

# Comparison of the Effectiveness of Buzzy, Distracting Cards and Balloon Inflating on Mitigating Pain and Anxiety During Venipuncture in a Pediatric Emergency Department

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**Abstract:** *Background* Painful medical procedures in childhood may have long-term negative effects on development and future tolerance of pain, evidence suggests that a significant number of children receive less than optimal management of procedure-related pain. *Objective* The present study aim to investigate the efficacy of three interventions methods (Buzzy, distracting cards and balloon inflating) on mitigating pain and anxiety associated with venipuncture in a group of pediatric patients. *Methods* A prospective randomized clinical trial with children who required venipuncture and aged 7 to 12 years was conducted in a pediatric ED. Data were obtained by conducting interviews with the children, their parents, and the observer. The pain levels of the children were assessed by the parent, observer as well as self-report using the Faces Pain Scale-Revised (FPS-R). The anxiety levels of children were assessed using Children Fear Scale (CFS). *Results* One hundred and eighty children (mean age,  $9.3 \pm 1.9$  years) were included. The pain levels of children showed statistically significant differences between the groups in the self-, observer- and parent-reported procedural pain ( $p = 0.012$ ,  $p = 0.036$ ,  $p = 0.014$  respectively). No significant differences were observed between the groups in procedural child anxiety levels according to the parents and observer ( $p = 0.42$ ,  $0.13$  respectively). *Conclusion* The results of the study suggests that the distraction method through Buzzy, distraction cards and balloon inflating are effectively decreased pain levels of children compared with the control group according to self-report, parent-report and observer-report.

**Keywords:** Buzzy, Distraction, Venipuncture, Children Pain, Anxiety

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## 1. Introduction

Pain perception in children is complex and children frequently undergo medical procedures that are applied using a needle, such as venipuncture and immunization which considered the most common sources of pain for children causes considerable stress and anxiety for children and their parents [1-4]. Venipuncture is one of the most widely used diagnostic and therapeutic procedures in pediatric patients. Analgesia during venipuncture may be efficiently achieved with distracting techniques [5]. The simple insertion of a needle has been shown to be one of the most frightening and distressing medical procedures for hospitalized children [6; 7]. Moreover, fear of pain experienced due to medical procedures in childhood usually continues up to

adulthood [8]. Although pain may be reduced by behavioral and pharmacologic interventions (e.g., age appropriate patient preparation, parental presence, distraction techniques, vapocoolant cold spray, vibration near the site, subcutaneous local anesthetics, topical anesthetic and systemic anesthetics) and there are data to support each of these individual treatments most of these preparations are impractical in nonelective settings because they are too time consuming and there is no single integrated intervention to optimize pain relief [9]. Furthermore, most current options require excessive cost, or staff training, which are formidable barriers to practice change [4].

Multiple different modalities exist to diminish the pain associated with venipuncture in pediatric patients, with a variety of associated costs and efficacies [10]. When used

appropriately; non-pharmacologic methods can be effective in dulling procedural pain. Non-pharmacologic methods used in children can be categorized in three main groups: supportive methods, cognitive/behavioral methods and physical methods [11-14]. Supportive methods comprise techniques, such as watching a video, reading a book, family's presence alongside the child during painful procedure; physical methods include touching, giving position, massage, skin stimulation, hot and cold pack application [11, 15]. In contrast, cognitive/behavioral methods are based on the premise that pain has a perceptual and behavioral dimension and are composed of relaxation and distraction methods [11, 13, 15-17].

Recent researches focusing on nurses' use of non-pharmacological methods for pain relief of children [8;18]. At present, the most widely used non-pharmacological method for pain relief of children during painful medical procedures is the distraction method. Distraction is a nursing attempt focusing patient's attention on any other stimulant so as to control and reduce pain better [3]. The rationale for the pain-reducing effects of distraction is the hypothesis that the brain has a limited capacity of focusing attention on stimulation [19]. If attention resources are diverted to focus on a distracting task, then little is left for attending to painful stimulation. It has also been suggested that distraction alters nociceptive responses by triggering an internal pain suppressing system [20]. Distraction method has been used in various ways including using Buzzy [21, 22], looking through kaleidoscopes [8], watching cartoon video [23] blowing bubbles [24], Distraction Cards [18; 8], listening to music [25] and ball squeezing [18; 17]. Cochrane review of the efficacy of various distraction methods for managing needle-related pain and distress in children indicates that distraction has a beneficial effect on self-reported pain [16]. Although a variety of distraction strategies have been studied, the study of the effects of distraction cards constitutes a new approach [3]. The current study will apply distraction through using distraction cards, balloon inflation and Buzzy. The Buzzy® is an inexpensive multiuse device generally well-accepted by patients and parents [26]. Buzzy®, is a rapidly vibrating plastic device shaped like a bee, with cooled wings. The body itself is multi-use and the wings (which are cooled in the freezer) can be purchased as multi-use or disposable. It operates on the theory of gate control and descending noxious inhibitory control, using vibration and cooling to decrease the perception of pain at the procedure site when placed 3-5 cm proximally 30-60 s prior to the procedure. Buzzy® has been shown in some studies to be superior to placebo and to vapocoolants and analgesic creams [6, 27, 3]. The visual distraction would reduce suffering and, at the same time, allow venipuncture to be performed in an emergency. The distraction diverts the stressful stimulus, and centering the patient on a pleasant stimulus [28]. The present study aims to investigate the efficacy of three interventions (Buzzy, distracting cards and balloon inflating) on mitigating pain and anxiety associated with venipuncture in a group of pediatric patients.

