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The Effect of The Musical Snow Globe Used in Infancy Vaccination Applications on The Level of Pain: A Randomized Controlled Study

Betül Akkoç, Tülay Kuzlu Ayyıldız

Zonguldak Bülent Ecevit University, Health Sciences Institute, Department of Child Health and Diseases Nursing, Zonguldak, Türkiye.

Correspondence Author: Betül Akkoç
E-mail: betulakkoc89@hotmail.com
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ABSTRACT

Objective: This randomized controlled trial was conducted to investigate the effect of a musical snow globe on reducing pain associated with vaccine administration in infants 2-6 months of age.

Methods: The sample of the study consisted of 78 infants (experimental group (EG):39, control group (CG): 39 babies) who applied to the family health center between the specified dates and met the case selection criteria. The Face, Legs, Activity, Crying, and Comfort (FLACC) Scale was used to assess infants' pain before, during, and after immunization. Heart rate and oxygen saturation in the infants' blood were measured as part of the study. During vaccine administration, infants in the experimental group were shown a snow globe with music, while infants in control group were vaccinated with a routine health application.

Results: There was no statistically significant difference (p>.05) between the SpO2 values before the interventions (EG: 99.46 CG: 99.56) and the SpO2 values after the interventions (EG: 96.30 CG: 96.05) of the babies in the experimental and control groups; In heart rates, there was no statistically significant difference (p>.05) between befoere the interventions (EG:127.31 CG:127.71) and after the interventions (EG:140.10 CG:147.66) values. However, a significant difference was found between SpO2 (EG: 95.20 CG: 93.23) and heart rate values (EG: 145.76 CG: 157.33) during the intervention (p<.05). There was no statistically significant difference between the FLACC scores (EG: 0.23 CG: 0.28) of the babies in both groups before the intervention (p>.05); however, the FLACC scores of the infants in the experimental group were lower than the infants in the control group at the time of the intervention (EG: 3.89 CG: 6.92) (p<.05) and afterwards (EG: 2.82 CG: 5.18) (p<.05). A significant difference was found between the babies in the experimental and control groups in terms of crying time. Babies in the experimental group cried for a shorter time (EG: 140.09 CG: 193.44) (p<.05).

Conclusion: The study showed that musical snow globe is an effective tool for reducing pain during vaccinations in infants.

Keywords: Infants, vaccine application, pain, musical snow globe

1. INTRODUCTION

Vaccine administration is one of the most common invasive and painful procedures children face in the neonatal period Infants are exposed to a total of 24 injections through vaccination in the first two years of life in United States (1). In Turkey, the total number of injections for routine vaccinations is twenty (2). The high number of vaccinations in healthy infants and children and the psychological trauma caused by vaccination pain necessitate intervention against the pain that occurs during vaccination (3).

Pain was considered as a fifth life finding and was stated that all infants, including preterm infants, experience the negative effects of pain (4). Therefore, the management of acute pain in infants and children is of great importance due to invasive procedures. The pain that occurs during immunization can affect the child physically, emotionally, and behaviorally if not properly managed. Deterioration in breathing patterns, inadequate oxygenation of tissues, changes in blood pressure, increases in pulse rates and oxygen consumption, and enlargement of pupils are among the negative physiological conditions caused by pain (5,6). Children may experience emotional and behavioral problems, such as difficulty socializing, anxiety, stress disorders, and rapid distraction (7).

Pharmacologic and nonpharmacologic measures are used to control infant pain during vaccine administration. However, due to some adverse reactions to pharmacologic measures, the use of nonpharmacologic measures has greatly increased (8). Some studies have been conducted to alleviate neonatal painful initiatives using one or more sensory stimuli based on the neonates' senses of sight, hearing, touch, taste, and smell (8,9).

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When selecting these methods, it is important to consider the child's age and developmental stage and that the method is appropriate for the child. It is necessary that attention distraction methods address the child both visually and auditorily, especially in infancy (10-13). The use of attention redirection methods in infants and children can prevent the child from focusing on pain, and the pain they feel can be reduced by redirecting attention (13,14). Studies have shown that skin-to-skin contact (13,15), the use of sucrose solution (16), foot reflexology (17), breastfeeding and maternal breast milk odor (15,18), the Exor Baby Music Mobile (19), and heat and cold applications are effective in treating infant pain (20).

2. METHODS

2.1. Design

This randomized, controlled trial was conducted in newborns 2 to 6 months of age admitted to a family health center for vaccination from June to December 2020.

