Comparison of the Effectiveness of Two Different Methods of Decreasing Pain During Phlebotomy in Children: A Randomized Controlled Trial

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Purpose: *The purpose of this study was to examine the effect of the applications of external cold and vibration and blowing soap bubbles during phlebotomy in children aged between 3 and 6 years.*
Design: *This study is a randomized controlled trial.*
Methods: *The sample was obtained using block randomization. Children were divided into three groups: "external cold and vibration group," "blowing soap bubbles group," and "control group." Children, their parents, the nurse, and the researcher rated the children's pain during phlebotomy.*
Findings: *A statistically significant difference between groups was found on pain scores. Pain scores were lower in the groups of external cold and vibration, and blowing soap bubbles than the control group.*
Conclusions: *The methods of external cold and vibration and blowing soap bubbles had a pain relieving effect in children aged between 3 and 6 years during phlebotomy.*

Keywords: *pain, child, phlebotomy, distraction research.*

CHILDREN MAY BE EXPOSED to painful interventions for the purpose of diagnosis, follow-up, or treatment.[1] The painful interventions most commonly performed on children include phlebotomy, injection, and vaccination. During these interventions, it is highly important to use methods that have pain relieving effect.[2] Pharmacologic and nonpharmacologic methods can be used separately or together to reduce the pain during invasive procedures.[3]

Background

Studies examining the effect of pharmacologic methods performed to relieve pain associated with invasive procedures on children examined the use of topical creams lidocaine and prilocaine (EMLA cream) and vapocoolant cold spray (ethyl chloride and fluoroethyl).[3-7] Studies of both pharmacologic and nonpharmacologic methods in interventional pain relief determined that nonpharmacologic methods were as effective as pharmacologic methods.[3,6-9] Nonpharmacologic

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methods are preferred in relieving interventional pain because pharmacologic methods have many side effects.[10] Many studies support the effectiveness of nonpharmacologic methods in managing the pain associated with invasive procedures in children.[7,11-27]

Frequently used nonpharmacologic methods include families staying with children,[2,4] touching,[28] positioning, giving a massage, hot and cold therapies,[2] external cold and vibration (Buzzy),[3,9,13,22,23,25,29] guided imagery,[30] controlled breathing,[15] distracting cards,[2,14,27] balloon inflating,[2,26] squeezing a soft ball,[2,12] looking at a kaleidoscope,[21,24] cough exercise,[26] blowing soap bubbles,[4,6,7,28] video games,[20] and listening to music.[14,31,32] Interventions used for optimal pain management should be effective, reliable, affordable, and should not extend the procedure time.[5]

Study Purpose

The purpose of this study was to examine the effect of the applications of external cold and vibration, or blowing soap bubbles on pain during phlebotomy in children aged 3 to 6 years.

Methods

Study Design

This prospective randomized controlled, single-blind study was conducted in the pediatric phlebotomy department of a university hospital located in Izmir between March and June 2017.

Setting and Sample

This study included 3- to 6-year-old children who were scheduled for a phlebotomy procedure. Children who did not want to participate in this study, who had a chronic disease, who had a fever and the possibility of a neurologic disease, who took an analgesic within the last 24 hours, who had had a surgical operation or a history of hospitalization, and who experienced an unsuccessful phlebotomy procedure during the first attempt were not included in this study. This study was examined and approved by Ege University Faculty of Nursing Ethics Committee (IRB:2016-127). In addition, written and oral consent was received from the parents.

Sample Size Calculation

Gpower 3.1.0 statistical program showed that 30 participants in each group were needed according to the one-way analysis of variance, used by Canbulat et al,[21] for the comparison of mean self-reported pain scores, based on an effect size of 0.20, at a power of 0.80, and an acceptable type I error size of 0.05 in three groups.[33] The necessary sample size is computed as a function of user-specified values for the required significance level α, the desired statistical power 1-β, and the to be detected population effect size.[33] The plan was to include 40 participants in each group, assuming that some participants would not complete the questionnaire.

