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The effects of sound-and-light toy as a distraction method on pain and physiological parameters in infants regarding circumcision procedure

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Ethics Committee Approval
Ethics Committee approval was taken from the Yozgat Bozok Unıversty Clinical Research Ethic Committee (Decision no: 2021.09.27_05). All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest
No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Circumcision is a common surgical procedure and a cause of pain and stress for infants. Nurses are in a key role for providing pain relief through implementation of non-pharmacological practices for pain management. This study aimed to assess the impact of distraction using a sound- and light-producing toy on pain and physiological parameters in infants regarding circumcision procedure.

Methods: This randomized controlled study was conducted with infants between six months and two years of age who presented to a private circumcision clinic. The sample consisted of 60 infants randomly allocated into intervention (n = 30) and control (n = 30) groups. During the procedure, the mothers of the infants in the intervention distracted the infants with the toy for 15 min. Infants in the control group were accompanied by their mothers during the procedure and did not receive any additional intervention other than the standard care. Data were collected using a questionnaire and the face, legs, activity, cry, consolability (FLACC) pain scale. Data were assessed using descriptive statistical analyses and parametric tests.

Results: Infants in the intervention and control groups were similar in terms of current and gestational ages, lengths, weights, and maternal and paternal ages and showed no differences in terms of physiological parameters before and after the procedure *(P* > 0.05*)*. Post-operative pain scores were lower in infants exposed to the toy with light- and sound than that in the infants in the control group; however, no significant difference between groups was found *(P* > 0.05*)*.

Conclusion: Considering the effect of sound- and light-producing toys on causing a reduction in pain severity, it may be recommended to use distracting practices by nurses to reduce/relieve pain associated with circumcision.

Keywords: Infant, Circumcision, Pain, Toy

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Introduction

Circumcision, the most common surgical procedure known worldwide, is estimated to have a global prevalence of 37% to 39% [1]. Owing to the high rates of circumcision among Muslim and Jewish men, the prevalence of this procedure in the Middle East and North Africa exceeds 95%. Circumcision prevalence in the United States (USA) is 91% among Caucasians, 76% among African-Americans, and 44% among Hispanics [1, 2]. The majority of the population in Turkey is Muslim, and circumcision is traditionally performed on male children at an early age. Although the most appropriate age for circumcision is between less than one year and one year of age, circumcision is reported to be performed usually between one and seven years of age in Turkey [3, 4].

Circumcision is a surgical procedure that typically heals within a week and has a low rate of adverse effects when performed by specialized physicians in a hospital setting. However, circumcision, which is a relatively frightening experience for children, is a cause of physiological stress and pain [5, 6]. Intra- and post-operative pain management is of particular importance in children during the circumcision procedure [6]. Pain relief in children is reported to minimize the need for medications during the post-operative period, shorten the length of hospital stay, improve patient satisfaction, and play an active role in reducing morbidity and mortality [7]. Pain management is best performed using a multimodal approach that combines pharmacological and non-pharmacological methods [8, 9]. Nurses are in a pivotal role to provide pain relief and improve the quality of life in children through implementation of non-pharmacological practices for pain management [10, 11].

Although a variety of methods are available for use in pain management for children, the American Pain Society, and studies in this area recommend using cognitive behavioral methods, particularly distraction in infants and young children [10–13]. Distraction can be used to strengthen coping mechanisms before and after an intervention, to minimize anxiety associated with an intervention, and to help calm the child after an intervention [14]. Guidelines and experts recommend using toy-mediated distraction during invasive procedures in children younger than three years as this technique is more effective in children in that age group [14–17]. However, to the best of our knowledge, no study has yet investigated these practices in the context of post-operative pain associated with circumcision. Thus, the aim of this study was to examine the effect of distraction using a sound- and light-producing toy on pain levels and physiological parameters in infants undergoing circumcision.

Materials and methods

Study design

This randomized controlled study was conducted between November 2021 and February 2022. Reporting of the study results is according to the latest version of the Consolidated Standards of Reporting Trials (CONSORT) guidelines. The hypotheses of the study are listed below.

