



The Use of the Buzzy, Jet Lidokaine, Bubble-blowing and Aromatherapy for Reducing Pediatric Pain, Stress and Fear Associated with Phlebotomy



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ABSTRACT

Purpose: This study aimed to investigate the effects of the Buzzy, Jet lidokaine, bubble-blowing and inhalation aromatherapy with lavender essence on pain, stress and fear in children undergoing phlebotomy.

Designs and methods: This study was a prospective, randomized controlled trial. The sample was comprised of children aged 5 to 10 years requiring blood tests. Children were assigned to five subgroups through randomization performed using a computer program: the Buzzy group (n = 39), Jet lidokaine group (n = 39), bubble-blowing group (n = 39), inhalation aromatherapy with lavender essence group (n = 39) and control group (n = 39). The children's levels of pain were evaluated and reported by the parents, observers and the children, who self-reported using the Oucher Pain Scale. The children's fear levels were assessed using the Children's Fear Scale, and salivary cortisol analysis was conducted to evaluate stress levels.

Results: A significant difference was found between the intervention and control groups in terms of levels of pain during and after phlebotomy in favor of the Buzzy group ($p < 0.05$). There was a significant difference between the fear scores of the children in the intervention and control groups before phlebotomy ($p < 0.05$). This difference was found to be caused by the bubble-blowing method. There was a significant difference between intervention and control groups fear levels in favor of the Buzzy group during phlebotomy ($p < 0.05$).

Practice implications: It is recommended that the Buzzy and bubble-blowing be used during phlebotomy in children to reduce the severity of their pain.

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Background

Several studies have shown that children and infants who have gone through numerous painful events have a greater sensitivity to pain, maladaptive responses, low quality cognitive and motor development, a phobia of needles and traumatic memories that may persist during adolescence and into adulthood (Krauss, Calligaris, Green, & Barbi, 2016; Valeri, Holsti, & Linhares, 2015). Thus, reducing the short- and long-term negative effects on children of these painful procedures by managing them adequately is an important part of nursing. Pain management involves both pharmacological and non-pharmacological methods (Taddio et al., 2010).

Pharmacological approaches including topical anesthetics have frequently been unsuccessful as they are expensive, can need long periods of time before an analgesic effect is felt (e.g., EMLA®, Ametop®) or are not effective for every age groups (e.g., vapocoolant sprays) (Cohen et al., 2008; Farion, Splinter, Newhook, Gaboury, & Splinter, 2008).

Although it has been well-studied (Baxter et al., 2013) and is broadly used, EMLA® (eutectic mixture of local anesthetics, lidocaine and prilocaine) requires 45 to 60 min of application for a complete anesthetic effect to occur (Zempsky, 2008). When time is short and there is no opportunity for applying a topical anesthetic, another option for achieving a comparatively pain-free phlebotomy insertion is to use a Jet lidokaine. This method employs a compressed carbon dioxide-driven device that delivers 0.2 ml of buffered 1% lidocaine transdermally and may be a better choice than a topical anesthetic in children whose needle procedure is urgently required. (Auerbach, Tunik, & Mojica, 2009; Kears, Yanger, Montero, Morelos-Howard, & Claudius, 2015; Lunoe et al., 2015). Nursing staff apply the Jet lidokaine, which is a needle-free injection, at the administration site identified and the lidocaine should have decrease sensation fully after 1 min. The Jet lidokaine functions in the same manner as the topical creams, blocking conduction of the nerve endings. One study found that children aged 8 to 15 years experienced better pain control with a Jet lidokaine in comparison that achieved through topical analgesics (Spanos et al., 2008). Another study noted that a needle-free injection of lidocaine before a peripheral intravenous catheterization (PIV) procedure gave effective pain control to children aged between 3 and 16 years old (Kelley, Russell, Devgon, & Rosen, 2017).

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Non-pharmacological methods that have been found effective in decreasing acute pain in children have included cognitive behavioral therapy, hypnosis, distraction and guided imagery, among others (Badr, 2013; Gupta et al., 2014; Vetri- Buratti et al., 2015). The use of auditory or visual distracters, touch, reading, singing, playing a game, bubble-blowing, or vibration or massage (Bagnasco, Pezzi, Rosa, Fornonil, & Sasso, 2012; Gupta et al., 2014; Sahiner & Bal, 2015), have for many years proven to be effective in helping the child not only cope with the medical procedure itself, but also to soften and mitigate any memories of the intervention (Uman, Chambers, McGrath, & Kisely, 2008).

Vibration involves two cortical areas responsible for perceptions of pain and touch (Hollins, McDermott, & Harper, 2014). Analgesic mechanisms that limit pain are activated by the vibration (Moadad, Kozman, Shahine, Ohanian, & Badr, 2016). A significant element of vibro-tactile analgesia is proposed to be connected to A-beta mediated afferent inhibition of dorsal horn nociceptive neurons (Staud, Robinson, Goldman, & Price, 2011). A device available on the market to assist health care staff to achieve patient distraction is the Buzzy (MMJ Labs; Atlanta, GA). This is a small plastic device made up of a vibrating motor and an ice pack. It is fixed to the child's arm just above the administration site using a Velcro strap. The vibration and the ice work together to distract the child from the insertion of the needle and any related pain by overwhelming the nerve endings with vibration and cold, which affect the pain receptors (Schumann, 2011). Studies have shown that the Buzzy reduces the pain linked to intravenous (IV) insertion, venipunctures and phlebotomy, as well as improving the child's degree of cooperation (Baxter, Cohen, McElvery, Lawson, & von Baeyer, 2011; Canbulat, Ayhan, & Inal, 2015; Inal & Kelleci, 2012; Moadad et al., 2016; Whelan, Kunselman, Thomas, Moore, & Tamburro, 2014). The Buzzy is cost effective and is reusable when cleaned appropriately before each new patient (Schumann, 2011).