Randomization

In this study, a total of 228 children were assessed for eligibility. After the assessment, 99 children who either did not agree to participate in this study (n = 11) or who had a chronic disease (n = 72) or a congenital disease (n = 16) were excluded from this study. A total of 129 children who met the study criteria were randomized. Participants were grouped using a random numbers' table and hiding block randomization (eight blocks) and randomization information. Blocks were created according to gender (two groups, female and male) and to age (four groups of age 3, 4, 5 and 6 years). After randomization, 33 children were excluded from this study because of an unsuccessful phlebotomy (n = 19) and missing data (n = 14). As it is presented in the flow diagram in Figure 1, the final sample consisted of 96 children meeting the study inclusion criteria.[34]

Instruments

SOCIODEMOGRAPHIC INFORMATION FORM. This form includes questions about the children's age, gender, the number of phlebotomy procedures performed within the last year, the time elapsed from the last phlebotomy procedure and the frequency, which parent was with the child during the phlebotomy, age of the parent, number

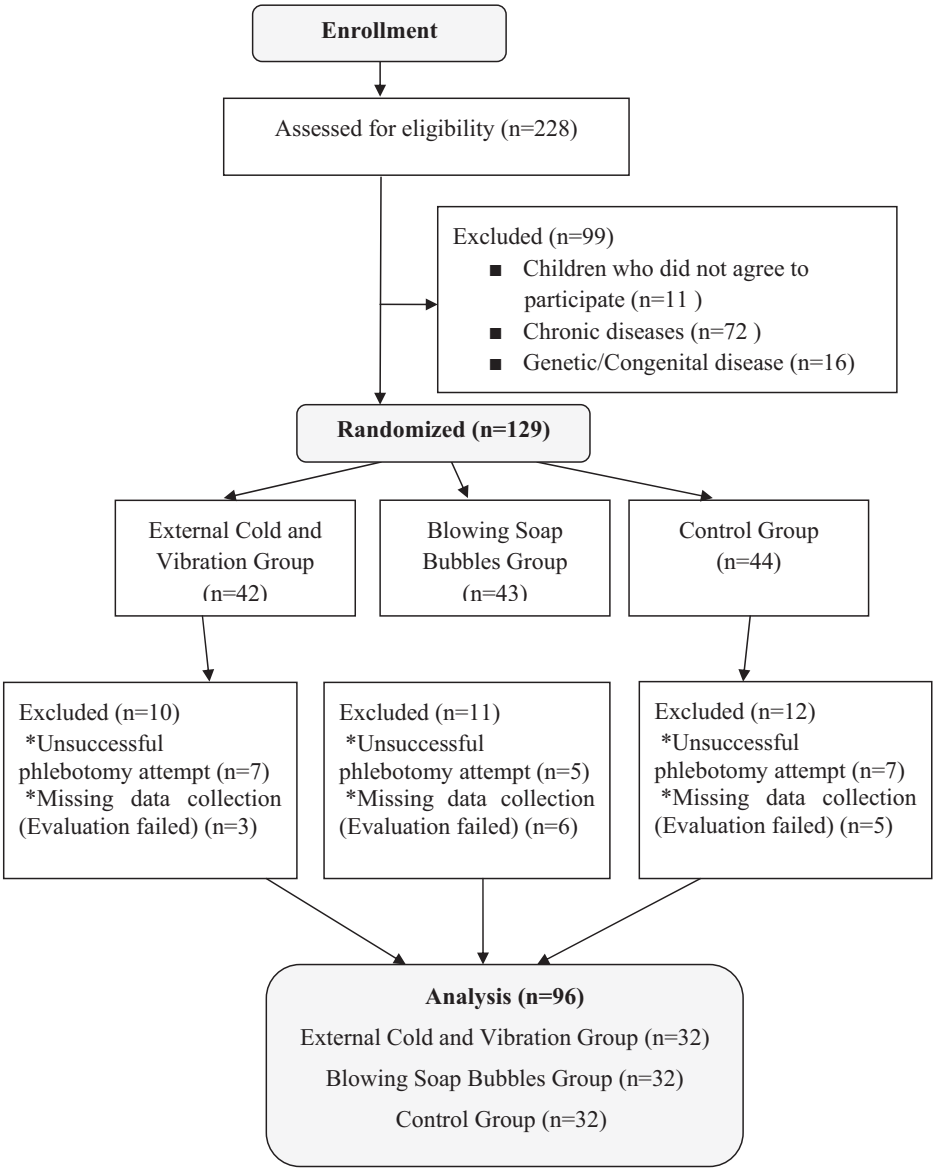

Figure 1. Selection of the study participants.

of children, educational status, and whether the parent has needle phobia.

