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Effects of three auditory stimuli on neonatal pain during heel lance: A randomized controlled trial

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ABSTRACT

Background: Neonatal procedural pain is frequent in intensive care settings, and effective non-pharmacological interventions are needed. Evidence comparing different auditory stimuli is limited.
Objective: To compare the effects of three auditory stimuli on neonatal pain during heel lance.
Methods: This assessor-blinded randomized controlled trial included eligible neonates born between 28 and 42 weeks of gestation who were randomly assigned to one of four groups: maternal prenatal music, white noise, heartbeat sound, or control.
Results: A total of 84 neonates were enrolled in the study. The enrolled neonates had a mean gestational age of 33.92 ± 3.41 weeks; 53.6% were male and 46.4% were female. During heel lance, the mean NIAPAS pain score was significantly lower in the white noise group than in the control group (8.81 ± 3.57 vs. 12.45 ± 2.45; $p = 0.007$). One minute after the procedure, mean pain scores were 2.48 ± 1.85 in the music group, 4.19 ± 2.53 in the heartbeat group, 3.07 ± 2.18 in the white noise group, and 7.26 ± 3.03 in the control group, with significantly lower scores in all intervention groups than in the control group (music: $p < 0.001$; heartbeat: $p = 0.030$; white noise: $p = 0.011$). Mean crying duration was 18.95 ± 9.11 s in the music group, 18.43 ± 11.43 s in the heartbeat group, 20.86 ± 11.49 s in the white noise group, and 27.14 ± 12.04 s in the control group. Crying duration was significantly shorter in the music ($p = 0.010$) and heartbeat ($p = 0.025$) groups than in the control group.
Conclusion: White noise reduced procedural pain, whereas maternal prenatal music and heartbeat sounds were effective in reducing post-procedural pain and crying. These findings suggest that simple auditory interventions may be incorporated into routine neonatal care as safe, inexpensive, and easily applicable non-pharmacological strategies for procedural pain management. Further studies are warranted to confirm these findings across different neonatal populations and clinical settings.

1. Introduction

Acute pain is defined as "an unpleasant somatic or visceral sensation caused by actual or potential tissue damage" (Obeidat et al., 2021). Until recently, it was believed that neonates do not perceive pain due to incomplete nerve myelination; however, evidence has shown that pain perception begins before 24 weeks of gestation (Johnston, 2020). Neonates in neonatal intensive care units (NICUs) are exposed to multiple invasive procedures and experience approximately 10–15 painful stimuli per day (Fernández et al., 2020). Heel lance is among the most common of these procedures and has been reported as the most frequent invasive intervention, accounting for 65.5% (Aydın and Karakoç, 2022).

Repeated painful interventions may result in short- and long-term physiological, neurodevelopmental, behavioral, and socio-emotional adverse effects (Lim and Godambe, 2017). Therefore, effective pain management is essential. Although pharmacological methods are widely used, many analgesics may cause adverse effects; for example, opioids can lead to somnolence and respiratory depression (Mangat et al., 2018). Consequently, non-pharmacological interventions are recommended as first-line strategies for the management of procedural pain in neonates. High-quality systematic reviews have consistently identified breastfeeding, oral sweet solutions, skin-to-skin care, and non-nutritive

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sucking as the most effective non-pharmacological interventions for reducing procedural pain in neonates (Johnston et al., 2017; Shah et al., 2023; Yamada et al., 2023). More recent systematic reviews and meta-analyses have further confirmed the effectiveness of breastfeeding and other non-pharmacological interventions for neonatal procedural pain management (Garcia-Valdivieso et al., 2023; Shi et al., 2024).

Among the various non-pharmacological interventions, auditory stimulation has gained increasing attention as a safe and easily applicable strategy for procedural pain management. Music therapy has been shown to reduce stress and pain and improve physiological parameters such as oxygen saturation and peak heart rate (Bieleninik et al., 2021; Anderson and Patel, 2018). Maternal heartbeat sounds have been reported to stabilize heart rate and respiration, reduce pain, and promote weight gain in preterm infants (Williamson and McGrath, 2019). In addition, rhythmic auditory stimuli have been associated with pain reduction (Taplak and Bayat, 2021). White noise, in particular, has been shown to decrease pain scores, stabilize vital signs, and positively influence the sleep–wake cycle in preterm infants (Cetinkaya et al., 2022).

Although breastfeeding, oral sweet solutions, skin-to-skin care, and non-nutritive sucking are recommended as effective non-pharmacological interventions for reducing procedural pain in neonates, their routine use may not always be feasible in neonatal intensive care units. Preterm or clinically unstable infants may be unable to breastfeed safely, mothers may not be present during painful procedures, and the routine use of sweet solutions may be limited by institutional policies or local clinical practice. Therefore, evaluating alternative, safe, and easily applicable interventions remains clinically important.