Inhalational aromatherapy is a method in which essential oils are inhaled, which may reduce pain, depression and mental stress, and lead to the improvement of vital signs (Seifi et al., 2014). The aroma molecules are first absorbed through the nasal mucosa. Then they are converted into nervous signals in the olfactory bulb, amygdala and the limbic system. This fosters therapeutic effects by causing a variety of neurotransmitters such as serotonin, enkephalin and endorphins to be released (Lv, Liu, Zhang, & Tzeng, 2013). Lavender (*Lavandula angustifolia*) is one of the essential oils most often used in aromatherapy; it is an aromatic plant of the Lamiaceae family and displays analgesic, anti-fungal, antibacterial, anti-bloating and muscle relaxant effects (Ali et al., 2015). Lavender essential oil can be safely used with children (Cetinkaya & Basbakkal, 2012; Soltani et al., 2013). Lavender essential oil is very commonly employed in aromatherapy as a result of its sedative, antispasmodic and anesthetic effects (Bikmoradi et al., 2014). Linalyl acetate and Linalool of Lavender essence stimulate the parasympathetic system, reducing heart and respiratory rates, and blood pressure and they consequently have a narcotic and sedative function (Sköld, Hagvall, & Karlberg, 2008). This study aimed to investigate the effects of the Buzzy, Jet lidokaine, bubble-blowing and inhalation aromatherapy with lavender essence on pain, stress and fear relief in children undergoing phlebotomy.

Design and method

Design and setting

This was a prospective, randomized clinical trial that assessed and compared the effects of phlebotomy on pediatric patients (5 to 10 years old) in the Phlebotomy Unit of a Maternity and Children Training and Research Hospital, Turkey between May 2016 and September 2017 when Jet lidokaine, Buzzy, bubble-blowing and inhalation aromatherapy with lavender essence were used prior to the procedure.

Sample size and randomization

Following previous studies, G*Power (v3.1.9.2) was deployed to determine the sample number. According to Jacob Cohen's effect size coefficients, assuming that evaluations carried out among five independent groups would have a large effect size ($d = 0.40$), it was determined that the groups should comprise least 39 people, with a total of 195, for levels of $\alpha = 0.05$ and $1-\beta = 0.95$ (90% power) (Fig. 1). Children were assigned to 5 subgroups through randomization performed using a computer program (www.randomizer.org): group 1 was the control group with children who received no intervention for pain relief ($n = 39$); group 2 received Jet lidokaine ($n = 39$); group 3 received distraction using bubble-blowing ($n = 39$); group 4 received external thermomechanical stimulation (Buzzy) ($n = 39$); and group 5 received inhalation aromatherapy with lavender essence ($n = 39$). Neither parents, children, nor observer were blinded to the group assignment.

Ethical considerations

To conduct this study, permission was obtained from the Ethics Committee of Clinical Research using the ethical consent form. The aim and the method of the study were explained to the children and their parents, and they were informed that if they did not want to continue, they could withdraw from the study without stating a reason. Written informed consent was obtained from children and their parents. The children and their parents were assured that the information they gave would be confidential and would not be used for any other purpose. The study thus fulfilled all the relevant ethical principles of informed consent, voluntariness, and the protection of the privacy protection of human subjects and safeguarded their individual rights.

Participants

Inclusion criteria were 5 to 10 years old children requiring blood tests. Also; child should be accompanied by a family member. Patients were excluded if they had received another local anesthetic, showed signs of skin infection or pathology at the site of insertion, had significant trauma or disease needing rapid evaluation (Glasgow coma scale [GCS] score < 15 and/or hemodynamically unstable), were developmentally delayed, had a chronic illness (i.e., diabetes, sickle cell disease, asthma, allergy, dermatitis, cystic fibrosis), had an altered sensorium, were allergic to lidocaine, had a neurosensory deficit in the insertion area, or had a developmental delay preventing the pain scale from being completed.

Outcome measures

The instruments applied to the children who made up the control and intervention groups were as follows: Procedural fear (CFS scores), pain (Oucher), parent perception of child distress (PRCD) scores of all children before, during and after the procedure were assessed by the observer. In addition, samples of the children's saliva were collected before and after the procedure in order to determine stress levels.

Children's perception of procedural pain was assessed using the Oucher Scale. The Oucher is a self-report of pain intensity for children aged between 3 and 12 and consists of two separate scales (Aradine, Beyer, & Tompkins, 1988). One scale has a series of six photographs of a child in varying degrees of distress and is to be used for children who are unable to count. In this study, screening items were used to decide which scale was suitable for each individual. Children able to determine the bigger of two numbers used the vertical numeric scale (0–10) printed next to the images of the faces. The range of scores is 0–10 for both scales. Discriminate validity was demonstrated by investigating the relationships between the Oucher and the two fear scales for children. Internal consistency (Cronbach's coefficient alphas) ranged from