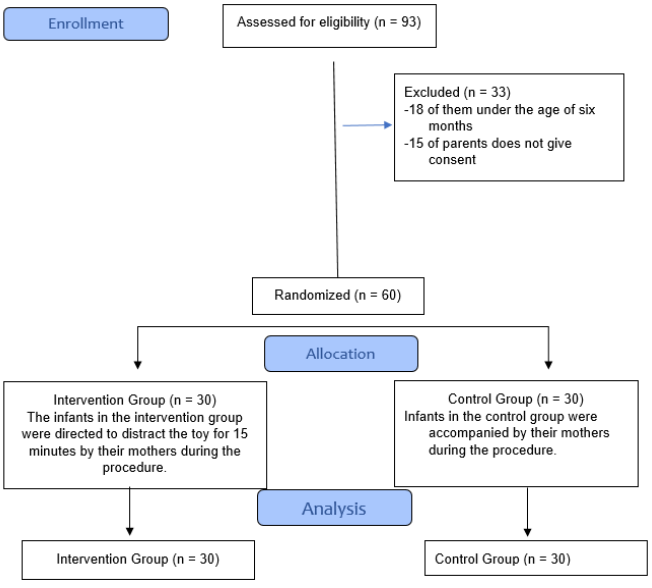
H_1: Distraction using a sound- and light-producing toy affects pain associated with circumcision in infants.

H_2: Using a sound- and light-producing toy affects post-operative physiological parameters associated with circumcision in infants

Recruitment, randomization, and sample size

The sample consisted of infants ranging in age from six months to two years of age who presented to a private circumcision clinic between the specified dates, who did not show any chronic diseases, and whose parents provided written consent to participate in the study. Between specified dates and while researchers were in the clinic, 93 infants were circumcised at the clinic, and 33 of them were excluded because they did not meet the criteria (Figure 1). The sample size consisted of 60 infants. Infants were randomly categorized into the intervention and control groups using Urn randomization. This method features two parameters represented by α and β, and the parameters represent balls of two different colors, namely black and white. A ball was drawn randomly from a black bag by a nurse other than nurse researchers with her eyes closed, and the infant was assigned to one of the study groups depending on the ball's color. This assignment process was repeated for each infant. The white ball represented the intervention group, and the black ball represented the control group [18, 19]. Based on this method, 60 infants were allocated into one of the study groups, 30 and 30 in the intervention and control groups, respectively. Power analysis was performed by researchers to determine the adequacy of the sample size. According to the power analysis in G*Power 3.1.9.2, 1-β was found as 0.85 (α = 0.05, Df = 58, effect size |p| = 0.72).

Figure 1: Consolidated Standards of Reporting Trials (CONSORT) flow diagram of the study



Intervention

At the time of initial presentation for circumcision, infants were evaluated by the surgeon in terms of overall medical history and any disease(s) that would prevent circumcision. Subsequently, the date and time were selected for circumcision in agreement with the family, and an appointment was scheduled. Prior to circumcision, families were sent videos to inform them about the circumcision process and steps that need to be taken before and after the procedure. Circumcision was performed by the same surgeon (researcher-MD). All infants

were administered local anesthetics that had been prepared before circumcision (Bupivacaine 0.5%, 1 mg/kg; Lidocaine, 1 mg/kg) via dorsal penile nerve block and infiltration anesthesia (ring block). Circumcision was performed using the sleeve technique. This technique consists of marking the skin and mucosal line to delimitate the circumcision limits followed by a circumferential incision of the skin and mucosa over the marked areas using a scalpel. The part of the skin and mucosa between the two incisions is excised circumferentially. The procedure is terminated by approximating the proximal skin to the distal mucosa using 5/0 Vicryl Rapide sutures. The first 5 min was spent taking the infant to the operating table, stabilizing him, and information was provided to parents by the pediatric surgeon. Circumcision required a median duration of 15 min in both groups. During the procedure, mothers remained with their infants. After the procedure, the infant was moved to another room with her parents to monitor his general condition and physiological parameters.

Intervention group (Group distracted using a toy with a light and sound): Before the surgery, mothers were introduced to the toy and received instruction on how to use toy. During the procedure, toy distraction was directed by their mothers for 15 min. Distraction consisted of concurrent visual and auditory stimuli with three different sets of soothing music and projection entertainment. The toy was sterilized after each use.

Control group: Infants in the control group were accompanied by their mothers during the procedure and did not receive any additional intervention other than standard care.

Physiological parameters and pain assessments were performed 15 min before and 30 min after the procedure for infants in both groups. Physiological parameters were measured by the same researcher. Pain assessments were implemented separately by two researchers (Ph.D., RN). Inter-rater agreement between the two researchers was evaluated according to the intra-class correlation coefficient (ICC), and the ICC was found to be higher than 0.90. The patients were routinely discharged with a home follow-up form 30 min after the circumcision procedure.