Despite these findings, studies directly comparing different auditory stimuli within a single randomized controlled design remain limited. Therefore, this randomized controlled experimental study aimed to determine the effects of music, white noise, and maternal heartbeat sounds on neonatal pain during heel lance.

2. Materials and methods

2.1. Study design

This study was designed as a randomized controlled, assessor-blinded trial to evaluate the effects of music, white noise, and heartbeat sounds during heel lance in infants. The trial was registered at ClinicalTrials.gov (NCT05828420) and is presented according to the CONSORT guidelines (Schulz et al., 2010).

2.2. Participants

Data were collected between October 2020 and January 2021 in the neonatal intensive care unit (NICU) of a public hospital. The study population consisted of infants born at 28–42 weeks of gestation. Infants who had received sedatives or analgesics within the previous 6 h or had a diagnosis of intracranial hemorrhage or hypoxic–ischemic encephalopathy were excluded. Infants in whom heel lance could not be successfully performed on the first attempt were also excluded.

The sample size was calculated based on a previous study (Rossi et al.). The primary outcome used for the sample size calculation was the neonatal pain score during heel lance, assessed using the Neonatal Infant Acute Pain Assessment Scale (NIAPAS). As no previous study directly comparing maternal prenatal music, white noise, heartbeat sound, and control groups was available, the calculation was based on an expected medium effect size for between-group differences in pain scores ($\eta^2 = 0.14$; $f = 0.25$). At least 80 infants were required to achieve 95% power. Considering a potential 20% attrition rate, additional participants were enrolled to account for possible losses. Randomization was performed using the Randomizer.org program (https://www.randomizer.org) and stratified block randomization according to gestational age (28–32, 33–37, and 38–42 weeks). Within each gestational age stratum, infants were randomly allocated in equal numbers to one of four study groups (maternal prenatal music, heartbeat sound, white noise, or control).

2.3. Data collection instruments

Data were collected using a structured form including demographic and clinical variables. Infant observation forms were used to record procedure duration and crying time.

Pain was assessed using the Neonatal Infant Acute Pain Assessment Scale (NIAPAS). NIAPAS was selected because it is a multidimensional pain assessment tool that evaluates both behavioral and physiological indicators of acute pain in neonates. It has demonstrated good validity and reliability for assessing procedural pain in both preterm and term infants and is considered suitable for use in neonatal intensive care settings (Pölkki et al., 2014; Kanbur et al., 2021). The scale evaluates facial expression, crying, muscle tone, alertness, response to stimuli, heart rate, respiration, and oxygen saturation, with total scores ranging from 0 to 18. Pain severity is classified as mild (0–5), moderate (6–9), and severe (10–18) (Pölkki et al., 2014). For mechanically ventilated infants who were unable to vocalize crying, the facial expression component of the NIAPAS was evaluated from the video recordings. Facial expressions were scored according to the NIAPAS criteria, including relaxed facial expression, frowning or displeased facial expression, pouting, grimacing, and tense facial muscles involving the eyebrows, cheeks, and chin. These observations were incorporated into the composite NIAPAS score. The Turkish validity and reliability of the scale were established by Kanbur et al., with a Cronbach's alpha of 0.914 (Kanbur et al., 2021). In the present study, Cronbach's alpha was 0.923.

Heart rate and oxygen saturation (SpO_2) were continuously monitored using the same Nihon Kohden Life Scope series bedside patient monitor (Nihon Kohden Corporation, Tokyo, Japan) for all enrolled neonates throughout the study. Respiratory rate was assessed by the researcher through direct observation and manual counting. The same monitor was used for all participants, and it was routinely calibrated by the hospital every six months to ensure measurement accuracy.

Video recordings were obtained using a Casio digital camera (16.1 MP). Auditory stimuli were delivered using JBL speakers. Sound intensity was measured using a Mastech sound level meter (measurement range: 30–130 dB).

2.4. Study procedure

Data collection was conducted between 08:00 and 09:00 a.m. All infants were fed approximately 1 h before the procedure. In routine NICU practice, mothers were not present during heel lance and non-pharmacological interventions such as sucrose or non-nutritive sucking were not used; therefore, all infants underwent the standard procedure.

Infants in the intervention groups were exposed to maternal prenatal music, white noise, or heartbeat sounds starting 10 min before the heel lance, continuing during the procedure, and for 20 min afterward. This duration was selected based on previous literature and the known half-life of stress hormones such as epinephrine and norepinephrine (1–3 min), with normalization typically occurring within 15–20 min after a stressful procedure (Puntillo et al., 2001).