The study was submitted to Clinical Trials, Protocol ID 121.020.20100140, Clinical Trials ID No: NCT04772430.

2.2. Sample

The inclusion criteria of the study were: Age between 2 and 6 months, term birth or greater than 38 weeks of gestation at birth, no congenital or chronic health problems, enrollment in the family health center for vaccination, no use of an analgesic medication in the past 4 hours, accompaniment by a parent, and no crying before vaccination. The study was conducted in two family health centers. For randomization, the experimental and control groups were drawn by lot among the family health centers.

In order to determine the intervention and control groups in the study, one family health center intervention and the other family health center control group were determined by drawing lots. The drawing of lots was independently made by a nurse other than the researcher.

Power analysis performed with the G-power 3.1.9.2 program showed that the minimum sample size required was 64, with a confidence level of 95% (margin of type 1 error =.05) and a power level of 90% (margin of type 2 error =.10). Forty newborns were included in each group in case there were situations that might disturb the homogeneity of the groups in terms of case losses and variables affecting pain.

In the first phase of the study, 166 newborns who came to both family health centers for vaccination were included. However, 67 infants were excluded from the study because they did not meet the inclusion criteria, 10 infants because their parents did not want to participate in the study, and 9 infants because they cried before use. The parents of two infants declined to participate in the study during enrollment. Seventy-eight infants completed all phases of the study. Figure 1 describes the study procedure. The design, conduct, and reporting of this study conformed to the guidelines of the Consolidated Standards of Reporting Trials

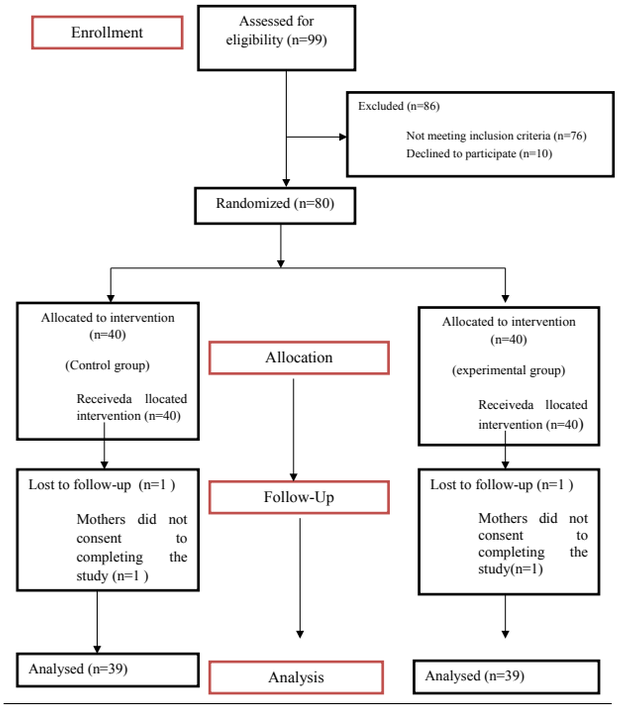

Figure 1. *CONSORT Diagram of this study.*

2.3. Instruments

Baby introductory information form

The form created by the researchers consists of two parts. The first part contains 10 questions about the baby's sex, age, weight, height, number of previous vaccinations, type of diet, nutritional status before vaccination, and duration of feeding.

Registration form

This is the form that records the infant's oxygen saturation level (SpO_2) before, during, and after use, crying duration, pulse, and respiratory values.

Face, Legs, Activity, Cry, Consolability (FLACC) Scale

Developed in 1997 by Merkel et al, this is a behavioural observation scale used in the assessment of procedural and postoperative pain in children aged two months to seven years. The FLACC Pain Scale score is determined by evaluating five categories such as facial expression, leg movements, activity, crying, and comfort (21). The adaptation of the scale to Turkish language was done by Şenaylı et al. (22).

In the current study, the intraclass correlation coefficient (ICC), which indicates the correlation between FLACC scores obtained during and after vaccination, was calculated by two independent observers under the same conditions to measure the inter-rater reliability of the FLACC scale. The ICC was .99, .97, and .98 before the procedure, during the procedure, and after the procedure, respectively.

Pulse oximeter device

In the study, a Mindray brand device was used to determine infants' oxygen saturation and heart rate before, during, and after paediatric use. Calibration of the device is checked annually. The PM-60 is a small and lightweight device for immediate and uninterrupted monitoring of SpO_2 and heart rate. The 2.4-inch colour screen LCD continuously displays SpO_2 and heart rate values.