Data Collection Tools

Introductory Questionnaire: This questionnaire was prepared by the researchers. It contained items related to the sociodemographic characteristics of the infant and their parents in addition to physiological parameters (heart rate, respiratory rate, oxygen saturation, body temperatures) of the infant.

The Face, Legs, Activity, Cry and Consolability (FLACC) pain scale: The FLACC pain scale was developed by Merkel et al. [20] in 1997 and is used to assess behavioral reactions to pain in children between the ages of two months and seven years who are unable to verbalize or communicate their pain. FLACC pain scale assesses five behavioral domains (facial expression, leg movement, activity, crying, and consolability), and each item is assigned a score of 0–2. The scale yields a minimum of 0 and a maximum of 10 points. Higher scores denote a higher level of pain, whereas lower ones denote less pain. The Turkish validity and reliability study for the FLACC pain scale was conducted by Şenaylı et al. [21] with toddlers and children one month to nine years of age who presented to a pediatric surgery clinic. This scale is observational scale and can be applied by healthcare professionals.

Pulse Oximeter

Infants in the intervention/control group had their pre- and postoperative oxygen saturation levels and heart rate measured by "plusMED plus-50DL Finger Type" Pulse Oximeter. The device has Conformité Européenne (CE) certification. The pulse oximeter was deemed suitable for use in children. The screen of the device displays oxygen saturation percentage (SpO_2) and the heart rate both numerically and as a bar graph. In case of non-contact, the device emits a visual signal.

Light- and Sound-Producing Toy

The toy has a plastic and soft structure for comfortable manipulation, and in accordance with the regulation of the Ministry of Health, does not involve any risk for children, namely, no small parts that can be swallowed. The toy projects green, blue, and red lights and stars. The light pulse lasts approximately 10 s. The toy is shaped like a ladybug (in dimensions, 10 x 22.50 x 22.50 cm), and when the wings unfold, it emits light and projects stars. The music consists of three different soothing tones.

Ethical aspects

Before starting the study, necessary permissions were obtained from the relevant institution and the Yozgat Bozok University clinical research ethics committee (Decision number: 2021.09.27_05). The parents provided written informed consent after being informed about the purpose of the study and the confidentiality of the data.

Statistical analysis

Data were analyzed using the IBM SPSS Statistics V 25.0 (IBM Corp., Armonk, NY, USA) software suite. Descriptive data were expressed in minimum (min), maximum (max), mean (mean), standard deviation (SD), and median (M) values. Data were checked for normality of distribution using the Shapiro–Wilk test. The homogeneity of variance was evaluated using Levene's test. For group comparisons, the independent and paired t-tests were used. Inter-rater agreement was analyzed using the intra-class correlation coefficient (ICC). Statistical significance was set at $P < 0.05$.

Results

Table 1 presents the demographic characteristics of the infants in the intervention and control groups. Infants included in the study had a mean current age of 10.87 (6.90) and 11.18 (6.58) months, mean length of 74.43 (11.06) and 73.97 (11.16) centimeters (cm), and weight of 9.48 (3.11), and 9.74 (3.06) kilograms (kg), respectively. The groups were similar in terms of gestational age, current age, height, weight, and maternal and paternal age ($P > 0.05$) as shown in Table 1.

Table 1: Similarity criteria of groups

Features	Intervention group (n = 30)		Control group (n = 30)		Test/*P*-value
	Mean (SD)	M(min–max)	Mean (SD)	M(min-max)	
Gestational age (week)	38.93 (0.76)	39(38–40)	39.16 (0.88)	39(38–41)	t = –1.058 *P* = 0.294
Current age (months)	10.87 (6.90)	6.50(6–24)	11.18 (6.58)	8(6–24)	t = –0.179 *P* = 0.858
Length (cm)	74.43 (11.06)	70.50(60–97)	73.97 (11.16)	71(60–99)	t = 0.160 *P* = 0.874
Weight (kg)	9.48 (3.11)	8.25(6–18)	9.74 (3.06)	9(6-18)	t = –0.332 *P* = 0.741
Maternal age (year)	30.14 (5.23)	30.50(19–39)	30.75 (5.03)	30(22–42)	t = –0.457 *P* = 0.649
Paternal age (year)	34.82 (5.90)	35(25–49)	34.72 (6.89)	35(22–52)	t = 0.061 *P* = 0.951

