Clinical and Experimental Health Sciences

Reducing the Pain of Infants due to Vaccine Injection: A Randomized Controlled Trial

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ABSTRACT

Objective: This study was conducted as a randomized controlled, and experimental to compare the effect of breastfeeding and distraction methods on vital signs, pain level, and the duration of crying due to vaccine injection in healthy infants.

Methods: The population of the study consisted of 120 infants between 1 and 12 months of age who had met the inclusion criteria. The sample group was randomized and divided into two groups. The control group was breastfed according to the clinical procedure, including 58 infants, and the distraction grincludedlude 62 infants. For both groups, the oxygen saturation (SpO_2), heart rate (HR), crying duration, and pain scores were compared both before and following vaccination sessions.

Results: The vaccination pain scores of the infants from the distraction group (4.39±2.18) were significantly lower than those of the breastfeeding group (7.05±1.55; p=0.001). The post-vaccination SpO_2 was higher in infants in the distraction group; whereas HR was lower in this group compared to the breastfeeding group. The post-vaccination crying durations of those in the distraction group were also shorter than those in the breastfeeding group.

Conclusion: The distraction method adopted by the use of a toy has been found to be effective in decreasing acute pain during vaccine administrations.

Keywords: Pain, infant, breastfeeding, distraction, vaccine injection

1. INTRODUCTION

Painful interventions such as the pricking of one's heel, venous blood sampling, and vaccination are frequently administered to infants (1). The pain experienced by infants during these interventions has a negative impact on their behaviour, their interaction with parents, their cerebral & sensory development, their growth development, and their diet, thus leading to eventual physiological and behavioural problems (2,3). Behavioural symptoms such as crying, impaired sleep patterns, exhaustion, changes in facial expression, irregularities in breastfeeding, and leg movement are among the symptoms (2-5). Physiological changes include symptoms such as an increased peak heart rate (HR) and decreased oxygen saturation (SpO_2) during pain (1,6).

Nonpharmacological methods are used alone or in accompaniment with pharmacological methods in order to reduce the pain that infants experience (4,6-8). Since pain during routine vaccination in infants is not a sign of disease, it is more appropriate to use non-pharmacological methods to reduce pain (3,5). Nonpharmacological methods include; position change, oral glucose/sucrose administration, pacifier giving, breastfeeding, reducing environmental stimuli, kangaroo care, massage, and games can be counted. While these methods used to reduce pain reduce the baby's pain, they also reduce the parent's stress (5, 8, 9).

Determining the method to be used in order to reduce the perception of pain in infants should be suitable for the age, development level, and area of interest of the baby and should stimulate major senses such as hearing, sight, touc,h, and movement. These are musical games with rhythm, blowing balloons, kaleidoscope, et,c. according to the age group (4, 6-10). Nurses play an important role when it comes to identifying pain, thus adversely affecting the quality of life of infants in particula and thus initiating the appropriate intervention for pain management and alleviation (3,6). In a study by Asadi-Noghabi et al. (2014), in which they examined what nurses know in the management of newborn pain, it

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was stated that nurses should initiate appropriate strategies for the evaluation, recognition, and treatment of infants in order to alleviate their pain (9).

In accordance with the literature (2-3,8, 10-12), this study was designed as a randomized controlled trial with the aim of comparing the effect of the methods of breastfeeding and distraction on the vital signs, pain level, and the duration of crying induced by vaccination.

2. METHODS

2.1. Design

The study was conducted as a randomized controlled experimental trial. In this study, two methods, breastfeeding, and distraction, were implemented and compared by examining how each reduced the acute pain level felt by infants during vaccination.

2.2. Sample

The population of the study consisted of infants of mothers who volunteered to participate in the study and met the inclusion criteria in the Vaccination Room of Child Health Clinic at the Istanbul University Cerrahpaşa Medical Faculty Hospital between June and December of 2015. The inclusion criteria for infants were determined as follows: being between 1-12 months of age, being terma newborn (>37+6 GW) according to the new Ballard method (14), having a birth weight of 2500-3500 g a,andd being breastfed, being deemed healthy by a physician. The exclusion critea for infanwasere determined as follows; mother's unwillingness to participate in the study; having any congenital abnormality, displaying any symptom of disease, has a health problem, having a developmental problem according to the Ankara Developmental Screening Inventory (15), taking analgesic medication within four hours prior the procedure (1,6).