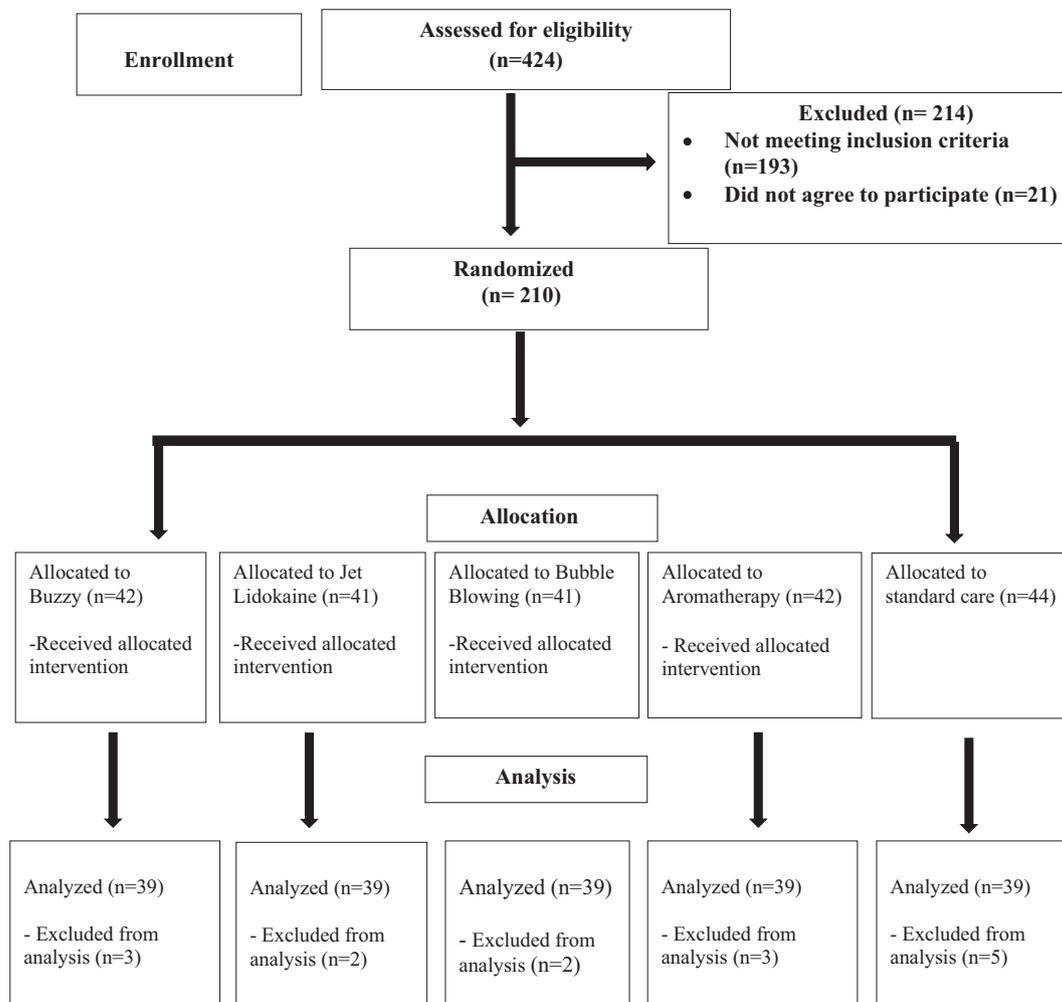


Fig. 1. Study enrollment, randomization, and procedures.

$r = 0.52$ to 0.98 . (Beyer & Aradine, 1986). Cronbach's coefficient alphas ranged from $r = 0.68$ to 0.75 in this study.

Procedural fear was assessed using the Children's Fear Scale. The CFS is a valid and reliable tool for evaluating procedural fear in young school-aged children between 5 and 10 years old (McMurtry, Noel, Chambers, & McGrath, 2011). The CFS is made up of five faces which are evenly distributed on a horizontal orientation. Each face represents a different degree of fear, with the left-most face marked as 0, with an expression said by the developers to show no fear, and the face on the far right marked as 4, demonstrating the most serious degree of fear. Participants self-reported their fear by placing a mark on the horizontal axis. Before the procedure, the children were told how the scale would be used. After the child stated that they understood, they were asked to say how frightened they were. Children were asked "Can you look at these faces and choose the one which shows how frightened you are of having a phlebotomy?" The mark given by each individual was then recorded. The CFS has shown good evidence of test-retest ($r = 0.76$, $p < 0.001$) and inter-rater ($rs = 0.51$, $p < 0.001$) reliability as well as construct validity among children (McMurtry et al., 2011). Cronbach's coefficient alphas ranged from $r = 0.73$ to 0.81 in this study.

A question from the Perception of Procedures Questionnaire (Kazak, Penati, Waibel, & Blackall, 1996) was used to assess the parents' perception of their child's distress. The question "How distressed was your child today during the phlebotomy?" was graded from 1 = "not at all" to 7 = "extremely distressed". Parents answered this question immediately after the phlebotomy was completed. The other questions from the questionnaire were not used to measure distress because they

focus on the child's behavior before the medical procedure, rather than in response to it. Internal consistency (Cronbach's coefficient alphas) ranged from $r = 0.80$ to 0.91 . Cronbach's coefficient alphas ranged from $r = 0.78$ to 0.85 in this study.

Saliva samples were collected from the children twice in both intervention groups and the control group (once on arrival at the clinic and once 25 min after the phlebotomy). The second collection time was 25 min later because peak cortisol responses are achieved 20–30 min after the stimulus causing pain (Cignacco, Denhaerynck, Nelle, Buhner, & Engberg, 2009; Cong, Ludington-Hoe, & Walsh, 2011). The children received no food before the collection of the samples (Cong et al., 2011). Collecting samples for analysis of salivary cortisol by using soft cotton swab is a comparative simple procedure. A cotton swab was gently positioned in the buccal and sublingual space of each child and left in place for 3–4 min. Cortisol levels were determined using a Salimetrics Salivary Cortisol Kit. Cortisol samples were analyzed using standard procedures in an accredited laboratory.