Maternal prenatal music consisted of the music most frequently listened to by the mother during pregnancy. Infants in the heartbeat group were exposed to heart sounds at an average rate of 70 beats per minute. Infants in the white noise group were exposed to a standardized white noise recording.

In all groups, an MP3 player was positioned at the head of the incubator. To maintain blinding, the same setup was used in the control group without active sound. Sound intensity was standardized at 45 dB, measured near the infant's ear.

Video recording began 11 min before heel lance (i.e., 1 min before sound exposure) and continued until 20 min after the procedure. Heel lance was performed in the supine position from the lateral surface of the right heel using a standardized technique. Heel lance procedures were performed by two experienced neonatal nurses using a standardized technique, and all procedures were completed on the first attempt.

Total procedure duration and crying time were calculated from video recordings. Crying in ventilated infants was assessed using non-auditory facial expressions. The study procedure is summarized in Fig. 2.

2.5. Outcome measures

Pain was assessed at five time points:

(1) 11 min before the procedure,
(2) 1 min before,
(3) during the procedure,
(4) 1 min after, and
(5) 20 min after the procedure.

2.6. Blinding and reliability

The study was assessor-blinded. Pain assessments were performed independently by two neonatal nurses with 10 years of NICU experience, who were not involved in the intervention and were blinded to group allocation.

Inter-rater reliability was evaluated using the intraclass correlation coefficient (ICC), demonstrating excellent agreement (ICC = 0.987; $p < 0.001$). Pain scores were calculated as the mean of the two observers' ratings.

2.7. Statistical analysis

Data were analyzed using SPSS version 22.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were presented as frequency (%) for