In accordance with the Pain diagnostic scale (Face, Legs, Activity, Cry, Consolability: FLACC) used for pain assessment in the sample group, it was considered that the difference of "1" unit in pain level would refer to a clinical/medical significance, whereupon the power analysis was then performed using G*Power (v3.1.7) software in order to determine the sample size. When the probability of Type 1 error (α) was accepted as 0.05 (at confidence level of 95%) and the probability of Type 2 error (β) was accepted as 0.10 (at confidence level of 90%), the value of delta was determined to be 2.86. By using the mean and standard deviations obtained from the study entitled as "The Effect of Foot Reflexology on Acute Pain in Infants: A Randomized Controlled Trial" (7), the effect size (d) was calculated as 0.666. Accordingly, the minimum sample size was calculated as a total of 74 infants, including 37 infants per group. When the data reliability and possible case losses were considered, 120 infant/mother couples, who had agreed to participate in the study, were contacted for data collection.

2.3. Randomization

In this study, the Urn method, which is a method of randomization that corresponds to full randomization, was used. In this method, there are two parameters, α, and β. These parameters refer to two balls of two different colours (16,17). The white ball was determined as being the "breastfeeding" g,oup; whereas the green ball was determined the as "distraction" group. The researcere placed the balls into a black bag, and the nurse administering the vaccination selected a ball from that bag. According to the colour of the selected ball, the infant was assigned to either the breastfeeding group or the distraction group (16,17) (Figure 2).

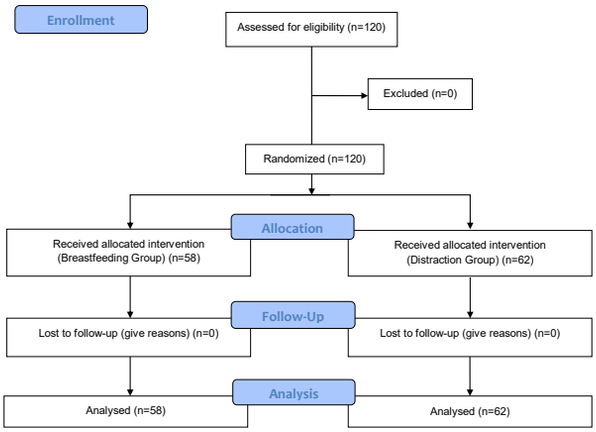

Figure 2. *Flow diagram of participant enrollment (CONSORT 2010).*

2.4. Measures and Equipments

2.4.1. Data collection form

The form is included the study application steps and descriptive characteristics of infants. The researcher had then filled out the form through the face-to-face interview method.

2.4.2. Ankara Developmental Screening Inventory (ADSI)

The inventory was developed by Savaşır et al. in 1994. The inventory is an assessment tool that provides in-depth and systematic information on the current development of infants and children. The reliability and validity study of the inventory adapted to Turkish society was conducted on 860 infants and children. The present skills and development of both (between 0-6 years) were assessed based uponhe the information provided by their mothers. The inventory also allows for the early detection and identification of those wh risk of developmental delay and irregularity. The inventory consists of 154 items target is obtained by asking their mothers, who respond with either "yes", "no, or "I don't know.".

The Cronbach's alpha coefficients of the inventory, which were calculated overa total score for 0-12 months, were declared as 0.98 for General Development(GD), 0.93 for Language/Cognitive(L-C), 0.92 for Fine Motor(FM), 0.91 for Gross Motor(GM) (0.92), and 0.92 for Social Skill/Self-Care(SS-SC) (15).

2.4.3. Pain diagnostic scale (Face, Legs, Activity, Cry, Consolability:FLACC)

The FLACC scale developed by Merkel et al. (18), includes the evaluation of five basic behavioural categories. The validity and reliability of the Turkish version of the Pain Diagnostic Scale (FLACC) was conducted by Şenaylı et al. (19). Each of facial expressions, leg movements, activity, crying, and consolability parameters also consists of three sub-items (19). The items are scored as 0, 1, and 2 point(s) respectively, with total score ranging between 0 to 10 point(s). The "0" point shows that there is no pain, 1-3 points refer to mild pain, 4-6 points refer to moderate pain, and 7-10 points refer to severe pain in infants (18,19).