Procedure

After being assigned to groups, the children and their parents went to the Phlebotomy Unit to undergo phlebotomy in treatment sessions occurring between 9:00 AM and 12:00 PM. All parents remained with their children in the Phlebotomy Unit. Venipuncture was performed using the Vacutainer® system, with a 21G butterfly needle. All venipuncture procedures were carried out by highly experienced pediatric nurses. All parents stayed with their children in the phlebotomy unit.

Children in each group were asked to assess the child's procedural pain and fear before (30–60 s), during and immediately after (1–3 min) the phlebotomy. Parents assessed child's distress before (30–60 s), during and immediately after (1–3 min) the phlebotomy was completed. Saliva samples were taken from the children 5 min before and 25 min after the phlebotomy.

Jet lidokaine device is a Food and Drug Administration–approved device which contains carbon dioxide gas that pushes a plunger rapidly down a barrel, forcing medicine to be expelled through a small hole. The jet device delivers medication into the epidermis to a depth of 5–8 mm in 0.2 s. After administration the medication quickly disperses 0.3 mL within the surrounding tissue. The jet device has been shown to be both safe and effective when used for the administration of vaccinations and a range of other pharmaceuticals. It does not have any sharp objects, thereby decreasing the risk of injuries, and it can be disposed of in a normal waste container (Kearl et al., 2015; Lunoe et al., 2015). The jet device was used at the application area 1 min before the phlebotomy.

The independent variable was the use of the Buzzy®, a recently developed reusable device, (MMJ Labs, Atlanta, GA), which uses cold and vibration together and is generally secured with a tourniquet next to the site of an injection or venipuncture to decrease the sensation of pain. The device consists of a reusable 8 × 5 × 2.5-cm handheld plastic bee which contains a battery-operated vibrating motor and a mechanism to attach an ice pack underneath. It can be pressed in place or tied around a limb using a Velcro strap or tourniquet. The Buzzy® device is positioned 3 to 5 cm above the application area just before phlebotomy. Sufficient contact with the skin is required. The cold pack is stored in a freezer and is attached to the device immediately before use. The application of the cold pack and the vibrations start 30–60 s before the procedure and continue until it is finished. Before the device was used on another patient it was cleaned with 70% alcohol. The cold pack was removed from the freezer just before each application.

Bubble-blowing was used to blow bubbles a toy containing soapy liquid. This toy allows soap bubbles to be produced when a specific part of the apparatus is blown into. It was used as methods of distracting children by allowing them to take a deep breath, blow out and create soap bubbles during the phlebotomy. Bubble-blowing was used 1 min before the phlebotomy.

Inhalation aromatherapy with lavender essence was created by adding a drop of lavender oil into a 20 ml-glass jar containing 20 ml of distilled water. 5 ml of this sample was then taken. The lavender essence was prepared separately for each child. Prior to phlebotomy, the sample was heated in a 20 ml-glass jar in a water bath and stored at 36–37°C. The glass jar containing the essence was held 10 cm from the child's nose from 5 min before the phlebotomy until 5 min afterwards.

None of the children in control group received any other intervention before, during and after phlebotomy. Only the routine procedure was conducted.

Data analysis

Statistical analysis was conducted using the SPSS Statistics software for Microsoft Windows XP (Version 21.0, SPSS Inc., Chicago, IL). Demographic and clinical characteristics of participants were described using frequency distributions for categorical variables and means/standard deviations (median, min-max) for continuous variables. Comparisons of pediatric procedural fear (CFS scores), pain (Oucher), parent perception of child distress (PRCD) with three sequential the measurements for the five groups were carried out using analysis of variance for repeated measures (RM-ANOVA) and the post-hoc advanced analysis Bonferroni test for binary comparisons were deployed for the statistical analyses. Mauchly's Test of Sphericity result was found as $p < 0.000$, and the Greenhouse-Geisser results were taken into consideration. Comparisons of pediatric stress (salivary cortisol) from the two sequential cortisol measurements for the five groups were conducted using analysis of

variance (One-Way ANOVA). The level of significance was set at $p < 0.05$.

Results

One hundred and ninety five children [90 (46.2%) girls and 105 (53.8%) boys] were included in the present study. The mean age of the children was 7.28 ± 1.91 years (range: 5–10 years). The children were randomized into 5 groups: Jet lidokaine ($n = 39$), Buzzy ($n = 39$), bubble-blowing ($n = 39$), aromatherapy ($n = 39$) and the control ($n = 39$) group. The characteristics of children are presented in Table 1. No statistically significant difference was found between the control and intervention groups in terms of gender, age, BMI, previous phlebotomy, previous hospitalization and diagnoses ($p > 0.05$; Table 1). Post-hoc ordinal variable regression was performed to examine the significance of potential factors affecting children's ratings of post-procedural pain and fear. However, we found that there was no statistically significant difference between the groups in terms of confounding variables aforementioned ($p > 0.05$).

The pain (Oucher) level evaluation of the study groups is shown in Table 2. As a result of the analysis of variance for repeated measures (RM-ANOVA), no difference was found between the groups for the children's procedural pain levels before phlebotomy ($p > 0.05$) (Fig. 2). However, there was a significant difference found between the pain levels of control and intervention groups during and after phlebotomy. As a result of post-hoc Bonferroni test conducted to determine in which group this difference originated, it was found that the difference originated in the Buzzy group, and that children in this group had less pain ($p < 0.05$).

