrition, socialization, and memory later in life.[8,9] Currently, non-pharmacologic methods to reduce pain in infants are gaining prominence. These methods are more cost-effective, easier to administer, and safer than pharmacologic approaches. They can also be used in combination with pharmacologic treatments.[10]

During eye examinations, Blefastop is used to keep the baby's eyelids open, and a scleral depressor is employed to examine the ocular fundus and to move the eye laterally, which can cause discomfort. The white light source used by the ophthalmologist further unsettles the infant. Studies have explored various non-pharmacologic interventions to reduce pain during eye examinations in preterm infants, including touch, positioning, non-nutritive sucking, breast milk, glucose, sucrose, white noise, and music.[11-19] However, these studies have yielded conflicting results, and the evidence remains insufficient. In our review of the literature, we found no study that definitively supports the claim that swaddling alone significantly reduces pain, nor any research comparing the effectiveness of non-pharmacological methods for reducing pain experienced by term infants during eye examinations. There is a need for studies assessing the efficacy of non-drug interventions in alleviating pain during eye examinations in healthy term infants after hospital discharge. White noise and swaddling were preferred for term infants returning for ophthalmological examination 30-36 days post-discharge due to their ease of use and ready availability.

The purpose of this study was to assess the impact of white noise and swaddling on procedural pain, heart rate, and oxygen saturation (SpO_2) in healthy term infants undergoing hospital eye examinations for post-discharge vision screening.

Hypotheses of the study:

H_1: Playing white noise to healthy term infants during eye examinations affects pain scores, heart rate, or oxygen saturation.

H_2: Swaddling healthy term infants during eye examinations affects pain scores, heart rate, or oxygen saturation.

H_3: Swaddling combined with listening to white noise during eye examinations affects pain scores, heart rate, or oxygen saturation.

METHODS

Design

This study adopted a prospective, randomized, controlled experimental design with four study groups (three intervention groups and one control group), in accordance with CONSORT guidelines.[20]

This randomized controlled trial was registered at ClinicalTrials.gov (registration number:NCT06535984).

Sample and Setting

The study was conducted between September 1, 2022, and March 1, 2023, in the neonatal eye outpatient clinic at a maternity hospital. In this hospital, healthy infants who do not require intensive care after birth receive a single eye screening examination between 30 and 36 days of age. Approximately 400 infants who do not require intensive care attend the neonatal eye outpatient clinic each month. Participants were divided into four groups: three intervention groups and one control group. Infants were assigned to these groups using simple randomization to ensure baseline comparability and to prevent selection bias. Randomization was performed using a computer-

generated random sequence created through the random.org website. To ensure comparability between groups, infants will be assigned to groups by simple random sampling. The allocation list was prepared by an independent researcher who was not involved in data collection or outcome assessment, thereby maintaining allocation concealment. Sample size estimation was performed using G-Power (version 3.0.10). With a 95% confidence interval, α=0.05, effect size =0.159, and power (1-β) =0.80, a total sample size of 27) 108 infants per group) was calculated for the four groups. The effect size (0.159) was not derived from pilot data or a specific previous study; rather, it was determined as a small-to-medium effect size based on general recommendations for behavioral and clinical research, considering the expected variability in pain and physiological parameters among infants. The sample size estimation was based on the primary outcome measure of the study, the premature infant pain profile (PIPP) score. The study included 120 infants divided into the swaddling group (n=30), the white noise group (n=30), the white noise + swaddling group (n=30), and the control group (n=30) (Figure 1).

The sample included infants with gestational age >37 6/7 weeks, birth weight ≥2000 g, and 5-minute Apgar score ≥7, who were aged 30-36 days postpartum and undergoing their first eye screening. The study excluded infants who had received care in the neonatal intensive care unit, who had required, who had a diagnosed or suspected congenital and/or genetic disorder, who had experienced hearing problems, who had undergone any surgical procedure, or who had received systemic analgesics within the last six hours. No infants withdrew during the study period.