2.4.4. Pulse oximeter device

The plus MED plus-50DL model Fingertip calibrated pulse oximeter (serial no:12.06.2012-70235-Made in P.R.C/China) was used to measure the oxygen saturation and HR of the infants.

2.4.5. Weighing instrument

The calibrated infant scale (SECA Mark-Production number:07.02.00700, made in Germany) was used to measure the weight of the infants in both groups.

2.4.6. Height measuring tape

A plastic, inflexible measuring tape was used to measure height of the infants in both groups.

2.4.7. Head circumference measuring tape

A plastic, inflexible measuring tape was used to measure the head circumference of the infants in both groups.

2.4.8. Stopwatch

Infant's crying duration was evaluated using Samsung Note II smart phone.

2.4.9. Toy

For distraction, a CE-approved single-unit multi-coloured toy with music and mirror, which is suitable for the characteristics of the infants, was used (8,10). (Photographs 1).

2.5. Procedures

2.5.1. Pilot study

The pilot study was conducted to a total of 10 infants. Following the pilot study, data collection form and process were reorganized.

2.5.2. Application phase

Infant-mother couples from both groups were acquainted in the vaccine room. The groups (breastfeeding or distraction) of mother-infant couples, who volunteered to participate in the study and met the inclusion criteria, were determined using randomization. All of the infants in the study were vaccinated by the same nurse, with the injector having the same sized needle tip (23G), sent by the Turkish Ministry of Health in a ready-to-use form. The pain score (both before and after vaccination) of the infants in both groups in accordance with the FLACC was assessed by both the researcher and the observing nurse. The infants in both groups were respectively subjected to the procedures shown in Figure 1.

Figure 1. *Toy used in the study*

Infants in the Breastfeeding Group (Control): In the hospital procedure, before the vaccination, the infants were left on the mothers' chest, whereupon they breastfed for 1 minute. The control group was breastfeed according to hospital procedure. The vaccination took place during that time slice. Given that the breastfeeding is a pain relief method that currently is used during vaccinations at the clinic in question, the breastfeeding group was determined as the control group.

Infants in the Distraction Group: The infants were given to lay upon their mothers' chests before the vaccination, whereupon the mothers were asked to shake the toy in front of her infant (in 25-30 cm distance). The infant was vaccinated while the mother distracted it with the toy.

During the vaccination, the stopwatch was started as soon as the infant first started to cry as from insertion in both groups. The stopwatch was stopped when the infant ceased crying. Immediately after the needle was removed from the

injection site, the subjects' physiological measurements (SpO_2, HR) were read from the pulse oximetry and FLACC and the pain scores were evaluated by both the researcher and the observer.

2.6. Data Assessment

The data obtained in the study were analyzed using the IBM SPSS Statistics 22 (IBM SPSS, Turkey) software. In the study, the compatibility of the parameters to normal distribution was evaluated using the Shapiro-Wilk test. The descriptive statistical methods (Mean, Standard deviation, Frequency) were used in order to assess the data of the study. The student t-test was employed in order to compare normally distributed quantitative data between the two groups; whereas, Mann Whitney U test was used to compare the data not showing normal distribution between two groups. The Kruskal Wallis test was used in the comparison of the data not showing normal distribution among more than two groups, whilst the Mann Whitney U test was re-used in order to determine the group causing the difference. In the evaluation of the pre – and post-vaccination data, the Paired Samples t-test was used for normally distributed data; whereas, the Wilcoxon Signed-Rank test was used from those who did not show normal distribution. The Chi-square, the Yates' correction for Continuity, and Fisher's Exact Chi-Square tests were used with the aim of comparing the qualitative data. The results were evaluated at confidence interval of 95% and significance level of $p<0.05$.

2.7. Ethical Considerations

In order to conduct the study, the permission was obtained via e-mail from Yesim Şenayli, who had translated Pain Diagnosis Scale into Turkish. Both written approval from Ethics Committee of Istanbul Universiy Cerrahapaşa Medical Faculty (IRB no: 83045809/604.01/02-69828) as well as permission from the institution where the data would be collected were obtained. The mothers of all of the infants were informed both about the purpose, plan, and period of the study, as well as about how the data would be used via "Informed Consent Form" before starting the study, alongside their consent asked both in written and verbal form.