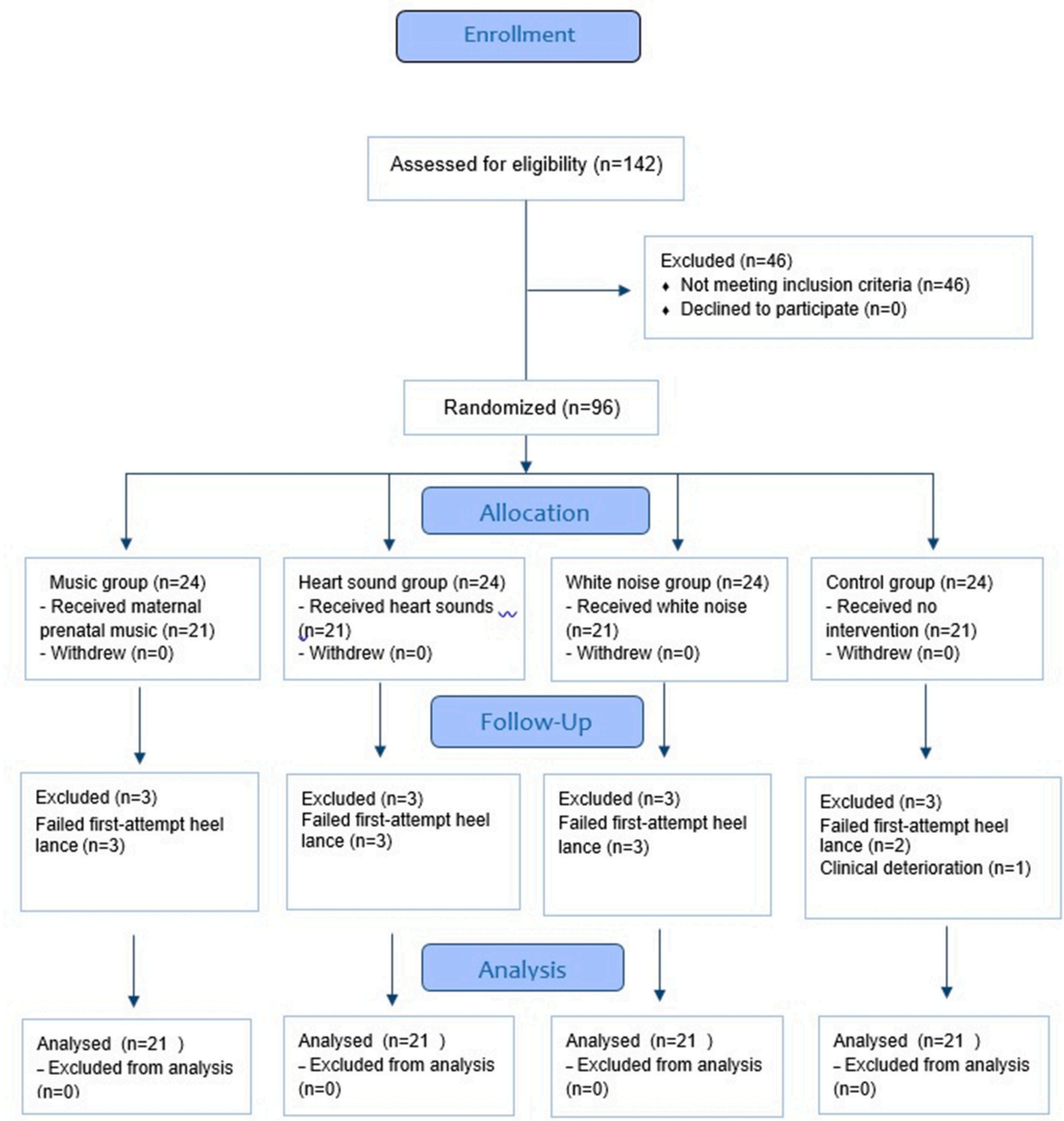

Fig. 1. CONSORT diagram.

categorical variables and mean ± standard deviation for continuous variables.

Parametric tests were used for normally distributed data, and non-parametric tests for non-normally distributed data. Chi-square test, Kruskal–Wallis test, Friedman test, and paired-samples *t*-test were applied as appropriate. Post hoc analyses were conducted using Bonferroni correction. Statistical significance was set at $p < 0.05$.

2.8. Ethical approval

The study was approved by the XXX Ethics Committee (date: 25.11.2019; approval number: 2019-23-17). Written informed consent was obtained from the legal guardians of all participants.

3. Results

A total of 96 infants were initially enrolled in the study. During the study period, 12 infants were excluded because heel lance could not be successfully performed on the first attempt (n = 11) or because of clinical deterioration during the procedure (n = 1). Consequently, the final sample consisted of 84 infants, with 21 infants allocated to each study group. The participant flow is presented in the CONSORT flow diagram (Fig. 1).

Baseline characteristics did not differ significantly between groups ($p > 0.05$; Table 1). The groups were comparable in terms of sex, gestational age, postnatal age, birth weight, 1- and 5-min Apgar scores, type of respiration, and diagnosis.