The fear (CFS) level evaluation of the study groups is presented in Table 2. As a result of the analysis of variance for repeated measures (RM-ANOVA), a difference was found between the groups for the children's procedural fear levels before and after phlebotomy ($p < 0.05$). As a result of post-hoc Bonferroni test performed to determine in which group this difference originated, it was found that the difference originated in the bubble-blowing group before phlebotomy, and that children in this group were less frightened before phlebotomy ($p < 0.05$). The difference between the intervention and control groups in terms of level of fear during phlebotomy was significant in favor of the Buzzy group, and the children in the Buzzy group were less frightened during phlebotomy ($p < 0.05$) (Fig. 3).

Evaluation of the parent perception of child distress (PRCD) in the study groups is given in Table 2. As a result of the analysis of variance for repeated measures (RM-ANOVA), no difference was found between the levels of parent perception of child distress (PRCD) among the groups before, during, and after phlebotomy ($p > 0.05$).

Evaluation of the levels of stress (salivary cortisol levels) of the study groups is given in Table 3. The cortisol levels of the children in the intervention groups were determined to be lower than those of the children in the control group before and after the procedure. However, this difference was not significant ($p > 0.05$) (Table 3) (Fig. 4).

Discussion

Pharmacological and non-pharmacological methods are used as forms of pain control for children undergoing acute painful interventions. This study was carried out to investigate and compare the effects of the Buzzy, Jet lidokaine, bubble-blowing and inhalation aromatherapy using lavender essence on pain, stress and fear relief in children during phlebotomy.

A child's response to painful stimulation is affected by age, developmental level, gender, cognitive development, communication skills, previous experience, culture, and the parents' response. In the results of this research, no statistically significant difference was found between children in terms of age, gender, BMI, and previous phlebotomy and hospitalization ($p > 0.05$) (Table 1). These findings suggest that

Table 1
Comparison of descriptive characteristics of the control and intervention groups (N = 195).

Variables	Jet lidokaine (n = 39) N (%)	Buzzy® (n = 39) N (%)	Bubble blowing (n = 39) N (%)	Aromatherapy (n = 39) N (%)	Control (n = 39) N (%)	Statistics test P-value
Gender						
Girl	15 (38.5)	19 (48.7)	20 (51.3)	17 (43.6)	19 (48.7)	$\chi^2 = 1.680$ $p = 0.794$
Boy	24 (61.5)	20 (51.3)	19 (48.7)	22 (56.4)	20 (51.3)	
Age	7.12 ± 2.12	7.92 ± 1.69	6.89 ± 1.74	7.28 ± 2.01	7.20 ± 1.89	F = 1.58 p = 0.180
BKI	19.35 ± 2.33	18.84 ± 2.36	19.15 ± 2.37	18.69 ± 2.77	19.33 ± 2.87	F = 0.480 p = 0.751
Previous phlebotomy						
≥ 3times	39 (100.0)	37 (94.9)	22 (56.4)	27 (69.2)	22 (56.4)	$\chi^2 = 6.166$ $p = 0.185$
3 times ≥	0 (0)	2 (5.1)	4 (43.6)	12 (30.8)	17 (43.6)	
Previous hospitalization						
Yes	27 (69.2)	19 (48.7)	35 (89.7)	38 (97.4)	35 (89.7)	$\chi^2 = 5.218$ $p = 0.270$
No	12 (30.8)	20 (51.3)	4 (10.3)	1 (2.6)	4 (10.3)	

the groups are similar in terms of demographic variables that may affect the perception of pain.

Evaluating the fear scores of the children before the procedure, the current study found that the most effective method to reduce fear was foam bubble-blowing ($p < 0.05$). Distraction, one of the non-pharmacological methods, involves focusing the patient's attention on something other than pain. Distraction methods include watching cartoons, blowing up balloons, playing video games, eating a lollipop, listening to music and being distracted by the parents. A recent Cochrane review of 39 trials with 3394 children found strong evidence to support the usefulness of distraction in reducing needle-related pain in children and adolescents; however, there is only limited evidence for differentiating which means of distraction are most effective (Uman et al., 2013). Although non-pharmacological methods are not yet extensively used in health services, the literature supports these methods (Dovney & Zun, 2012; Kaheni, Rezai, Bagheri-Nesami, & Goudarzian, 2016; Nilsson, Enskär, Hallqvist, & Kokinsky, 2013).

Children are especially vulnerable to a phobia of needles. Making injections and venous access procedures as pain free as possible is an ethical necessity (Sahiner, Inal, & Akbay, 2015). In the present study, children's levels of fear and pain during phlebotomy were significantly lower in the Buzzy group than in the other groups. This is in accord with earlier studies (Baxter et al., 2011; Canbulat et al., 2015; Inal & Kelleci, 2012; Whelan et al., 2014), and supports the use of this very simple intervention for reducing pain during an IV insertion. Nevertheless, the children's mothers did not rate their child's distress as significantly different whether or not a Buzzy was used. This finding may demonstrate their concern about their child's pain and their related inability to be objective. The results of the present study are supported by

an earlier study of 78 children between 8 and 15 which found that parents' Visual Analogue Scale (VAS) score ratings did not correlate with the children's VAS pain scores (Kelly, Powell, & Williams, 2002). In contrast, various other studies suggest that parental pain scores show a strong correlation with children's scores and can be reliably used especially when children are not able to put their pain into words (Khin et al., 2014; Rajasagaram, Taylor, Braitberg, Pearsell, & Capp, 2009). These conflicting findings may reflect the different age groups of the children evaluated, as well as the different settings, and further investigation is warranted.