3. RESULTS

It was determined that there was no statistically significant difference between the infants in the breastfeeding and distraction groups in terms of gender, diet, age of gestation, age, body weight, height, and head circumference in this study ($p>0.05$;Table 1).

Table 1. *Comparison of descriptive and vaccination characteristics of infants (N=120)*

Descriptive Characteristics		Breastfeeding Group (n=58)	Distraction Group (n=62)	t	[a]p
		Mean±SD	Mean±SD		
Age	Gestational age (week)	39.07±0.81	38.87±0.78	1.362	0.176
	Current age (month)	6.17±4.31	6.61±4.05	-0.573	0.567
Weight (g)	Birth	3405.34±436.10	3328.39±359.70	1.057	0.293
	Current	7284.07±2032.80	7526.94±1993.94	-0.661	0.510
Height (cm)	Birth	50.78±2.40	50.63±1.64	0.394	0.695
	Current	66.84±7.97	67.29±7.77	-0.316	0.753
Head circumference (cm)	Birth	35.60±0.78	35.41±0.68	1.373	0.172
	Current	42.55±5.38	42.11±3.18	0.542	0.589
Descriptive Characteristics		**n (%)**	**n (%)**	χ^2	[b]p
Gender	Girl	28 (%48.3)	30 (%48.4)	0.001	[b]0.990
	Boy	30 (%51.7)	32 (%51.6)		
Nutrition type	Only breast milk	27 (%46.6)	24 (%38.7)	1.879	[c]0.598
	Breast milk+baby food	5 (%8.6)	7 (%11.3)		
	Breast milk +supp. food	26 (%44.8)	31 (%50)		
Vaccine Application Characteristics					
Vaccine type	Hepatitis B	12 (%20.7)	12 (%19.4)	0.667	0.881
	KPA	22 (%37.9)	22 (%35.5)		
	DaBT-IPA-Hib	16 (%27.6)	16 (%25.8)		
	Measles	8 (%13.8)	12 (%19.4)		
Vaccine area	Vastus Lateralis	50 (%86.2)	50 (%80.6)	0.327	0.567
	Deltoid	8 (%13.8)	12 (%19.4)		
Practice method	IM	50 (%86.2)	50 (%80.6)	0.327	0.567
	SC	8 (%13.8)	12 (%19.4)		

[a]*Student t Test;* [b]*Chi-square TestYates' Continuity Correction;*[c]*Fisher's exact Chi-square Test*

Moreover, no statistically significant difference between the groups in terms of vaccine type, the injection site, or the method of vaccine administration (p>0.05;Table 1) was found.

When the physiological symptoms of the infants in both groups were evaluated before the vaccination, no statistically significant difference was found between the groups in terms of SpO_2 (t=-1.941; p=0.055) and HR (t=1.762; p=0.081). It was determined that after the vaccination, the mean SpO_2 levels of the infants decreased less (t=-13.499; p=0.001), and HR increased less in the distraction group than the breastfeeding group, which hence was statistically significant (t= 9.203; p=0.001; Table 2).

When pain total mean scores of the infants were compared within the group in terms of the age, the pain score was determined to be statistically significantly higher in the breastfeeding group (Table 3). The crying duration of the breastfeeding group was significantly longer than that of the distraction group in terms of the age (p<0.05; Table 2).

When the pain total mean scores of the infants were compared within the group in terms of vaccine type, it was determined that pain mean scores in both breastfeeding (χ^2=28.434; p=0.001) and distraction (χ^2=-36.457; p=0.001) groups showed a statistically significant difference according to the vaccine type. It was also found that while the vaccine causing the highest level of pain in the breastfeeding (8.23±0.87) and distraction (6.23±1.15) groups was the CPV vaccine, the least painful vaccine was measles vaccination for both groups. The pain scores in the infants of breastfeeding group were higher than those of the infants in distraction group, which in turn was statistically significant (p<0.01; Table 4).

When pain total mean scores of the infants were compared within the group in terms of the method of vaccine administration, the pain score of the infants vaccinated with the IM method in both breastfeeding (Z=-2.462; p=0.014) and distraction (Z=-3.204; p=0.001) groups was found to be higher (Table 5). The crying durations of the infants, moreover, confirmed this result. The crying duration in both groups after the IM method was significantly longer than that of the SC administration (p<0.05; Table 5).