There were no significant differences in mean pain scores at 11 min

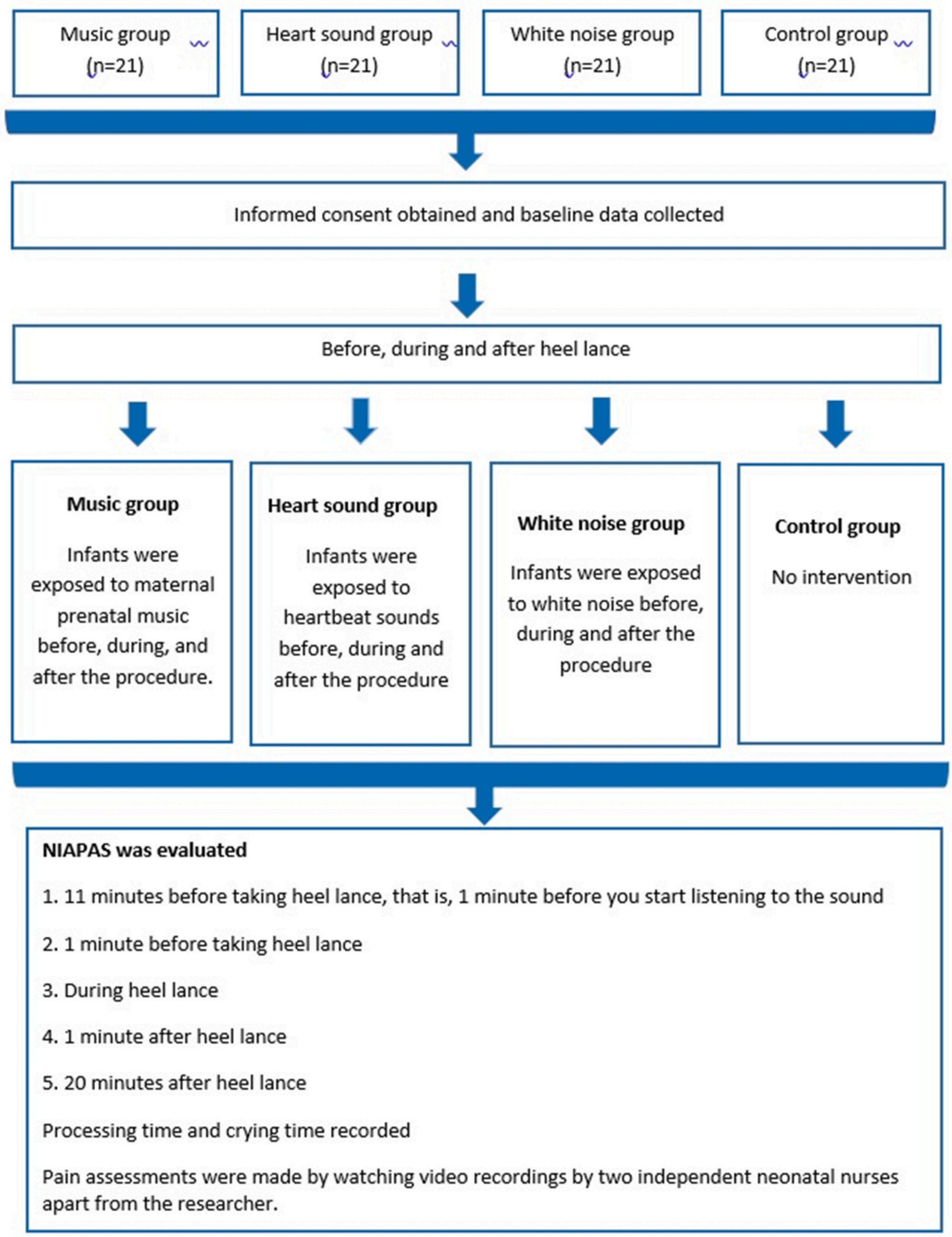

Fig. 2. Flow chart.

Table 1
Baseline characteristics of infants by study group (N = 84).

Characteristics		White Noise (n = 21)	Heart Sound (n = 21)	Music (n = 21)	Control (n = 21)	Total (n = 84)	Test	p
		n (%)	n (%)	n (%)	n (%)	n (%)		
Sex	**Female**	7 (33.3%)	12 (57.1%)	8 (57.1%)	12 (57.1%)	39 (46.4%)	$\chi^2 = 3.973$	p = 0.264
	Male	14 (66.7%)	9 (42.9%)	13 (42.9%)	9 (42.9%)	45 (53.6%)		
Gestation Week	**Mean±SD**	33.92 ± 3.42	34.10 ± 3.50	34.24 ± 3.47	33.67 ± 3.45	33.92 ± 3.41	*KW* = 0.205	p = 0.977
Birth weight	**Mean±SD**	2101.19 ± 995.28	2242.86 ± 1145.16	2192.86 ± 1180.65	2216.19 ± 1083.38	2188.27 ± 1084.56	*KW* = 0.166	p = 0.983
Postnatal age	**Mean±SD**	10.38 ± 12.24	16.81 ± 21.75	9.71 ± 8.18	19.24 ± 23.03	14.04 ± 17.63	*KW* = 2.040	p = 0.564
Apgar scores 1 min.	**Mean±SD**	6.62 ± 1.16	6.81 ± 0.92	6.71 ± 0.84	6.10 ± 1.41	6.56 ± 1.12	*KW* = 3.081	p = 0.379
Apgar score 5 min.	**Mean±SD**	8.05 ± 0.86	8.29 ± 0.84	8.24 ± 0.70	7.76 ± 1.09	8.08 ± 0.89	2 KW = 2.986	p = 0.394
Type of Respiration	**Connected to a mechanical ventilator**	3 (14.3%)	3 (14.3%)	2 (9.5%)	4 (33.3%)	12 (19.0%)	$\chi^2 = 1.523$	p = 0.958
	CPAP	7 (33.3%)	6 (28.6%)	8 (38.1%)	5 (19.2%)	26 (23.8%)		
	Spontaneous respiration	11 (52.4%)	12 (57.1%)	11 (52.4%)	12 (26.1%)	46 (57.1%)		
Diagnosis	**Preterm and**	13 (61.9%)	15 (71.4%)	15 (71.4%)	11 (52.4%)	54 (64.2%)	$\chi^2 = 10.863$	p = 0.762
	Mild asphyxia	1 (4.8%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	2 (2.3%)		
	TTN	1 (4.8%)	3 (14.3%)	2 (9.5%)	5 (23.8%)	11 (13.0%)		
	Pneumonia	1 (4.8%)	1 (4.8%)	2 (9.5%)	2 (9.5%)	6 (7.1%)		
	Polycythemia	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.1%)		
	Hypoglycemia	4 (19.0%)	2 (9.5%)	2 (9.5%)	2 (9.5%)	10 (11.9%)		

Music group: Classical music was played for 4 infants, Turkish folk music for 6 infants, Turkish classical music for 4 infants, and pop music for 7 infants. χ^2: Chi-Square Test, KW: Kruskall-Wallis Test, *p < 0.05, **p < 0.001.

before the procedure ($\chi^2 = 0.290$; p = 0.962) or 1 min before the procedure ($\chi^2 = 1.066$; p = 0.785). During the procedure, a significant difference was observed ($\chi^2 = 11.337$; p = 0.010). Mean pain scores were lowest in the white noise group (8.81 ± 3.57), followed by the music (10.05 ± 3.69), heartbeat (10.17 ± 4.65), and control groups (12.45 ± 2.45). Post hoc analysis with Bonferroni correction showed that the white noise group had significantly lower pain scores than the control group (p = 0.007).