Interventions

Healthy term infants who were swaddled during the eye examination formed the swaddling group (intervention group 1). Infants who listened to white noise formed the white-noise group (intervention group 2). Infants who were both swaddled and exposed to white noise during the eye examination constituted the white noise + swaddling group (intervention group 3). The control group received routine care and follow-up. The outpatient clinic nurse (the third researcher) numbered the infants in order of admission and assigned them to groups using simple randomization. All infants were examined by the same ophthalmologist (the fourth investigator). Another outpatient nurse, who was not part of the research team, measured the infants' pain scores, heart rate, and oxygen saturation at three times: before the examination (T1), 30 seconds after the ophthalmologist began examining the first eye (T2), and immediately after finishing the examination of the second eye (T3). No adverse events or complications related to the interventions were observed during the study.

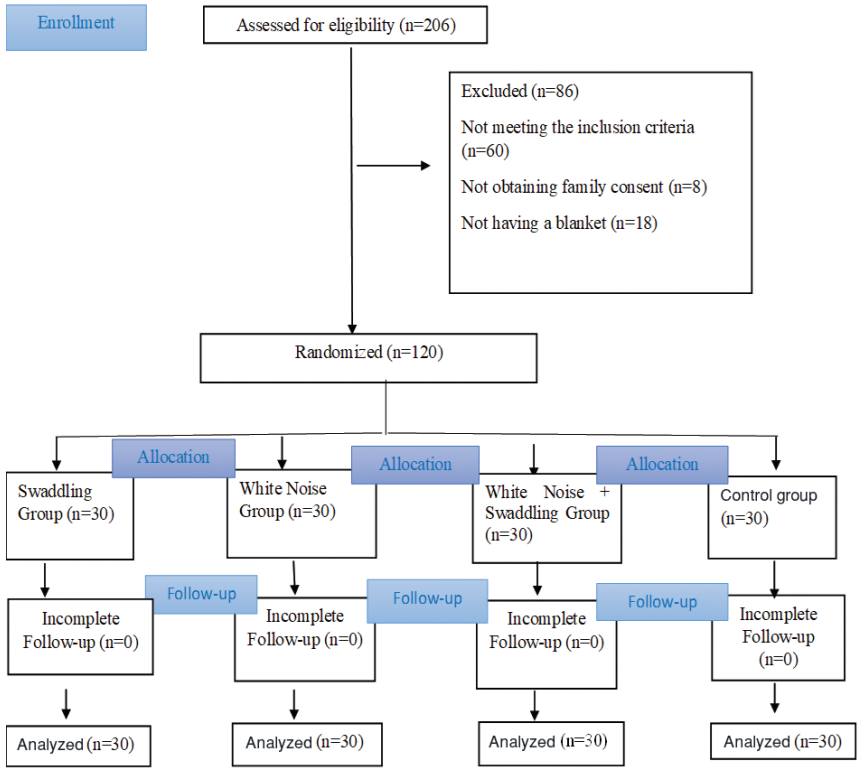

Figure 1. Consort flow diagram

Eye Examination Preparation

All healthy term infants included in the study (intervention groups 1, 2, and 3, and the control group) underwent routine procedures at the outpatient eye clinic prior to the examination. Families with appointments for their baby's eye examination were instructed to feed their infant one hour before the appointment. On the day of the examination, the third investigator inquired about the time of the last feeding. Following this, pupil dilation was initiated in the waiting room. According to the hospital's standard procedure, pupil dilation involved instilling phenylephrine and tropicamide eye drops twice, at five-minute intervals. Approximately 45 minutes later, once the pupils were dilated, each infant was taken to the preparation room. One drop of proparacaine was instilled into each eye of the infants before the examination. Proparacaine-containing drops are used to provide topical anesthesia for rapid and short-term diagnostic or surgical procedures.[21] During these procedures, which occur before the examination, the baby remains with the parent, usually in the mother's arms. Once the infant is taken into the examination room, the parent does not accompany them. Instead, a third researcher brings the infants into the examination room without their parents and places them on the examination table. The left foot of all infants was fitted with a pulse oximetry probe.

Eye Examination Procedure

The third investigator positioned the infant supine and aligned the infant's head in the midline with a slight extension. The eye examination was performed by an ophthalmologist (the fourth researcher). Each eye examination lasted approximately one to one-and-a-half minutes.

Participant Groups

Swaddling group (n=30); The third researcher swaddled each infant in its thin blanket. The swaddling involved bringing the infant's left hand close to the left buttock and wrapping it with the upper right end of the blanket. Similarly, she wrapped the baby's right hand with the blanket's upper-left end by bringing that end closer to the right hip. She wrapped the baby's legs with the lower part of the blanket, ensuring that the baby's head could move freely. All environmental conditions during the procedure were kept constant. The room temperature was maintained at approximately 22-24 °C, and the examination was performed in a dim, quiet environment. No changes in lighting or room temperature were made during the interventions.