Table 2. *Distribution and comparison of SpO2. HR and crying duration of infants before and after vaccination (N=120)*

Physiological Features		Breastfeeding Group (n=58)	Distraction Group (n=62)	t	[a]p
		Mean±SD	Mean±SD		
Oxygen Saturation (%)	Before vaccination	96.90±1.52	97.44±1.52	-1.941	0.055
	After vaccination	90.72±2.02	95.31±2.34	**-11.446**	**0.001****
	Difference	**-6.17±1.77**	**-2.13±1.51**	**-13.499**	**0.001****
	t	**27.279**	**-19.142**		
	[d]p	**0.001****	**0.001****		
Heart Rate (HR)	Before vaccination	126.67±9.56	123.71±8.85	1.762	0.081
	After vaccination	148.29±11.74	132.85±10.37	**7.649**	**0.001****
	Difference	**21.62±8.60**	**9.15±5.90**	**9.203**	**0.001****
	t	**11.107**	**-12.198**		
	[d]p	**0.001****	**0.001****		
Crying Duration (seconds)	After vaccination	59.22±26.72	24.69±18.53	**8.174**	**0.001****

[a]*Student t Test;* [d]*Paired Sample t Test* *p<0.05;**p<0.01

Table 3. *Comparison of pain scores of infants before and after vaccination (N=120)*

FLACC		Breastfeeding Group (n=58)	Distraction Group (n=62)	Z	[e]p
		Mean±SD	Mean±SD		
Face	Before vaccination	0.09±0.28	0.08±0.27	-0.110	0.913
	After vaccination	1.52±0.50	1.11±0.55	**-3.871**	**0.001****
	Difference	**1.43±0.57**	**1.03±0.57**	**-3.653**	**0.001****
	Z	**-6.718**	**-6.764**		
	[f]p	**0.001****	**0.001****		
Legs	Before vaccination	0.03±0.18	0.03±0.18	-0.068	0.946
	After vaccination	1.67±0.47	0.98±0.78	**-4.972**	**0.001****
	Difference	**1.64±0.48**	**0.95±0.76**	**-5.039**	**0.001****
	Z	**-6.888**	**-5.929**		
	[f]p	**0.001****	**0.001****		
Activity	Before vaccination	0.00±0.00	0.00±0.00	0.001	1.000
	After vaccination	1.12±0.50	0.55±0.50	**-5.430**	**0.001****
	Difference	**1.12±0.50**	**0.55±0.50**	**-5.430**	**0.001****
	Z	**-6.834**	**-5.831**		
	[f]p	**0.001****	**0.001****		
Cry	Before vaccination	0.00±0.00	0.03±0.18	-1.374	0.170
	After vaccination	1.57±0.50	0.89±0.52	**-6.157**	**0.001****
	Difference	**1.57±0.50**	**0.85±0.51**	**-6.397**	**0.001****
	Z	**-6.847**	**-6.761**		
	[f]p	**0.001****	**0.001****		
Consolability	Before vaccination	0.02±0.13	0.03±0.18	-0.524	0.600
	After vaccination	1.16±0.37	0.85±0.40	**-4.010**	**0.001****
	Difference	**1.14±0.40**	**0.82±0.43**	**-3.933**	**0.001****
	Z	**-7.107**	**-7.005**		
	[f]p	**0.001****	**0.001****		
Total pain score	Before vaccination	0.12±0.42	0.18±0.69	-0.060	0.952
	After vaccination	7.05±1.55	4.39±2.18	**-6.300**	**0.001****
	Difference	**6.93±1.58**	**4.21±2.13**	**-6.373**	**0.001****
	Z	**-6.652**	**-6.753**		
	[f]p	**0.001****	**0.001****		

[e]*Mann Whitney U Test;* [f]*Wilcoxon Signed Ranks Test* ***p<0.01*

Table 4. *Comparison of pain scores and crying duration of infants according to vaccine types (N=120)*