Delta chronometer SW 305

It is simple and practical to use and operates on a 1.5 V battery. The chronometer was put into operation when sampling began, and each step of the process was performed in sequence.

The snow globe

The snow globe used in the study was in soft shades of pink, cream, and yellow. Inside the snow globe was a baby figure sleeping over the moon. The snow globe was 18x15 cm, had the shape of a glass dome and the snow machine inside constantly created the impression of snow falling on the scene. The snow globe was accompanied by classical music and worked continuously when the button was turned on.

2.4. Conducting the Study

Parents who agreed to participate in the study were asked to fill out the Baby Introduction Form. The temperature of the intervention room where the vaccination was performed was set at 24°C. The humidity was 30%, the lighting was 1000 lux, and the noise level was 35 dB(A) during the day, which met occupational health and safety requirements. At the facility where the study was conducted, these measurements are taken regularly for occupational safety reasons. No other procedures were applied in the intervention room during vaccination to avoid external factors. No one was allowed to enter the room except the baby and its parents, the nurse who administered the vaccine, and the researcher.

The infants were placed supine on a couch for vaccination. All infants were awake and wearing clean diapers during the injection, and their parents were in the same room. The pulse oximeter was attached to the baby's right wrist on the stretcher, and the baby's heart rate and SpO_2 were recorded prior to vaccination. This device was left on the baby's wrist throughout the procedure. Then, the researcher and a nurse separately measured the FLACC scale values. Before vaccination, the timer was kept ready, which was activated as soon as the baby began to cry. The baby's injection site was opened by the nurse and cleaned with 70% ethyl alcohol according to aseptic principles. The vaccines were injected into the vastus lateralis muscle at a 90° angle using a 23-mm needle. The injection lasted approximately 20 seconds. After the procedure, light pressure with dry cotton was applied to the inoculated area. The timer was turned on until the baby stopped crying. The infants' heart rate and SpO_2 were recorded during sampling, and the degree of pain was assessed using the FLACC scale. Two minutes after administration of the vaccination, the heart rate and SpO_2 were recorded again, and the level of pain was assessed using the FLACC scale. The administration of the vaccination took an average of one minute in each of the babies.

After the pain scores were assessed with the FLACC scale, in contrast to the infants in the control group, the snow globe was placed at a distance of 20-30 cm so that the infants in the experimental group could see it before inoculation. The snow globe was kept in operation throughout the vaccination. All infants in the experimental and control groups were injected with the same vaccine by the same nurse.

2.5. Ethical Aspects of the Research

Parental informed consent, facility approval, and ethics committee approval (date: 24.06. 2020 and number: 2020-13) were obtained.

2.6. Data Analysis

The SPSS 22.0 program was used for statistical analysis. Mean-standard deviation (minimum-maximum), number, percentages, Kolmogrov-Smirnov test, chi-square, Mann-Whitney U test, Friedman test, and T test for paired samples were used to analyze the data. Results were analyzed with a 95% confidence interval, and p <.05 was considered statistically significant (23,24).

3. RESULTS

The study found that the infants in both groups were similar in terms of sex, age, weight, length, number of previous vaccinations, type of diet, nutritional status before vaccination, and duration of feeding, and no statistically significant difference was found between them (p>.05) (Table 1).

Table 1. *Descriptive characteristics of babies*

Characteristics	EG (n=39) Mean±SS	CG (n=39) Mean ±SS	Total (n=78) Mean ±SS	Test Value Z	p
Age (month)	3.79±1.50	3.74±1.60	3.79±1.54	-0.146	.88[a]
Weight (g)	6523±984.55	6608±117.85	6565±1047.33	0.357	-.77[a]
Length (cm)	60.66±4.32	60.05±5.31	60.35±4.82	-0.561	.57[a]
Number of previous	4.46±1.93	4.35±2.04	4.41±1.97	-0.228	.82[a]
Gender	n (%)	n (%)	n (%)		
Girl	21 (53.8)	22(56.4)	43(55.1)	0.523	.82[b]
Boy	18(46.2)	17(43.6)	35(44.9)		
Nutrition					
Yes	25 (64.1)	33 (84.6)	58(74.4)	4.303	.38[b]
No	14 35.9)	6(15.4)	20(25.6)		
Diet					
Breast milk	39 (100.0)	33(84.6)	72(92.3)	6.500	.39[b]
Breast milk+ formula	0 (0.0)	6 (15.4)	6 (7.7)		

[a]*Mann Whitney U Testi* [b]*Ki-Kare Testi p<.05*

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Table 2. *Comparison of the physiological parameters and pain scores of the groups according to the procedure time*