White noise group: the third researcher turned on a pre-recorded rain sound file before the start of the eye examination and played it for the infants until the end of the examination. The sound was played on a mobile phone (Samsung Galaxy A32, 2021) at approximately 50-55 dB, as measured with a sound-level meter app, and the speaker was positioned approximately 30-40 cm from the infant's head to avoid discomfort. The same recording was used throughout the study to ensure acoustic consistency.

White noise + swaddling group: the third researcher swaddled the infants in this group as described for the swaddling group, and turned on a pre-recorded rain sound file before the examination began, which was played continuously until the end of the examination.

Control group: The healthy term infants in this group received routine care at the eye outpatient clinic. In routine outpatient clinic practice, infants are examined with their clothes on, and no non-pharmacologic methods are applied during the examination. As in the intervention groups, infants in the control group received proparacaine eye drops and pupil dilation as part of the routine clinical protocol prior to the examination.

A single outpatient clinic nurse who was not part of the research team conducted all data collection activities. This nurse works in the neonatal eye outpatient clinic and has a neonatal intensive care nursing certificate.

Data Collection Tools

"The infant ınformation and monitoring form" and "the PIPP" were used during data collection.

Infant Information and Monitoring Form

Researchers prepared the form, which contained 11 questions.[11,22,23] The form included information about the infant's demographic characteristics, mode of delivery, birth weight, gender, gestational age, Apgar score, postnatal age, diet, oxygen therapy, and phototherapy. Additionally, pain scores (T1, T2, and T3), heart rates, and oxygen saturation levels were recorded.

The Premature Infant Pain Profile

The infants' pain scores were evaluated using the PIPP. The Turkish validity and reliability of the scale developed by Stevens et al.[24] were assessed by Taplak and Bayat.[25] The scale includes seven indicators (heart rate, oxygen saturation, gestational age, behavioral state, nasolabial furrow, brow bulge, and eye squeeze), each scored from 0 to 3. The total score ranges from 0 to 21, with higher scores indicating more severe pain.[24]

Statistical Analysis

Statistical analyses were conducted using IBM's SPSS software (version 27). Descriptive statistics summarized the study findings. The association between two categorical variables was assessed.

Data were assessed using Pearson's chi-square (χ^2) test. For data with a normal distribution, comparisons among three or more independent groups were performed using one-way ANOVA (F-value), while repeated-measures ANOVA (F-value) was applied for comparisons involving three or more related groups. When data were not normally distributed, the Kruskal-Wallis H test (χ^2 statistic) was used to compare three or more independent groups, and the Friedman test (χ^2 statistic) was used to compare three or more dependent groups.

Ethical Approval

All procedures were conducted in compliance with the ethical standards of the Institutional and National Research Committee and within the guidelines of the Declaration of Helsinki. This study was approved by the Ankara Bilkent City Hospital No. 2 Clinical Research Ethics Committee (decision number: E2-22-2419, date: 16.10.2022). Information about the study's aims, procedures, and other relevant details was provided to the infants' parents. They signed a written consent form before the study commenced.

RESULTS

Comparison of The Groups on Terms of Demographic Data

A total of 120 neonates [females n=68 (56.6%) and males n=52 (43.4%)] were included in the study and were randomly assigned to the swaddling (n=30), white noise (n=30), white noise plus swaddling (n=30), and control (n=30) groups. There were no significant differences between the intervention and control groups with respect to mode of delivery, gender, birth weight, gestational age, and 1- and 5-minute Apgar scores. The groups were also similar with respect to feeding method, oxygen therapy, phototherapy, postnatal age, and current weight (p>0.05). The groups were homogeneous in terms of these characteristics. Other demographic data are shown in Table 1.