In the present study, Jet lidocaine during phlebotomy was found to be less effective than the Buzzy and bubble-blowing. In contrast to these findings, in a different study children of 1 to 6 years were randomized into 3 groups: intervention (J-Tip), control (vapocoolant spray), and sham (vapocoolant spray and pop of an empty J-Tip) and the use of the J-Tip reduced venipuncture pain compared with vapocoolant spray or sham treatment (Lunoe et al., 2015). In another study, Pediatric Emergency Department patients aged between one month and 21 years were prospectively enrolled in Phase 1 (J-tip® only) then Phase 2 (Buzzy® + J-tip®) for analgesia before venipuncture or the start of IV. Age-appropriate pain scale scores were collected for the procedure, as well as for the administration of lidocaine via J-tip®. Patients receiving either intervention reported lower scores on pain scales during venipuncture or start of IV than the no analgesia group. The combined intervention did not show a significant decrease in scores on pain scale scores over the J-tip® alone (Kearl et al., 2015). However, other studies demonstrated a lower pain score at needle insertion for children given a J-Tip compared with lidocaine or prilocaine cream and for children given a J-Tip compared with no pain treatment (Auerbach et al., 2009;

Table 2
Comparison of the Oucher, CFS and PRCD scores between the control and intervention groups.

Groups measurements		Oucher scores X ± SD Med (Min-Max)		CFS scores X ± SD Med (Min-Max)		PRCD scores X ± SD Med (Min-Max)	
Jet lidokaine (n = 39)	Before	3.20 ± 3.51	2.00(0.00–10.00)	1.92 ± 0.62	2.00(1.00–3.00)	1.30 ± 0.46	1.00 (1.00–2.00)
	During	4.71 ± 4.41	3.00(0.00–10.00)	1.46 ± 0.50	3.00(1.00–4.00)	1.64 ± 0.48	2.00 (1.00–2.00)
	After	2.82 ± 3.42	1.00(0.00–10.00)	1.33 ± 0.48	1.00(1.00–2.00)	1.23 ± 0.42	1.00 (1.00–2.00)
Buzzy® (n = 39)	Before	2.41 ± 3.35	1.00(0.00–10.00)	1.82 ± 0.60	2.00(1.00–3.00)	1.33 ± 0.51	1.00 (1.00–2.00)
	During	3.51 ± 3.49*	2.00(0.00–10.00)	1.33 ± 0.47*	2.00(1.00–4.00)	1.66 ± 0.67	2.00 (1.00–3.00)
	After	1.43 ± 2.47*	0.00(0.00–0.00)	1.46 ± 0.51	1.00(1.00–2.00)	1.23 ± 0.38	1.00 (1.00–2.00)
Bubble blowing (n = 39)	Before	2.15 ± 2.73	1.00(0.00–10.00)	1.79 ± 0.52*	2.00(1.00–3.00)	1.51 ± 0.56	2.00 (1.00–3.00)
	During	4.53 ± 3.25	4.00(0.00–10.00)	1.66 ± 0.73	2.00(1.00–3.00)	1.94 ± 0.86	2.00 (1.00–3.00)
	After	1.66 ± 2.36	1.00(0.00–9.00)	1.66 ± 0.53	2.00(1.00–3.00)	1.25 ± 0.39	1.00 (1.00–3.00)
Aromatherapy (n = 39)	Before	2.94 ± 3.05	1.00(0.00–10.00)	1.82 ± 0.68	2.00(1.00–3.00)	1.38 ± 0.51	1.00 (1.00–2.00)
	During	5.46 ± 2.75	5.00(1.00–10.00)	1.97 ± 0.77	2.00(1.00–4.00)	1.87 ± 0.75	1.00 (1.00–2.00)
	After	2.89 ± 2.77	2.00 (0.00–10.00)	1.97 ± 0.73	2.00(1.00–3.00)	1.17 ± 0.28	2.00 (1.00–3.00)
Control (n = 39)	Before	2.64 ± 2.38	2.00(0.00–8.00)	2.20 ± 0.80	2.00(1.00–3.00)	1.51 ± 0.45	2.00 (1.00–2.00)
	During	5.87 ± 2.87	6.00(1.00–10.00)	2.66 ± 0.90	3.00(2.00–4.00)	1.92 ± 0.65	2.00 (1.00–3.00)
	After	2.84 ± 2.60	2.00 (0.00–10.00)	2.07 ± 0.73	2.00(1.00–3.00)	1.23 ± 0.37	1.00 (1.00–2.00)
Test	Time	F = 0.73	P = 0.000	F = 9.17	p = 0.000	F = 15.39	p = 0.000
	Group	F = 3.65	p = 0.001	F = 5.91	p = 0.015	F = 0.75	p = 0.556
	Time X group	F = 8.32	p = 0.030	F = 9.17	p = 0.036	F = 1.88	p = 0.115

* Post hoc advanced analysis result.