WONG-BAKER FACES PAIN RATING SCALE. The Wong-Baker Faces Pain Rating Scale comprises six facial expressions and is rated between 0 and 10.

Data Collection

The aim of the study was explained and written informed consent was obtained from the mothers after the children and their mothers came to the phlebotomy department. Then, information about the children was collected using the Sociodemographic Information Form. The researcher ensured randomization according to age and gender, and children were included in one of the 3 groups. A total of three groups were formed with all ages included in each group.

GROUP 1: EXTERNAL COLD AND VIBRATION GROUP. The researcher placed the Buzzy Bee on the arm of each child in this group. The Buzzy

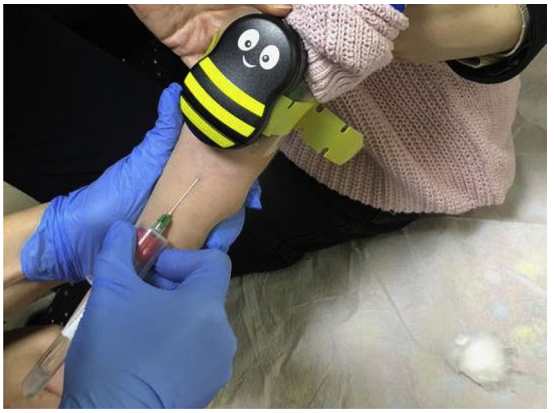

Figure 2. The Buzzy Bee. Photograph taken by researcher during phlebotomy. This figure is available in color online at www.jopan.org.

Figure 3. The soap bubble appliance. Photograph taken by researcher during phlebotomy. This figure is available in color online at www.jopan.org.

Bee provides external cold and vibration. It was placed on the arm, which the nurse preferred for the phlebotomy procedure. The Buzzy Bee affects the nerves and reduces the pain, thanks to its cold wings and vibration. Also, it helps to distract attention and reduces the feeling of pain and fear, thanks to Bee-Stractor, Flippits, and DistrACTION cards used during the phlebotomy. The nurse performed the procedure 15 seconds after the Buzzy Bee was fastened on the child's arm, 5 cm above the area in which the phlebotomy was to be performed (Figure 2).

GROUP 2: BLOWING SOAP BUBBLES GROUP. The researcher told the children included in this group that they could blow soap bubbles during the phlebotomy, and a bubble machine was placed in their hand on the side not to be used for the phlebotomy. After the children started to blow soap bubbles, the nurse performed the phlebotomy procedure after a 15-second wait (Figure 3).

GROUP 3: CONTROL GROUP. During the phlebotomy, no interventions were given to the children included in this group.

There are six booths in the phlebotomy department, and six nurses work in these booths. This unit provides service between 8 a.m. to 12 p.m. and 12 p.m. to 4 p.m. In this unit, parents stay with their children while nurses perform the phlebotomy procedure. A pediatric nurse who had a 20-year experience in phlebotomy volunteered to help conduct this study. Before the start of this study, the nurse was trained by researchers. Throughout this study, no conflict of interest occurred with the nurse. In all groups, the researcher and the children's parents stayed with the children during the phlebotomy procedure. If the blood began to flow into the tube within 5 seconds, the phlebotomy procedure was considered successful. Children who experienced an unsuccessful phlebotomy procedure for the first time were excluded from this study. The same nurse performed the phlebotomy procedure on all the children using a 5-mL injector and 22-G needle. If the procedure was successful, the researcher first personally assessed the children's pain using the Wong-Baker Faces Pain Rating Scale. After this assessment, parents and the nurse were asked to assess the children's pain using the Wong-Baker Faces Pain Rating Scale. Moreover, the researcher, children, parents, and the nurse made their assessments without knowing any of the pain scores attributed to someone else.

Data Analysis

The researcher used SPSS 23.0 software to analyze the data collected. Data obtained from the Sociodemographic Information Form and the Wong-Baker Faces Pain Rating Scale were analyzed using descriptive statistics tests. The Shapiro-Wilk analysis was used to check whether these data showed a normal distribution. The Shapiro-Wilk test is one of the most popular tests for normality assumption diagnostics, which has good properties of power, and it is based on correlation within given observations and associated normal scores. This study

used the χ^2 test and t test to analyze all basic characteristics between groups and all parametric data. Intergroup parameter comparisons were made using the Kruskal-Wallis test. The value of $P < .05$ was accepted to be statistically different.