Comparison of The Groups in Terms of PIPP Score, Heart Rate, and SpO_2

The groups did not differ significantly in PIPP scores before the eye examination (T1), at 30 seconds into the examination (T2), or at the end of the examination (T3) (p>0.05). The PIPP score in the swaddling + white noise group at T3 was lower than in the other groups, although this difference was not statistically significant (Figure 2). The groups did not differ significantly in PIPP scores before the eye examination (T1, p=0.601), at 30 seconds into the examination (T2, p=0.108), and at the end of the examination (T3, p=0.526). The PIPP score in the swaddling + white noise group at T3 was lower than in the other groups, although this difference was not statistically significant (Figure 2). The mean PIPP score of all infants at T1 was significantly lower than that at T2 and T3 (p<0.001). In both the white noise group and the swaddling group, the mean PIPP score at T3 was lower than at T2 (p<0.001). Heart rate values were comparable between groups at T1 (p=0.418), T2 (p=0.892), and T3 (p=0.742). Heart rates at T1, T2, and T3 varied significantly across all infant groups (p<0.001). In all three intervention groups (swaddling + white noise, white noise, and swaddling), heart rate values at T1 were lower than those at T2 and T3, while values at T3 were lower than those at T2 (p<0.001). In the control group, only the heart rates at T1 were lower than those at T2 and T3 (p<0.001). There were no statistically significant differences in SpO_2 between groups at T1 (p=0.710), T2 (p=0.230), and T3 (p=0.854). At T3, although the SpO_2 value in the white noise group was slightly higher than in the other groups and those in the control and swaddling groups were slightly lower, these differences were not statistically significant. SpO_2 values in all groups at T2 and T3 were lower than at T1 (p<0.001). In addition, the SpO_2 values of infants in the white noise group at T3 were higher than at T2 (p<0.001) (Table 2).

Primary Outcomes

The primary endpoints of the study were the total pain score from PIPP, the instantaneous heart rate measured by the monitor, and the oxygen saturation.

DISCUSSION

In this randomized controlled trial, we investigated the effects of swaddling and white noise—alone and in combination—on pain, heart rate, and oxygen saturation in healthy term infants undergoing routine post-discharge eye examinations. Although our study was methodologically robust, our findings indicated that these interventions did not significantly reduce pain scores or improve heart rate and oxygen saturation during the examination. The analysis showed no differences in pain scores, heart rates, or saturation values among the groups before, 30 seconds into, or at the end of the eye examination. However, all groups exhibited an increase in pain and heart rate and a decrease in oxygen saturation during the examination compared with baseline.

Newborns experience varying degrees of pain during invasive procedures, such as eye examinations conducted for diagnosis and treatment.[26] During painful interventions, infants experience increases in respiratory rate, heart rate, and blood pressure, and a decrease in oxygen saturation.[27] Studies have shown that infants experience significant pain even when local anesthetics are used during the procedure.[26,28]

White noise is a constant, uniform sound composed of

Table 1. Descriptive characteristics of infants (n=120)

Characteristics	Swaddling group (n=30)		White noise group (n=30)		Swaddling + white noise group (n=30)		Control group (n=30)		Test* p-value
	n	%	n	%	n	%	n	%	
Mode of delivery Vaginal Caesarean	 12 18	 40.0 60.0	 14 16	 46.7 53.3	 15 15	 50.0 50.0	 13 17	 43.3 56.7	 χ2=0.673 p=0.879
Gender Girl Boy	 15 15	 50.0 50.0	 18 12	 60.0 40.0	 17 13	 56.7 43.3	 18 12	 60.0 40.0	 χ2=0.814 p=0.846
Feeding Breast milk Formula food Both	 21 1 8	 70.0 3.3 26.7	 25 1 4	 83.3 3.4 13.3	 28 - 2	 93.3 - 6.7	 25 2 3	 83.3 6.7 10.0	 χ2=7.882 p=0.247
Oxygen therapy Yes No	 8 22	 26.7 73.3	 8 22	 26.7 73.3	 3 27	 10.0 90.0	 6 24	 20.0 80.0	 χ2=3.385 p=0.336
Phototherapy application Yes No	 6 24	 20.0 80.0	 6 24	 20.0 80.0	 7 23	 23.3 76.7	 5 25	 16.7 83.3	 χ2=0.417 p=0.937
	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	Test** p-value
Birth weight	3280.50±431.96	3222.5 (465.0)	3249.83±415.41	3282.5 (498.0)	3224.83±409.1	3297.5 (408.0)	3137.67±550.14	3190.0 (558.0)	χ2=2.230 p=0.526
Week of gestation	39.00±0.98	39.0 (2.0)	39.00±1.08	39.0 (2.0)	38.70±0.99	38.0 (1.0)	38.83±0.91	39.0 (1.0)	χ2=2.682 p=0.443
Apgar 1 minute	7.73±0.69	8.0 (1.0)	7.37±0.56	7.0 (1.0)	7.27±0.74	7.0 (1.0)	7.63±0.62	8.0 (1.0)	χ2=7.265 p=0.064
Apgar 5 minutes	9.17±0.38	9.0 (0.0)	8.97±0.49	9.0 (0.0)	8.90±0.66	9.0 (0.0)	9.07±0.45	9.0 (0.0)	χ2=3.905 p=0.272
Postnatal age	40.63±7.53	40.0 (9.0)	42.07±6.01	40.0 (5.0)	41.9±10.91	40.0 (5.0)	39.53±5.83	40.0 (4.0)	χ2=1.831 p=0.608
Current weight	4444.83±639.58	4400.0 (813.0)	4363.57±597.52	4276.0 (725.0)	4339.00±835.49	4225.0 (900.0)	4263.50±624.29	4245.0 (763.0)	χ2=1.157 p=0.763