At 1 min after the procedure, a significant difference was also found ($\chi^2 = 27.661$; p < 0.001). Mean pain scores were 3.07 ± 2.18 (white noise), 4.19 ± 2.53 (heartbeat), 2.48 ± 1.85 (music), and 7.26 ± 3.03 (control). Post hoc analysis indicated that pain scores in the heartbeat (p = 0.030), music (p < 0.001), and white noise (p = 0.011) groups were significantly lower than those in the control group. No significant difference was observed at 20 min after the procedure ($\chi^2 = 6.250$; p = 0.100) (Table 2; Fig. 3).

Mean crying duration was 20.86 ± 11.49 s in the white noise group, 18.43 ± 11.43 s in the heartbeat group, 18.95 ± 9.11 s in the music group, and 27.14 ± 12.04 s in the control group. Twelve infants were mechanically ventilated; crying in these infants was assessed using non-auditory facial expressions. A significant difference in crying duration was observed ($\chi^2 = 8.256$; p = 0.041). Post hoc analysis showed that crying duration was significantly shorter in the music (p = 0.010) and heartbeat (p = 0.025) groups compared with the control group (Table 3).

The duration of the heel lance procedure did not differ significantly among the four groups (white noise: 14.95 ± 3.62 s; heartbeat: 15.62 ± 2.83 s; music: 16.14 ± 4.12 s; control: 15.76 ± 2.45 s; $\chi^2 = 1.816$, p = 0.611). Therefore, differences in crying duration were unlikely to be attributable to variations in procedure duration.

4. Discussion

The most important strategy in neonatal pain management is to avoid pain-inducing interventions whenever possible (Maciel et al., 2019). However, this is often not feasible, as many diagnostic and therapeutic procedures are necessary to ensure clinical stability and recovery (Benoit et al., 2017). Therefore, effective pain reduction strategies are essential. Non-pharmacological methods are widely used in neonatal pain management due to their safety, ease of application, and low cost, and are frequently preferred by nurses (Kumar et al., 2020).

Recent studies have demonstrated the effectiveness of white noise in relieving pain (Cetinkaya et al., 2022; Küçükoğlu et al., 2016; Döra and Büyük, 2021). White noise has also been reported to positively influence physiological responses and enhance sensory perception (Bureš et al., 2017). In the present study, infants in the white noise group experienced the lowest pain scores during heel lance, with significantly lower scores compared to the control group. Similar findings have been reported in previous studies, where white noise exposure before or during invasive procedures resulted in reduced pain scores (Cetinkaya et al., 2022; Döra and Büyük, 2021; Kahraman et al., 2020; Karakoç and Türker, 2014). Ren et al. (2022) also reported shorter durations of pain-related expressions in the white noise group, although the difference was not statistically significant (Ren et al., 2022).

Auditory interventions such as music therapy, white noise, and maternal voice stimulation utilize the sense of hearing and may influence the autonomic nervous system. These interventions have been shown to reduce stress, crying duration, and hospitalization time in neonates, particularly in NICU settings (Corrigan et al., 2020). In the present study, although pain scores during the procedure were lower in the music and heartbeat groups compared to the control group, the differences were not statistically significant. However, at 1 min after the procedure, all intervention groups showed significantly lower pain scores compared to the control group. These findings are consistent with previous studies reporting that music and auditory stimulation reduce pain perception and improve physiological and behavioral responses

Table 2
Comparison of the mean NIAPAS scores of the groups (N = 84).

PAIN SCORE	White[a] Noise (n = 21)	Heart Sound[b] (n = 21)	Music[c] (n = 21)	Control[d] (n = 21)	Test	p
	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)		
11 min before the procedure	1.78 ± 1.88 0-7.5	2.09 ± 2.16 0-8	2.50 ± 3.51 0-14	2.19 ± 2.56 0-7	*KW* = 0.290	p = 0.962
1 min before the procedure	1.31 ± 1.35 0-5.5	1.48 ± 1.21 0-4	1.40 ± 1.41 0-5	2.45 ± 3.02 0-11	*KW* = 1.066	p = 0.785
During the procedure	8.81 ± 3.57 3-15	10.17 ± 4.65 1-15	10.05 ± 3.69 1-17	12.45 ± 2.45 6.5-16	***KW* = 11.337** **a<d**	**p = 0.010*** **(p = 0.007)**
1 min after the procedure	3.07 ± 2.18 0-7.5	4.19 ± 2.53 0-10	2.48 ± 1.85 0-6	7.26 ± 3.03 0-12	***KW* = 27.661** **a<d** **b < d** **c < d**	**p<0.001*** **(p = 0.011)** **(p = 0.030)** **(p<0.001)**
20 min after the procedure	1.50 ± 1.39 0-05	1.05 ± 1.07 0-4	1.02 ± 0.87 0-2.5	2.05 ± 1.80 0-7	*KW* = 6.250	p = 0.100
Test	**Fr = 59.480**	**Fr = 69.210**	**Fr = 64.111**	**Fr = 69.731**		
p	**p<0.001**	**p<0.001**	**p<0.001**	**p<0.001**		