SD: standard deviation

The distribution of physiological parameters for the infants in the intervention and control groups before and after the procedure is presented in Table 2. Pre- and post-operative heart rates (beats per minute) were 95.75 (8.94) and 94.93 (8.45) in infants in the intervention group and 99.31 (9.15) and 97.50 (8.08) in infants in the control group, respectively. Pre- and post-operative respiratory rates (breaths per minute) was 20.50 (2.53) and 21.07 (2.85) in infants in the intervention group and 21.50 (2.32) and 21.81 (1.63) in infants in the control group, respectively. Pre- and post-operative oxygen saturation levels (mm Hg) for the intervention group were 95.75 (2.10) and 95.43 (2.42) and for the control group were 95.38 (2.13) and 95.22 (2.39), respectively. Pre- and post-operative body temperatures (°C) for the intervention group were 36.62 (0.24) and 36.62 (0.19) and for control group were 36.68 (0.19) and 36.62 (0.17), respectively. No statistically significant differences between the groups in terms of physiological parameters ($P > 0.05$) were noted (Table 2).

Table 2: Comparison of physiological parameters before and after the procedure

Parameters	Intervention group (n = 30)		Control group (n = 30)		Test/*P*-value
	Mean (SD)	M(min-max)	Mean (SD)	M(min–max)	
Heart rate					
Pre-procedure	95.75 (8.94)	97(80–116)	99.31 (9.15)	98(82–118)	t = –1.520 *P* = 0.134
Post-procedure	94.93 (8.45)	92(82–118)	97.50 (8.08)	97(82–116)	t = –1.203 *P* = 0.234
Test/*P*-value	t = 0.713; *P* = 0.482		t = 1.574; *P* = 0.126		
Respiratory rate					
Pre-procedure	20.50 (2.53)	20(18–28)	21.50 (2.32)	22(18–28)	t =–1.594 *P* = 0.116
Post-procedure	21.07 (2.85)	20(18–28)	21.81 (1.63)	22(20–24)	t = –1.253 *P* = 0.215
Test/*P*-value	t = –0.955; *P* = 0.348		t = –0.668; *P* = 0.509		
Oxygen saturation					
Pre-procedure	95.75 (2.10)	96(90–99)	95.38 (2.13)	95.5(92–99)	t = 0.683 *P* = 0.497
Post-procedure	95.43 (2.42)	96(88–98)	95.22 (2.39)	95.5(88–99)	t = 0.336 *P* = 0.738
Test/*P*-value	t = 0.000; *P* = 1.000		t = -0.671; *P* = 0.507		
Body temperature					
Pre-procedure	36.62 (0.24)	36.6(36.0–37.2)	36.68 (0.19)	36.7(36.2–37.2)	t = –1.0.49 *P* = 0.298
Post-procedure	36.62 (0.19)	36.6(36.2–37.0)	36.62 (0.17)	36.6(36.3–37.2)	t = 0.000 *P* = 1.000
Test/*P*-value	t = –0.091; *P* = 0.928		t = 1.579; *P* = 0.124		

SD: standard deviation, M: median

Pre- and post-operative pain scores for the infants are shown in Table 3. Pre-operative pain scores of the infants in the intervention and control groups were 0.71 (1.50) and 0.93 (1.07), and no significant intergroup difference was observed *(P* = 0.441). However, post-operative pain scores were 5.03 (3.01) in the intervention group and 6.15 (2.81) in the control group. Although mean pain scores were lower in infants in the intervention group, no significant intergroup difference was observed (*P* = 0.142). According to intra-group comparisons, post-operative pain scores were significantly higher in both groups than pre-operative scores ($P < 0.001$) as shown in Table 3.

Table 3: Comparison of Face, Legs, Arms, Cry, Consolabilty (FLACC) pain scores before and after the procedure

FLACC Pain Scores (0-10)	Intervention group (n = 30)		Control group (n = 30)		Test/*P*-value
	Mean (SD)	M(min–max)	Mean (SD)	M(min–max)	
Pre-operative	0.71 (1.50)	0.0(0.00–5.00)	0.93 (1.07)	1.00(0.00–5.00)	t = –.776 *P* = 0.441
Post-operative	5.03 (3.01)	5.0(1.00–10.00)	6.15 (2.81)	5.0(1.00–10.00)	t = –1.488 *P* = 0.142
Test/*P*-value	t = 6.791; *P* < 0.001		t = 11.580; *P* < 0.001		

SD: standard deviation

Discussion

Toys are readily available, can easily be used as a source of distraction, and are thought to have a clinically important effect in reducing pain in children in cooperation with parents. Studies have reported that using toys of different types as a means of distraction is effective in reducing/relieving pain in children [14, 15, 22]. In the current study, the aim was to evaluate the impact of toy-mediated distraction on circumcision pain in infants aged six months to two years. No significant difference was observed in terms of the pre-operative FLACC scale scores and physiological parameters between the intervention and control groups; thus, it is evident that measurements were similar in both groups.