*Pearson X2test, **Kruskal-Wallis test, Mdn: Median, M: Mean, IQR: Interquartile range, SD: Standard deviation

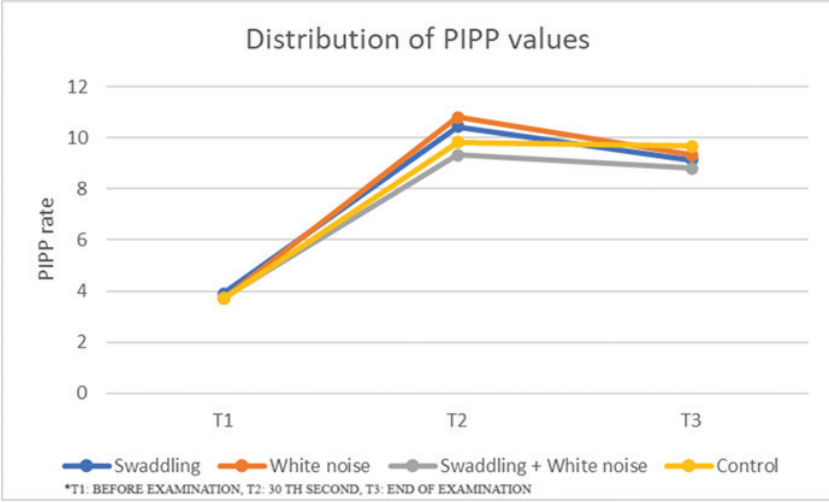

Figure 2. Distribution of PIPP values across groups at different measurement times (T1: before eye examination; T2: 30 seconds of eye examination; T3: End of eye examination).

Error bars represent the variability of the data (standard deviation/standard error as applicable)

PIPP: Premature infant pain profile

many different frequencies (e.g., the howling of the wind, the flow of water, or the running of a fan). The potential mechanism of action of white noise may be explained by desensitization and sensory modulation theories, which suggest that consistent auditory input can help regulate the infant's sensory responses and reduce reactivity to painful stimuli.[29] White noise can have a calming effect on emotional states, reducing pain and anxiety. It also elicits stochastic resonance in hearing, which can positively affect behavioral and physiological responses.[17] Some studies[30,31] have shown that white noise reduces pain scores during invasive procedures, is effective in increasing weight gain and improving comfort, but has no positive effect on pain scores during severely painful procedures such as endotracheal aspiration.[22] Contrary to studies showing that white noise during eye examinations decreased pain scores and positively affected saturation and heart rate[17,18] a studies found no positive effect on pain scores and physiological parameters.[23] Similarly, our findings indicate that the pain scores (PIPP>9-10 points), heart rates, and oxygen saturation of infants exposed to white noise were not improved, suggesting that applying white noise during eye examinations may be ineffective in reducing pain. Considering that infants' crying during the examination may have reduced their ability to perceive the white noise, future studies should explore whether using a slightly higher sound intensity within safe limits or adjusting the timing of the intervention—such as starting the white noise earlier or maintaining it longer—could enhance its effectiveness.