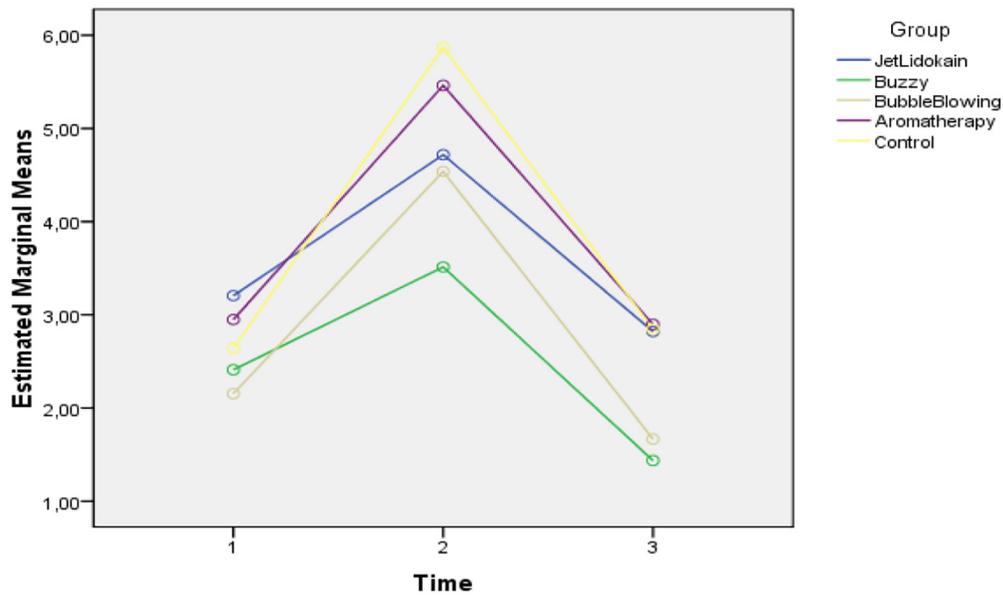


Fig. 2. Qucher scores.

Spanos et al., 2008). The findings of the present study are not similar to the literature. Although the children were told and shown that there was no needle at the tip of the injector in the Jet lidocaine application, the appearance of the injector may have caused them to be anxious.

In this study, one group received aromatherapy during phlebotomy. However, it was found to be less effective than Jet lidokaine, Buzzy and bubble-blowing. Many studies have been conducted on decreasing the severity of pain in patients using aromatherapy. A previous study showed that inhalation aromatherapy using lavender essence had a significant impact on severity of pain in neonates during blood sampling, which is not in line with our results. ($p < 0.001$) (Razaghi, Sadat-Hoseini, Aemmi, Mohebibi, & Boskabadi, 2015). Another study showed

that inhalation aromatherapy using lavender essence helped to reduce the severity of pain severity of children during intravenous catheter insertion (Ali et al., 2015). Furthermore, another study indicated that inhalation aromatherapy had a significant effect in decreasing peripheral venous cannulation pain in patients who underwent surgery ($p < 0.01$) (Karaman et al., 2016). The results of another study showed that inhalation aromatherapy using lavender oil essence reduced the pain of needle insertion ($p < 0.001$) (Kim et al., 2011). By contrast, and in agreement with our results, a study indicated that inhalation aromatherapy with lavender and orange oil essence had no significant effect on pain during the self-monitoring of blood glucose in children (Małachowska, Fendler, Pomykała, Suwała, & Młynarski, 2016).

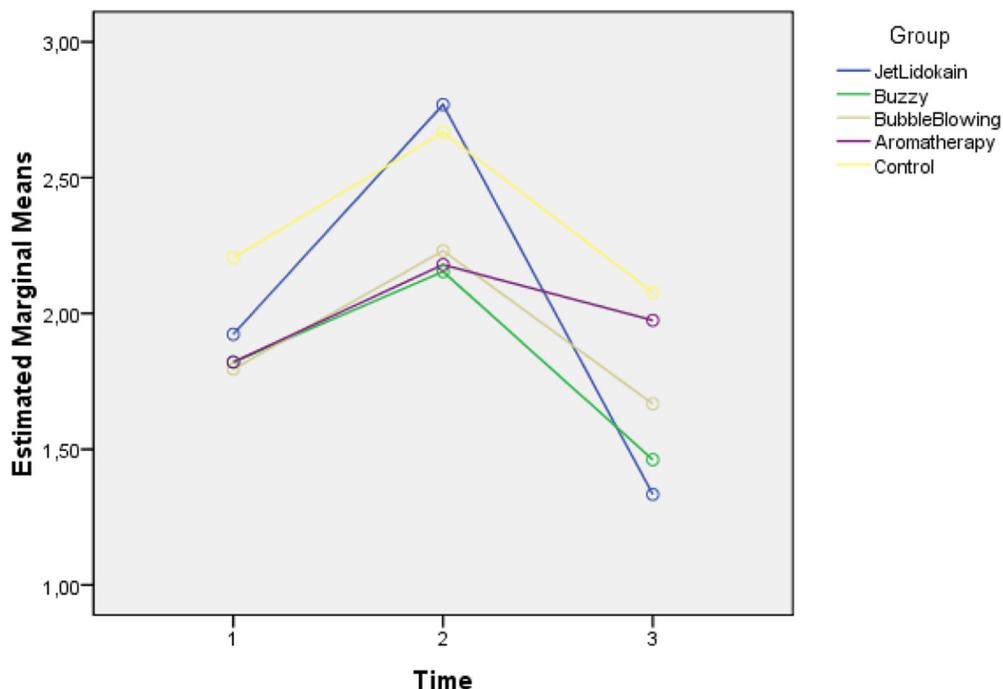


Fig. 3. CFS scores.

Table 3
Comparison of the cortisol level between the control and intervention groups.