KW: Kruskal Wallis-Test, Fr: Friedman Test, Post hoc comparisons were performed using Bonferroni correction.
*p < 0.05, **p < 0.001.

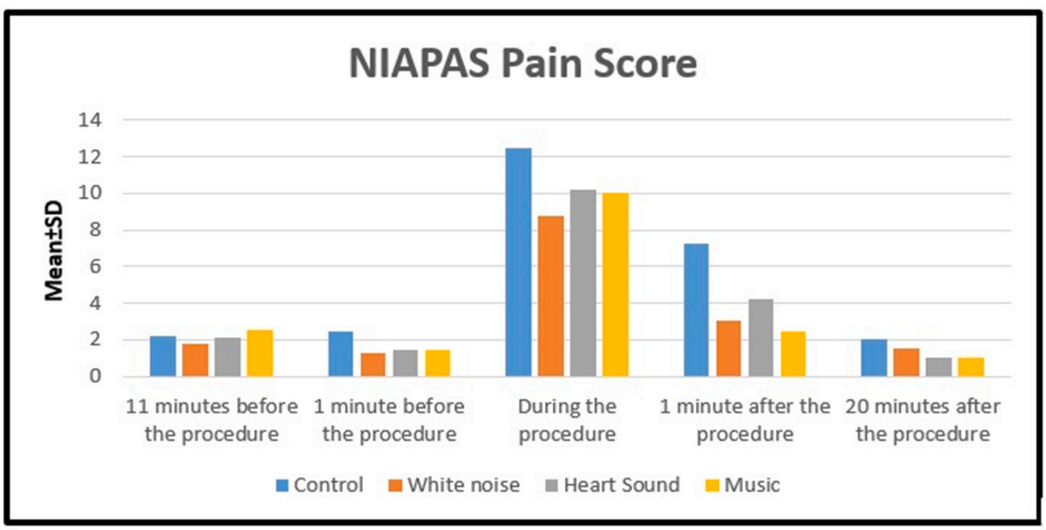

Fig. 3. Distribution of mean NIAPAS scores of the groups.

Table 3
Comparison of the mean crying times of the groups (N = 84).

	White Noise[a] (n = 21)	Heart Sound[b] (n = 21)	Music[c] (n = 21)	Control[d] (n = 21)	Test	p
	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)	Mean ± SD (Min-Max)		
Crying time (sec)	20.86 ± 11.49 0-35	18.43 ± 11.43 0-32	18.95 ± 9.11 0-30	27.14 ± 12.04 0-45	***KW* = 8.256** **c < d** **b < d**	**p = 0.041*** **(p = 0.010)** **(p = 0.025)**

KW: Kruskal Wallis-Test, Post hoc comparisons were performed using Bonferroni correction. *p < 0.05, **p < 0.001.

(Rossi et al., 2018; Shabani et al., 2016; Cavaiuolo et al., 2015).

There are limited studies examining the effects of heartbeat sounds during painful procedures in neonates (Shabani et al., 2016; Cavaiuolo et al., 2015; Küçük Alemdar and Güdücü Tüfekçi, 2018). In one study, exposure to maternal heartbeat sounds before, during, and after an invasive procedure was found to reduce pain and improve comfort levels in premature infants (Küçük Alemdar and Güdücü Tüfekçi, 2018). Similarly, other studies have reported positive effects of maternal heartbeat sounds on physiological parameters such as heart rate and oxygen saturation (Sarhangi et al., 2021). In the present study, consistent with the literature, the heartbeat group demonstrated lower pain scores than the control group during the procedure (although not statistically significant) and significantly lower pain scores at 1 min after the procedure.