Findings

Sample Characteristics

Distribution of sociodemographic data by groups is presented in Table 1. Groups show a homogeneous distribution according to the child's age, gender, the number and frequency of phlebotomy procedures performed within the last year, the time elapsed from the last phlebotomy procedure, which parent was with the child during the phlebotomy, age of the parent, number of children, educational status, and whether the parent has needle phobia ($P < .05$) (Table 1).

Comparison of Pain Scores

The distribution of Wong-Baker Faces pain scores by groups are presented in Table 2. According to the Wong-Baker Faces pain scores, this study found a statistically significant difference between groups. This study determined that the pain score on the Wong-Baker Faces Pain Rating Scale was lower in the groups of external cold and vibration and blowing soap bubbles than the pain score of the control group (Table 2).

Table 1. Characteristics of Children and Parents

	External Cold and Vibration Group (N = 32)	Blowing Soap Bubbles Group (N = 32)	Control Group (N = 32)	Analysis
Children characteristics				
Age (y), M ± SD	4.93 ± 0.16	4.93 ± 0.19	4.21 ± 0.18	$P = .462$
Gender, N (%)				
Boy	17 (53.1)	16 (50.0)	16 (50.0)	$\chi^2 = 0.083$, $P = .959$
Girl	15 (46.9)	16 (50.0)	16 (50.0)	
Number of phlebotomies, N (%)				
None	4 (12.5)	7 (21.9)	7 (21.9)	$\chi^2 = 1.618$, $P = .806$
1	10 (31.2)	11 (34.4)	10 (31.2)	
≥2	18 (56.2)	14 (43.8)	15 (46.9)	
Time elapsed since the last phlebotomy, N (%)				
< 1 mon	9 (28.1)	8 (25.0)	6 (18.8)	$\chi^2 = 7.860$, $P = .249$
1-6 mon	16 (50.0)	12 (37.5)	18 (56.2)	
6-12 mon	5 (15.6)	5 (15.6)	1 (3.1)	
>12 mon	2 (6.2)	7 (21.9)	7 (21.9)	
The parent next to the child, N (%)				
Mother	29 (90.6)	27 (84.4)	27 (84.4)	$\chi^2 = 0.712$, P=.701
Father	3 (9.4)	5 (15.6)	5 (15.6)	
Parent characteristics				
Parent age (y), M ± SD	33.43 ± 4.77	34.81 ± 5.77	33.50 ± 4.87	$P = .488$
Number of children, N (%)				
1	14 (43.8)	15 (46.9)	13 (40.6)	$\chi^2 = 0.643$, $P = .958$
2	14 (43.8)	14 (43.8)	14 (43.8)	
≥3	4 (12.5)	3 (9.4)	5 (15.6)	
Level of education, N (%)				
Elementary	12 (37.5)	9 (28.1)	8 (25.0)	$\chi^2 = 1.563$, $P = .815$
High school	11 (34.4)	11 (34.4)	13 (40.6)	
University	9 (28.1)	12 (37.5)	11 (34.4)	
Phlebotomy fear of parent, N (%)				
Yes	7 (21.9)	7 (21.9)	8 (25.0)	$\chi^2 = 0.118$, $P = .943$
No	25 (78.1)	25 (78.1)	24 (75.0)	

M, mean; SD, standard deviation.

Table 2. Comparison of Pain Scores According to Groups

Wong-Baker Faces Pain Rating Scale	External Cold And Vibration Group (N = 32) M ± SD	Blowing Soap Bubbles (N = 32) M ± SD	Control Group (N = 32) M ± SD	Analysis
Self-reported	3.12 ± 0.38 Min: 0 Max: 8	2.15 ± 0.35 Min: 0 Max: 9	7.37 ± 0.38 Min: 3 Max: 10	KW = 49.891, P = .000
Parent-reported	2.50 ± 0.29 Min: 0 Max: 7	2.53 ± 0.37 Min: 0 Max: 8	6.25 ± 0.33 Min: 3 Max: 10	KW = 45.041, P = .000
Nurse-reported	2.68 ± 0.24 Min: 0 Max: 5	2.34 ± 0.36 Min: 0 Max: 9	5.56 ± 0.35 Min: 2 Max: 10	KW = 39.194, P = .000
Researcher-reported	2.53 ± 0.25 Min: 0 Max: 6	2.40 ± 0.35 Min: 0 Max: 8	7.87 ± 0.31 Min: 4 Max: 10	KW = 59.881, P = .000

KW, Kruskal-Wallis; M, mean; SD, standard deviation.