Salivary cortisol ($\mu\text{g/dL}$)	Jet lidokaine (n = 39) X \pm SD	Buzzy® (n = 39) X \pm SD	Bubble blowing (n = 39) X \pm SD	Aromatherapy (n = 39) X \pm SD	Control (n = 39) X \pm SD	Statistics test P-value
Before phlebotomy	1.69 \pm 0.78 Min-max 0.46–3.12	1.51 \pm 0.74 Min-max 0.33–3.36	1.45 \pm 0.73 Min-max 0.32–3.21	1.55 \pm 0.77 Min-max 0.75–3.42	1.56 \pm 0.72 Min-max 0.62–3.08	F = 0.520 p = 0.721
After phlebotomy	3.25 \pm 1.79 Min-max 1.20–6.80	2.89 \pm 1.78 Min-max 1.36–5.40	3.17 \pm 2.02 Min-max 1.50–7.50	3.24 \pm 1.77 Min-max 1.90–6.85	3.39 \pm 1.82 Min-max 1.96–8.60	F = 0.374 p = 0.827

SD, Standart deviation.

Moreover, another study reported that inhalation aromatherapy with lavender essence oil had no significant effect on post-tonsillectomy pain in children despite reducing the need for analgesics (Soltani et al., 2013).

Limitations

There are several known limitations related to this study. First, the observer, children and parent were not blinded to the intervention, which could have caused bias in both the child and parent ratings. Children might have responded differently to pain based on their physical condition, emotional and cultural states. Additionally, a further drawback of the Jet lidocaine is the “popping” noise that is heard when the carbon dioxide is released. This may frighten a child and increase his/her anxiety, which may cause them to move. For this reason, the use of a distraction method during the Jet lidocaine application may be recommended. Another limitation of this study is that the relation of aroma and memories can be influential. Aroma can trigger memories. Hence, if the smell of the lavender essence applied to children is closely associated with negative or positive memories, it can affect the results.

Clinical implications

Based on our study findings; the Buzzy and bubble-blowing methods can be used to decrease pain and the negative responses of

children during painful procedures such as phlebotomy and vascular access. Nurses and other health care professionals in children's units could be taught in in-service trainings about the importance of pain relief and the effectiveness of easy-to-use and cost-effective methods such as bubble-blowing and the Buzzy. The effectiveness of these methods could be further supported with evidence-based studies of different painful procedures and in different age groups. Parents could be informed about non-pharmacological methods that are effective in children's pain management such as bubble-blowing.

Conclusion

A significant difference was found between intervention and control groups in terms of pain levels during and after phlebotomy in favor of the Buzzy group. There was a significant difference between the fear scores of the children in intervention and control groups before phlebotomy. This difference was found to be caused by the bubble-blowing method. There was a significant difference between the fear levels of the intervention and control groups in favor of the Buzzy group during phlebotomy.

Using the Buzzy, with its external cold-vibration stimulation, as well as the bubble-blowing method were both effective in relieving pain in children during phlebotomy. Although distraction techniques have long been seen as cost-effective for pain management in children, most methods are impractical or ineffective in children undergoing

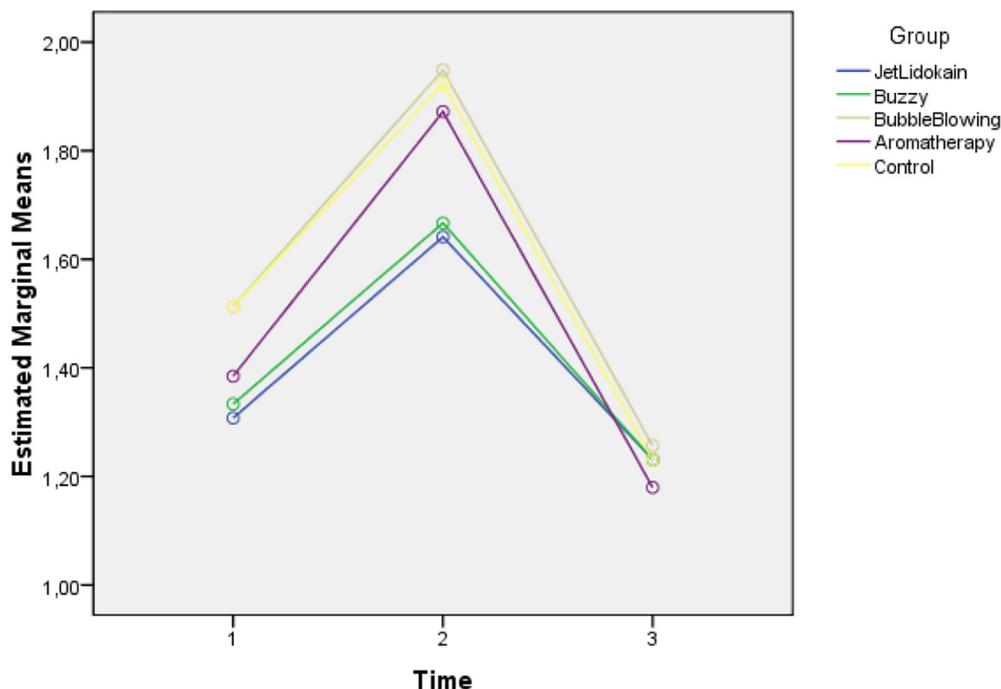


Fig. 4. PRCD scores.

phlebotomy. Therefore, it is recommended that the Buzzy and bubble-blowing be used routinely during phlebotomy in children to reduce the severity of their pain. However, further studies with bigger samples in different age and cultural groups are required to provide conclusive evidence.

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