Total pain score	Applied Vaccine Types				χ^2	[g]p
	Hepatitis B	CPV	DaBT-IPA-Hib	Measles		
	Mean±SD	Mean±SD	Mean±SD	Mean±SD		
Breastfeeding Group	7.33±1.37	8.23±0.87	5.88±1.15	5.75±1.39	**28.434**	**0.001****
Distraction Group	5.08±1.73	6.23±1.15	2.69±1.40	2.58±1.73	**36.457**	**0.001****
Z	**-2.970**	**-4.799**	**-4.546**	**-3.153**		
[e]p	**0.003****	**0.001****	**0.001****	**0.001****		
Crying Duration (sec)						
Breastfeeding Group	60.75±26.06	78.41±22.27	41.38±19.04	39.88±12.83	**23.602**	**0.001****
Distraction Group	22.42±13.28	43.77±11.95	9.31±7.16	12.50±12.02	**39.386**	**0.001****
Z	**-3.669**	**-4.803**	**-4.640**	**-3.286**		
[e]p	**0.001****	**0.001****	**0.001****	**0.001****		

[g]*Kruskall Wallis Test;* [e]*Mann Whitney U Test* ***p<0.01*

Table 5. *Comparison of pain score and crying duration of infants according to vaccine application method (N=120)*

Total Pain Score		Vaccine Application Method		Z	[e]p
		IM	SC		
		Mean±SD	Mean±SD		
Breastfeeding Group		7.26±1.48	5.75±1.39	**-2.462**	**0.014***
Distraction Group		4.82±2.06	2.58±1.73	**-3.204**	**0.001****
	Z	**-5.670**	**-3.153**		
	[e]p	**0.001****	**0.002****		
Crying Time (seconds)					
Breastfeeding Group		62.32±27.13	39.88±12.83	**-2.087**	**0.037***
Distraction Group		27.62±18.70	12.50±12.02	**-2.612**	**0.009****
	Z	**-6.007**	**-3.286**		
	[e]p	**0.001****	**0.001****		

[e]*Mann Whitney U Test *p<0.05;**p<0.01*

4. DISCUSSION

This study set out to compare the effects of breastfeeding and distraction using a toy on the pain level experienced by infants during vaccinations both of which are two effective methods in accordance with the studies examining the efficiency of the pain relief intervention.

In a study conducted by Karimi et al. (20), including 4-6 months-old infants, the infants were divided into breastfeeding, sensorial saturation, and control groups. It was reported that peripheral mean SpO_2 of the infants in the breastfeeding group (95.3+2.1 in 4 month-old infants; 95.5+1.7 in 6 month-old infants) receiving pentavalent vaccination was lower than those in the sensorial saturation group (96.9+1.2 in 4 month-old infants; 96.3+1.8 in 6 month-old infants), who received a stimulus in all of their five senses ($p<0.001$). When comparing with results of the present study, SpO_2 was found to be 90.72±2.02 in infants belonging to the breastfeeding group and 95.31±2.34 in those of the distraction group after vaccination. The SpO_2 level of those in the breastfeeding group in the study by Karimi et al., was higher than those of breastfeeding group in the present study. In addition, the SpO_2 level of the infants in the distraction group was similar to that of participants in Karimi et al.,'s study. In the present study, a stimulus was given for the distraction group infants' senses of hearing (a toy with sound and music), sight (a colorful and moved toy) and touch (given that the procedure was performed on the mother's chest). In addition, in Karimi's study, the stimuli were also given to stimulate those in the sensorial saturation group's senses of taste and smell. Similar SpO_2 levels suggested that when the sensory stimuli were used effectively, they relieved the infants. In the present study, a stimulus was given for the distraction group infants' senses of hearing (a toy with sound and music), sight (a colorful and moved toy) and touch (given that the procedure was performed on the mother's chest). In addition, in Karimi's study, the stimuli were also given to stimulate those in the sensorial saturation group's senses of taste and smell. Similar SpO_2 levels suggested that when the sensory stimuli were used effectively, they relieved the infants.

In study conducted by Thomas et al. (21), involving 40 infants aged 5-15 weeks, the pain scores of infants after the DBT vaccination were evaluated using the NIPS (Neonatal Infant Pain Scale). Here, it was reported that pain total score of the infants was 4.7±1.3 in the breastfeeding group and 6.6±0.5 in the control group. When the pain score (5.88±1.15) of the breastfeeding group after the DaBT-IPA-Hib vaccination was assessed over 10 points in the present study, this score was observed to be closer to Thomas et al.,'s results (21). Furthermore, both the pain score (Table 3) and crying duration of the distraction group were statistically lower than the breastfeeding group (Table 4). These results suggested that auditory and visual sensory stimuli such as color, motion, and sound were more effective in relieving pain the infants in this age group.