Groups		Before transaction[a]	During transaction[b]	After Transaction[c]	p	p[c-d]	p[c-e]	p[d-e]
EG	FLACC scores	0.23± 0.62	3.89± 2.95	2.82± 2.15	.001[f]	.001[g]	.001[g]	.003[g]
CG		0.28±0.82	6.92 ± 2.14	5.18 ± 2.23	.001[f]	.001[g]	.001[g]	.001[g]
	p	.768[a]	.001[a]	0.001[a]				
EG	Mean heart rates	127.31±15.47	145.76±20.08	140.10±19.42	.001[f]	.001[g]	.001[g]	.002[g]
CG		127.71±14.72	157.33±18.95	147.66±20.78	.001[f]	.001[g]	.001[g]	.002[g]
	p	.905[a]	.011[a]	.101[a]				
EG	Mean SpO_2 level	99.46±1.33	95.20±3.42	96.30±2.62	.001[f]	.001[g]	.001[g]	.004[g]
CG		99.56±1.27	93.23±2.92	96.05±2.08	.001[f]	.001[g]	.001[g]	.001[g]
	p	.347[a]	.008[a]	.635[a]				

[c]Before transaction, [d]During transaction, [e]After Transaction, [f]Friedman test, [g]Wilcoxon signe dranks test, [a]Mann Whitney U Test

There were no statistically significant differences between the SpO_2 values of the infants in the experimental and control groups before (EG: 99.46 CG: 99.56) (p>.05) and after the interventions (EG: 96.30 CG: 96.05) (p>.05); however, a significant difference (p<.01) was found between their SpO2 values during the intervention (EG: 95.20 CG: 93.23). The infants' SpO_2 values were lower during the intervention than before and after the intervention. There were statistically significant differences between infants in both groups in terms of SpO_2 values before, during, and after the intervention (p<.001) (Table 2, Figure 2).

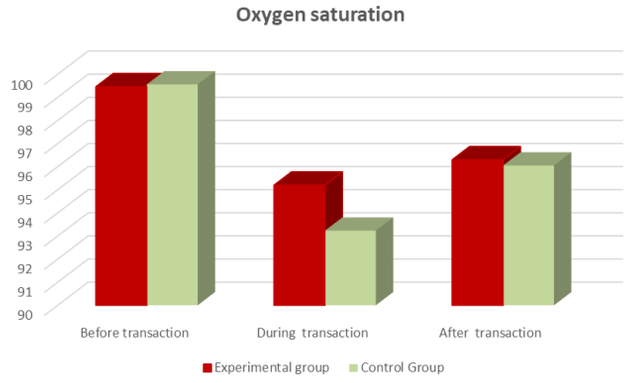

Figure 2. *Spo2 mean value distributions of experimental and control group infants according to the time of procedure*

Although no statistically significant differences were found between the heart rates of the infants in the experimental and control groups before (EG:127.31 CG:127.71) (p>.05) and after the interventions (EG:140.10 CG:147.66) (p>.05), a significant difference (EG: 145.76 CG: 157.33) (p<.01) was found during the intervention. Infants' heart rate values were higher during the procedure than before and after the procedure. There were statistically significant differences between the infants of both groups in terms of heart rates before, during and after the procedures (p<.001) (Table 2, Figure 3).

No statistically significant differences were found between the FLACC scores of the infants in both groups before the intervention (EG: 0.23 CG: 0.28) (p>.05); however, the FLACC scores of the infants in the experimental group were lower than those of the infants in the control group during (EG: 3.89 CG: 6.92) (p<.001) and after (EG: 2.82 CG: 5.18) (p<.001) the intervention. There was a statistically significant difference between FLACC scores of infants in both groups before, during, and after interventions (experimental group, p<.001; control group, p<.001) (Table 2, Figure 4). A significant difference was found between the infants in the experimental and control groups in terms of crying duration. It was observed that the infants in the experimental group cried for a shorter time (EG: 140.09 CG: 193.44) (p<.001) (Table 3).