Wong-Baker Faces pain scores assessed by parents, the nurse, and the researcher showed that there was no statistically significant difference between the external cold and vibration group and the blowing soap bubbles group ($P > .05$). According to the same pain scores given by parents, the nurse, and the researcher, there was a statistically significant difference between both the external cold and vibration group and the control group and the blowing soap bubbles group and the control group ($P > .05$) (Table 3).

Discussion

Vibration and movement can relieve pain according to the gate control theory reported by Melzack and Wall.[35] One of the main hypotheses of the gate control theory is that afferent signals, which are mediated by fibers with myelin, presynaptically inhibit small pain fibers on the dorsal horn of the spinal cord. Afferent signals, which are mediated by big fibers, have an analgesic effect.[35,36] This hypothesis supports that peripheral transcutaneous electrical nerve stimulation shows the analgesic effect.[36] Published studies showed that during a phlebotomy,[11,13,25] vaccination,[23] peripheral intravenous cannulation[22] in children, the Buzzy Bee, by ensuring external cold and vibration, has an effect on pain relief. Studies comparing the Buzzy Bee with pharmacologic methods show that the Buzzy Bee method is more effective.[3,8,9] Taddio et al[37] determined that during vaccination, the reliability of the Buzzy Bee was low, the reliability of topical anesthesia was moderate, and that distracting practices such as playing music, playing a video, playing with toys, and doing breathing exercises (blowing soap bubbles and so forth) was very low. Results of study proved the effectiveness of the Buzzy Bee method in pediatric pain management.[25,29]

Progressive muscle relaxation can be used to reduce both pain and the subjective intensity of pain. Diaphragmatic breathing is the easiest method of relaxation. Moreover, blowing soap bubbles ensures that children are relaxed, because it encourages them to breathe deeply.[38] A study by Hedén et al[7] examined the effects of standard care (EMLA cream) and blowing soap bubbles, and of standard care and the heated pillow method on children with the oncological disease. They found no significant difference between methods. Sparks[28] found that blowing soap bubbles and touching methods considerably reduced children's pain and that touching was more effective in relieving pain compared with the method of blowing soap bubbles; however, no statistically significant differences were found between groups. A study by French et al[15] determined that controlled breathing techniques, such as blowing soap bubbles during vaccination, were

Table 3. Pairwise Comparisons of Groups

Wong-Baker Faces Pain Rating Scale	External Cold And Vibration–Blowing Soap Bubbles	Blowing Soap Bubbles–Control	External Cold And Vibration–Control
	P	*P*	*P*
Self-reported	.387	.000	.000
Parent-reported	1.000	.000	.000
Nurse-reported	1.000	.000	.000
Researcher-reported	1.000	.000	.000

effective in relieving the pain. Boivin et al[6] also showed that children to whom EMLA cream was applied and children using the blowing soap bubbles method had lower pain scores compared with the control group. The present study determined that pain scores were lower in the groups of external cold and vibration and blowing soap bubbles than pain scores in the control group.

Conclusions

Study findings show that the methods of external cold and vibration and blowing soap bubbles had a pain relieving effect on children in all age groups during phlebotomy. It is recommended that the effect of these methods on other painful interventions be studied. We applied two different methods in 3- to 6-year-old children who were scheduled for a phlebotomy procedure. The methods of external cold and vibration and blowing soap bubbles had a pain relieving effect during phlebotomy on children ages 3 to 6 years. Nurses can use these methods with children during phlebotomy. Reducing the emotional and physical effects of painful interventions in children is an important part of nursing practice. Distracting practices is among nonpharmacologic methods commonly used by nurses for pain management. Both Buzzy and blowing soap bubbles are among quick, effective, inexpensive, and reusable methods that do not require extra time, do not have any side effects, and can be used safely in children.

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