Swaddling is a method that reduces excessive movement by wrapping the baby's arms and legs.[32] Safe swaddling of newborns can reduce the pain experienced during medical interventions, support neuromuscular development, and reduce physiological and behavioral stress.[32,33] Swaddling alone has been reported to relieve pain during invasive procedures, such as aspiration.[34] However, it has been concluded that in premature infants, swaddling alone is not effective in reducing pain during retinopathy examinations, nor is it effective when combined with other non-pharmacologic methods such as sucrose, breast milk, or distilled water.[35] Metreş and Yıldız[12] similarly reported that swaddling combined with a pacifier was more effective at reducing pain during eye examinations in premature infants than a pacifier alone. Another study reported that a modified developmental care bundle—including environmental modifications, swaddling, oxygen supplementation, and cue-based individualized care—can reduce pain and stress in premature infants during ROP examinations.[36] The results of our study indicate that this method did not alleviate pain or positively influence physiological responses during highly painful procedures, such as eye examinations performed on healthy term infants. These findings suggest that the intense pain induced by detailed eye examinations may not be adequately managed by swaddling alone or by swaddling combined with white noise. Although the differences in PIPP scores between the groups were not statistically significant, the lower pain scores observed in infants who received the combined white noise and swaddling intervention and the higher scores observed in the control group suggest that the combined application of these methods may provide partial benefits in pain management. In addition, all infants received proparacaine eye drops as part of

Table 2. Comparison of infants' premature infant pain profile, heart rate, and SpO_2 values at T1, T2, and T3

Variable	Swaddling group (n=30)		White noise group (n=30)		Swaddling + white noise group (n=30)		Control group (n=30)		Test p-value	Effect size (η^2)
PIPP	**M ± SD**	**Mdn (IQR)**	**M ± SD**	**Mdn (IQR)**	**M ± SD**	**Mdn (IQR)**	**M ± SD**	**Mdn (IQR)**		
T1 (1)	3.90±0.61	4.0 (0.0)	3.70±0.92	4.0 (1.0)	3.73±1.14	4.0 (1.0)	3.70±0.95	4.0 (1.0)	$\chi2$=1.866 p=0.601*	0.000
T2 (2)	10.43±1.89	10.0 (2.0)	10.80±2.28	12.0 (2.0)	9.33±2.75	9.5 (4.0)	9.83±2.52	10.0 (4.0)	$\chi2$=6.069 p=0.108*	0.035
T3 (3)	9.13±1.61	9.0 (2.0)	9.33±1.86	10.0 (2.0)	8.80±2.47	8.0 (3.0)	9.67±2.09	10.0 (3.0)	$\chi2$=2.230 p=0.526*	0.002
Test p-value	$\chi2$=51.254 **p<0.001**¥ (1<2,3) (2>3)		$\chi2$=52.667 **p<0.001**¥ (1<2,3) (2>3)		$\chi2$=47.345 **p<0.001**¥ (1<2,3)		$\chi2$=48,828 **p<0.001**¥ (1<2,3)‡			
Heart rate	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)		
T1 (1)	147.83±14.17	150.0 (22.0)	142.77±13.55	144.0 (25.0)	145.23±14.31	143.0 (23.0)	141.67±18.98	143.0 (31.0)	F=0.953 p=0.418*	0.024
T2 (2)	166.67±14.14	165.5 (16.0)	165.87±19.24	166.5 (22.0)	167.17±18.05	168.0 (30.0)	162.70±19.58	163.5 (23.0)	$\chi2$=0.620 p=0.892*	0.000
T3 (3)	159.77±13.97	161.5 (12.0)	156.63±18.20	158.0 (24.0)	159.77±20.67	163.0 (31.0)	157.23±15.87	159.0 (19.0)	$\chi2$=1.248 p=0.742*	0.002
Test p-value	$\chi2$=38.034 **p<0.001**¥ (1>2,3) (2>3)		F=20.505 **p<0.00**§ (1>2,3) (2>3)		$\chi2$=41.496 **p<0.001**¥ (1>2,3) (2>3)		$\chi2$=21.529 **p<0.001**¥ (1>2,3)‡			
SpO_2	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)	M ± SD	Mdn (IQR)		
T1 (1)	95.53±1.94	95.5 (3.0)	95.43±1.65	95.0 (3.0)	95.10±1.79	95.0 (2.0)	95.10±1.86	95.0 (2.0)	F=0.461 p=0.710*	0.011
T2 (2)	90.10±4.13	91.0 (5.0)	90.40±3.82	90.0 (5.0)	89.70±3.53	90.0 (4.0)	91.37±4.26	92.0 (6.0)	$\chi2$=4.309 p=0.230*	0.019
T3 (3)	91.83±3.59	92.0 (3.0)	92.47±3.06	93.0 (4.0)	91.63±4.23	92.5 (4.0)	92.43±3.24	92.0 (3.0)	$\chi2$=0.781 p=0.854*	0.000
Test p-value	$\chi2$=36.207 **p<0.001**¥ (1>2,3)‡		F=36.727 **p<0.00**§ (1>2,3) (2<3)‡		$\chi2$=34.207 **p<0.001**¥ (1>2,3)‡		$\chi2$=25.304 **p<0.001**¥ (1>2,3)‡			