Table 3. *Comparison of the mean total crying time of groups*

Groups		Mean ±SD	Median	Min	Max
EG	Crying times	140.09±1.09	40	0.00	540
CG		193.44±2.50	1.85	0.00	720
p		.001[a]			

[a]Mann Whitney U Test, SD: Standart deviation

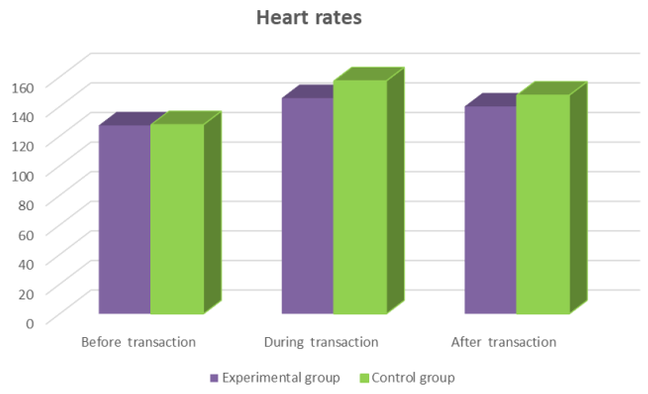

Figure 3. *Heart rates mean value distributions of experimental and control group infant saccording to the time of procedure*

4. DISCUSSION

The assessment of pain in infants is difficult because they cannot express themselves verbally. Therefore, physiological variables are the parameters that allow pain assessment (18,25,26). In this study, the infants' heart rates and oxygen saturation were measured before, during, and after vaccination to allow physiological assessment.

The increase in heart rate of infants in the experimental group during vaccination was significantly lower than that

of infants in the control group (Figure 3). The decrease in oxygen saturation was significantly higher in infants in the control group than in those in the experimental group during vaccination (Table 2, Figure 2).

In the study conducted by Jain, Kumar, and McMillan (25) to determine the effect of massage on pain levels during heel blood sampling in infants, no significant differences were found between infant groups in oxygen saturation levels before, during, and after the procedures, and the heart rate of infants in the massage group was lower (25). In the study conducted by Ozkan et al. (26), it it was found that oxygen saturation decreased less during the procedure in the group that received foot massage during blood sampling at the heel of newborns (26). Maternal breast milk odour (18), breastfeeding (10,27), and ShotBlocker application (28) were found to have positive effects on infants' heart rates during procedures with needles.

The verbal utterance of the individual is the most accurate and precise way to assess pain; however, it is not possible to assess the pain of infants with verbal utterance. Therefore, pain assessment in infants can be done using behavioural responses. The FLACC scale is one of the scales commonly used to assess pain in infants. In this study, the FLACC mean scores of infants in the control and experimental groups did not show statistically significant differences before the interventions. However, it was found that the FLACC values of infants in the experimental group were statistically significantly lower than those of infants in the control group during and after vaccination (Table 2, Figure 4). The results of this study suggest that the audible snow globe is effective in reducing infants' pain. Similar results have been obtained in previous studies. In the study conducted by Susilawati et al. (29), it was found that electrical nerve stimulation through the skin can reduce injection-related pain during vaccination in infants. In the study by Hogan et al. (30), tactile stimulation was reported to be effective in reducing pain in infants. Raouth Kostandy et al. (13) found in their study that skin-to-skin contact had a positive effect on reducing pain during immunizations in infants. In the study by Efe and Erkul (31), breastfeeding during vaccination was reported to be effective in reducing pain. The effectiveness of music and pressure application in reducing pain during vaccination was found in the study conducted by Kant (14). Göl and Altuğ Ozsoy (32) found in their study that rapid vaccine injection without aspiration and manual pressure application before vaccination effectively affected pain intensity and duration of crying in infants.

Crying is a form of communication in infants and children. It is one of the most important responses of infants during invasive and painful procedures. Crying is an observable and assessable behaviour in pain assessment (32). In the study by Ipp et al. (33), it was found that the longer the infants' crying lasted during immunisation, the higher their pain scores were. In this study, it was observed that infants in the control group cried longer during vaccination than infants in the experimental group (Table 3). The previous studies also indicated that various distraction methods were effective in reducing the duration of crying during vaccination. In the study by Dilli et al. (10), breastfeeding during vaccination was found to reduce the duration of crying in infants younger than six months. In the study by Ozdemir and Güdücü Tüfekçi (19), it was observed that infants who were vaccinated in a room where music was played from a cell phone cried for a shorter time than those not distracted by a device.

No study was found in the literature that evaluated the effectiveness of the snow globe in reducing pain during vaccination in infants. Therefore, this study is considered the first research to evaluate the effectiveness of snow globe in reducing pain during vaccination in infants.

5. CONCLUSIONS

In the study, it was found that the infants who were made to watch a musical snow globe during vaccination had less pain, less increase in heart rate, and less decrease in oxygen saturation during and after vaccination. This study suggests that the musical snow globe is effective in reducing pain during vaccinations in infants.

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