Gedam et al. (10), compared the effectiveness of three methods on reducing the pain experienced by infants and children during vaccination and divided 350 infants into three groups: a distraction with a sound and light toy group, a cartoon group, and a control group. When the methods were compared, it was reported that while the FLACC pain score of the infants in the distraction with toy group was 2.30 during the vaccination, this score increased to 4.62 after the vaccination. In the same study, while the pain score of the infants in the control group was 5.3 during the vaccination, it increased to 6.20 after the vaccination. It was determined that post-vaccination pain score of the group, to which the sound&light toy was applied, was lower than those in the breastfeeding group, thus entailing a statistically significant difference ($t=11.29$; $p<0.05$). When compared with the results of the study, it was found that while the FLACC pain total score of the infants in the distraction group was close to the results of Gedam et al. (10). It was also revealed in the present study that the infants in the breastfeeding group had a similar level of pain (Table 3) with those in control group in Gedam et al's study (10).

Özdemir and Tüfekçi (11) conducted a study involving 120 two month-old infants by holding a multi-coloured toy phone that played music 20-25 cm away from their faces in order to reduce the acute pain felt during the DaPT-IPV-Hib vaccination, and thereupon their FLACC pain scores were evaluated. When the methods applied in the study were compared, the FLACC scores were found to be 5.13±2.11 among those in the experimental group, and 6.65±2.69 among those in the control group during the vaccination. When both groups were compared based on the results of the study, the pain scores during the vaccination were reported to be lower in the toy group at a statistically significant level (t=3.66; p=0.001). The FLACC pain total score was determined as 2.69±1.40 in the distraction group vaccinated with DaPT-IPV-Hib (Table 4). When the results of the present study were compared with those of Özdemir and Tüfekçi's study (11), it was observed that the post-vaccination pain score of those in the distraction group was lower in the present study. This difference was thought to be associated with the toy used, the sample size, and measurement time. In fact, unlike the present study, only one vaccination was applied in Özdemir and Tüfekçi's (11) study, and the pain scores both during and after the vaccination were evaluated. It was reported that the pain score of the infants, for whom toy method was used, decreased to 1.26±2.01 after the vaccination. This value was similar with the present study given that it was very close to the pain score (2.69±1.40) of the infants in the distraction group vaccinated with DaPT-IPV-Hib (Table 4).

When the groups were compared in terms of the administration of vaccination method, the pain scores of the infants in the distraction group were found to be lower than the breastfeeding group in both IM and SC vaccines (Table 5). In both groups, the pain scores in IM injection were higher than those in SC injection (Table 5).

In the systematic review, there was only low quality evidence suggesting that touch/massage, non-nutritive sucking, water; holding, and toy distraction were effective on the pain regulation of older infants. They also emphasized that key reasons for the lack of reliable evidence for the findings stemmed from the low quality of randomised controlled trials in the field, as well as from the limited number of studies within the same intervention (6). The results of the current study are important for the quality of evidence involving a larger sample group.

5. CONCLUSION

It was determined in accordance with the results of the study that breastfeeding was effective in reducing pain felt by infants, but when pain scores and crying durations were compared according to the vaccine type and vaccination method, distraction was more effective in reducing pain experienced by infants older than one month. This result has suggested that infants beyond one month of age are more extroverted and they are more susceptible to the stimuli from their surrounding environment. In fact, this result confirmed higher HR and lower SpO_2 level in the breastfed infants, as well. Breastfeeding is preferable prior to one month of age to reduce interventional pain, whereas distraction appears to be preferable for those above one month of age.

Implications for clinical pratice

Distraction method is more effective than breastfeeding when it comes to reducing acute interventional pain experienced by infants older than one month of age since those who fall within these age groups are very much affected by environmental stimuli. Breastfeeding is preferable prior to one month of age, whereas distraction appears to be preferable for those above one month of age. Practice such as distraction, should be used as a nursing intervention additionally breastfeeding to reduce the pain after vaccination among infants. Its use should be expanded and encouraged through in-clinic trainings for nurses.

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