In this study, mean post-operative pain scores were 5.03 (3.01) in the intervention group and 6.15 (2.81) in the control group. Mean pain scores were lower for infants exposed to distraction mediated by the light- and sound-producing toy; however, the difference was not statistically significant. No differences between the groups in terms of physiological parameters were found. Since no previous study on the use of toys in infants during the circumcision process is available, the data were discussed with the findings of other studies using toys as a method of distraction in pain management. According to this concept, Ateş Beşirik and Gözen [23] investigated the impact of breastfeeding and toy-mediated distraction as a means to reduce/relieve pain in 120 infants between 1 and 12 months of age, and assessed pre- and post-immunization pain levels using the FLACC scale. Post-immunization pain scores in infants in the toy group (4.39 [2.18]) were significantly lower than those in the breastfeeding group (7.05 [1.55]). The post-vaccination SpO_2 value was higher in infants in the toy distraction group, whereas heart rate was lower in this group compared to the breastfeeding group. Dabas [24] conducted a study to investigate the effect of distraction techniques on pain severity in 100 infants who were 10–14 weeks of age and received a pentavalent vaccine. Infants were allocated to one of four groups: (1) electronic toy group, (2) key toy group, (3) simple toy group, or (4) control group. Analysis using the FLACC pain scale revealed that the mean pain score was higher in the control group (7.16 [0.16]) as compared to that of the electronic toy group (2.60 [0.16]), key toy group (4.80 [0.22]), and simple toy group (5.44 [0.18]). These results are in line with our results. Ristia et al. [15] conducted a study with 34 children aged 1–5 years and asked the parents of infants in the intervention group to try to distract their children using a teddy bear during intravenous access on the children (n = 17), while the control group received no intervention (n = 17). Pain severity was evaluated using the

FLACC scale with a single measurement after the procedure. They reported that the mean pain score in the intervention group was lower than that of the control group, which is consistent with our results. Gedam et al. [25] investigated the effectiveness of audio–visual distraction techniques in 350 children during and after vaccination. In addition, children in the first group were encouraged to play with light- and sound-producing toys, children in the second group were encouraged to watch cartoons, and children in the third group did not receive any distraction while receiving their immunizations. Pain levels were assessed using the FLACC pain scale. Pain scores were lower in children in the intervention groups during and after the procedure than those in the control group. The study results demonstrated that light- and sound-producing toys and cartoons were effective in producing a reduction in pain during routine medical interventions in children. Logan et al. [22] conducted a study with 54 children aged 3–10 years who were randomly allocated to one of three interventions: (1) interactive teddy bear, (2) digital avatar version of the teddy bear, and (3) normal plush teddy bear. They assessed distress and pain levels before and after the procedure. Children exposed to interactive teddy bears were reported to have more positive results characterized by higher levels of joy and compliance compared to those exposed to plush toys. These results are similar to the results of the current study.

Strengths and limitation

The present study has some important strengths. First, this study is the first to evaluate the effects of a sound–light toy on pain during circumcision in children aged six months to two years. Second, the strength of the study is that the method of this study is based on the CONSORT guidelines. On the other hand, our study has several limitations. Because of the nature of the intervention, study subjects and outcome assessors could not be blinded to the intervention. In addition, in this study, post-operative pain assessment of children was obtained at 30 min to evaluate the real pain that the children will feel after the surgery, to have intensive patient circulation in the clinic, and to prevent bias. Our study was conducted in a private clinic, which may limit the generalizability of our results.

Practice implications

Circumcision is one of the most common procedural painful interventions experienced by the majority of boys in Turkey. In this process, the comfort of infants deteriorates, and their physiological parameters are affected. Pain intervention with non-pharmacological methods can prevent harmful pain-related effects. In this study, an evidence-based randomized controlled study approach was used to determine the effect of distraction with a sound-light toy on pain during circumcision in infants aged six months to two years. It has been determined that a non-pharmacological practice, such as the use of toys with sound and light during circumcision, leads to a reduction in post-operative pain in infants. Based on this result, nurses should include non-pharmacological methods in pain management.

Conclusion

In this study, post-operative pain scores were lower in infants exposed to toy with light- and sound than that in the infants in the control group; however, no significant difference between groups was found. Considering distraction using a light- and sound-producing toy had an effect on reducing the severity of post-operative pain associated with circumcision in infants, further studies using different distraction practices or non-pharmacological methods are warranted in infants.

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