¥Kruskal-Wallis test, §ANOVA test, **Repeated Measures test, *Friedman test, M: Mean, Mdn: Median, IQR: Interquartile range, SD: Standard deviation

‡Comparison of the groups' scores at T1 (1) before the eye examination, T2 (2) at the 30th second of the eye examination, and T3 (3) at the end of the eye examination

T1: Before eye examination, T2: 30 seconds of eye examination, T3: End of eye examination

the routine clinical protocol prior to the examination. The analgesic effect of this topical anesthetic may have reduced the overall pain response during the procedure, thereby masking the differences between the intervention and control groups. Furthermore, in our study, the second measurement (T2) was taken at the 30th second of the eye examination, a time previous research has identified as when infants typically exhibit the most intense pain and stress responses. This standardized time point ensured comparability between groups. However, the duration of the eye examination varied slightly among infants (approximately 1-1.5 minutes per eye). This variability may have influenced the T3 measurements, as some infants were exposed to the procedure for a longer duration, potentially resulting in differences in cumulative stress or in recovery time. Another limitation is that the temporal recovery of pain and physiological parameters after the procedure could not be evaluated, as no T4 measurement was obtained. This prevented the assessment of whether any intervention provided an advantage during the recovery phase. Additionally, due to the nature of the interventions, it was not possible to blind the nurse performing the assessments, which may have introduced observer bias in the evaluation of pain scores. The findings of the study highlight the need to develop new, more effective strategies to manage pain during detailed eye examinations in healthy term infants.

Study Limitations

Infants who presented for an eye examination were assessed in a quiet, dark environment. However, the infants' crying during the procedure might have reduced their ability to hear the white noise, diminishing its effectiveness. The pain scores and physiological values of the infants returning to normal levels (T4) could not be assessed. Another limitation of the study was that the nurse who evaluated the infants' physiological findings and pain scores could not be blinded because of the study design. Video recordings were not used for the blinded assessment of PIPP scores. Therefore, the possibility of observer bias cannot be completely ruled out; such bias may have influenced the evaluation of pain scores.

CONCLUSION

In this study, healthy term infants experienced procedure-related pain during detailed eye examinations, accompanied by a significant increase in heart rate and a decrease in oxygen saturation. Our findings suggest that non-pharmacological interventions, such as white noise and swaddling, whether applied individually or in combination, may not be sufficient during invasive procedures such as eye examinations, thereby indicating the need to revise pain management protocols. To better understand the effectiveness of different non-pharmacological methods in managing pain and changes in heart rate and oxygen saturation during eye examinations of term infants, larger randomized controlled trials are recommended.

Ethics

Ethics Committee Approval: This study was approved by the Ankara Bilkent City Hospital No. 2 Clinical Research Ethics Committee (decision number: E2-22-2419, date: 16.10.2022).

Informed Consent: Information about the study's aims, procedures, and other relevant details was provided to the infants' parents. They signed a written consent form before the study commenced.

Footnotes

Authorship Contributions

Surgical and Medical Practices: Ö.Ö., Concept: S.G.B., H.Ç., E.B.A., Ö.Ö., Design: S.G.B., H.Ç., Data Collection or Processing: S.G.B., E.B.A., Ö.Ö.,Analysis or Interpretation: S.G.B., H.Ç., E.B.A., Literature Search: S.G.B., H.Ç., Writing: S.G.B., H.Ç., E.B.A.

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