Although the intervention groups demonstrated significantly lower pain scores than the control group at certain assessment points, pain scores during the heel lance procedure remained within the severe pain range according to the NIAPAS classification. This finding suggests that auditory interventions alone may reduce the intensity of procedural pain but are insufficient to eliminate pain during heel lance. Current evidence from systematic reviews indicates that breastfeeding, oral sweet solutions, skin-to-skin care, and non-nutritive sucking are among the most effective first-line non-pharmacological interventions for procedural pain in neonates. (Shah et al., 2023; Johnston et al., 2017; Yamada et al., 2023). Therefore, auditory interventions should be considered complementary rather than replacement strategies, particularly when first-line evidence-based non-pharmacological interventions are not clinically feasible. When these interventions can be implemented, they should remain the standard of care, with auditory stimulation serving as an adjunctive rather than a substitute strategy.

Crying is one of the most observable indicators of pain in infants and is commonly used to assess pain severity and duration (Johnston et al., 2017). In this study, the most effective interventions in reducing crying duration were music and heartbeat sounds, followed by white noise. Although white noise reduced crying duration, the difference compared to the control group was not statistically significant. Previous studies have similarly reported that music and white noise reduce crying duration and pain-related behaviors in neonates (Cetinkaya et al., 2022; Keith et al., 2009; Ju, 2019). In addition, although no direct evidence exists regarding the effect of heartbeat sounds on crying duration during painful procedures, studies have shown that maternal heartbeat sounds reduce apnea and bradycardia episodes and improve oxygen saturation in neonates (Küçük Alemdar and Güdücü Tüfekçi, 2018; Doheny et al., 2012).

In the present study, 11 infants were excluded because heel lance could not be successfully completed on the first attempt according to the predefined study protocol, while one additional infant was excluded because of clinical deterioration during the procedure. All heel lance procedures were performed by two experienced neonatal nurses using a standardized technique, thereby minimizing operator-related variability. Therefore, unsuccessful first-attempt procedures are more likely to reflect the technical challenges of heel lance in a heterogeneous NICU population than differences in operator performance. Future studies should investigate strategies to improve first-attempt success, such as optimizing puncture site selection, adhering to standardized heel lance protocols, and evaluating the potential role of automated lancet devices.

In recent years, increasing evidence has highlighted the negative neurodevelopmental consequences of repeated painful procedures in neonates. Therefore, it is essential for healthcare professionals to minimize pain exposure and implement effective pain management strategies. The use of easily applicable pain assessment tools and non-pharmacological interventions should be encouraged as part of routine clinical practice in neonatal care. In addition, parental presence and participation during non-urgent painful procedures should be encouraged whenever clinically feasible. Current evidence supports breastfeeding, skin-to-skin care, oral sweet solutions, and non-nutritive sucking as first-line non-pharmacological interventions for procedural pain management in neonates. However, when these interventions cannot be implemented because of the infant's clinical condition, auditory interventions such as music, white noise, and maternal heartbeat sounds may be considered complementary strategies rather than replacements for first-line pain management approaches.

This study has several limitations. First, the control group received routine care rather than evidence-based first-line non-pharmacological pain management interventions, such as breastfeeding, skin-to-skin care, oral sweet solutions, or non-nutritive sucking. Therefore, the effectiveness of the auditory interventions evaluated in this study cannot be directly compared with these recommended first-line interventions. Second, although heel lance procedures were performed according to a standardized institutional protocol by two experienced neonatal nurses, the procedures were not all performed by the same healthcare professional, which may have introduced a small degree of procedural variability. Finally, although all data were collected under similar NICU conditions and at comparable times of the day, environmental noise levels were not objectively measured; therefore, their potential influence on the study outcomes cannot be completely excluded.

5. Conclusions

Although auditory interventions demonstrated statistically significant reductions in pain scores and crying duration compared with routine care, procedural pain remained within the moderate-to-severe range during heel lance. These findings suggest that auditory interventions may provide additional benefit as complementary non-pharmacological strategies but should not replace evidence-based first-line interventions such as breastfeeding, skin-to-skin care, oral sweet solutions, or non-nutritive sucking. Improving routine procedural pain management practices in neonatal intensive care units through greater implementation of evidence-based interventions and parental participation, whenever clinically feasible, may further reduce neonatal pain. Future studies should compare auditory interventions directly with first-line pain management strategies and evaluate their combined use in clinical practice.

Ethics Committee approval

The study was approved by Istanbul Bakirköy Dr. Sadi Konuk Training and Research Hospital Clinical Trials Ethics Committee (date: 25.11.2019, number: 2019-23-17). The legal guardians of the infants included in the study were informed about the aim, type, and implementation procedure of the study and how and where the data would be used. Their written informed consents were obtained.

Trial registration

ClinicalTrials.gov (NCT05828420).

Presented or pre-print or published as an abstract or as a thesis

This manuscript is derived from a doctoral thesis. The study was presented as an oral/poster presentation at the 66th National Turkish Pediatric Congress. It has not been published as a full-text article.

Declaration of generative AI

No generative AI or AI-assisted technologies were used in the preparation of this manuscript.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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