### *Significance of the study*

One of the most common painful procedures in pediatrics, including in Emergency, is venipuncture. The WHO and several Pediatric Societies advocate improving the approach to pain and anxiety in children in a medical environment [29]. In addition, nurses should be aware of the harmful effects of procedural pain and anxiety in children, use of distraction methods and have knowledge about different non-pharmacological methods that may reduce their impact. This study contributes to the literature on non-pharmacological pain relief methods.

## **2. Methodology**

### **2.1. Study Design**

The current study was a prospective randomized clinical trial that evaluated and compared the effects of distraction cards, using Buzzy and balloon inflating, on pain and anxiety levels in children during phlebotomy.

### **2.2. Setting and Participants**

The study population consisted of children aged 7–12 years who attended the emergency department in Pediatric hospital, in Zagazig city, Egypt and requiring venous access, either for blood analysis or to pass a catheter into a peripheral vein. The recruiting period was from June to August 2015 inclusive, on two fixed days per week. The sample is compromised of 180 pediatric patients who referred by the treating physician for venous access and met the selection criteria. Inclusion criteria were 7 to 12 years' old patients requiring blood tests or venous access, first needle stick during this admission, parent or primary caregiver presents at the time of needle stick and they are developmentally appropriate for age. Potential participants were excluded if they previously experienced with Buzzy, sedated, unconscious or have known chronic illness (i.e. sickle cell disease, diabetes, cystic fibrosis). All data were obtained by interviewing the children, their parents, and the observer before and after the procedure. The phlebotomy process took an average of three minutes.

### **2.3. Research Measures**

The data of current study were obtained using: the "Demographic and Basic Information Form", "Faces Pain Scale-Revised (FPS-R)" for measuring children level of pain, "Children Fear Scale (CFS)" for measuring children level of anxiety, and materials for intervention including "Buzzy", "distraction cards" and "balloons". Baseline information regarding participants' demographic data including age, sex, was obtained from medical staff reports. In addition, previous venipuncture (Yes or No; asking parents) if the child has had a venipuncture in the last three months, technique of venipuncture (venous access for blood extraction or for catheterization). Participants' reasons for admission to ED were retrieved from medical records and categorized as follows: trauma, respiratory, Fever, gastrointestinal or other.

### 2.3.1. Faces Pain Scale-Revised (FPS-R)

Children's self-reported pain levels were obtained using the Faces Pain Scale-Revised (FPS-R). The FPS-R is a 0- to 10-point scale consisting of 6 cartoon faces that range from a neutral expression (0, "very happy/no pain") to a crying face (10, "severe pain"). The FPS-R has been validated down to age 4 years, is cited in more than 140 studies, and is deemed by reviewers as a "well established measure" [30]. Children were asked to draw a circle around the face that could best represent the amount of pain they were experiencing, which is then numerically represented. The measurement was reported retrospectively, to prevent interruption of the distraction the child was allocated to receive.

### 2.3.2. Children Fear Scale (CFS)

CFS was used to evaluate the children's level of anxiety. CFS is a 0 to 4 scale, showing five cartoon faces that range from a neutral expression (0 = no anxiety) to a frightened face (4 = severe anxiety). Anxiety level for all children was evaluated using CFS by both parents and observer.

### 2.3.3. Vibration Instrument

The Buzzy device is a reusable, 3- inch by 2-inch, FDA Class I minimal risk plastic device that looks like a bumble bee and can provide both steady vibration and cold therapy simultaneously (<http://buzzy4shots.com>). This device has been found to be an effective treatment in reducing venipuncture pain in children [3, 6]. Buzzy® device, as a clinic tool for alleviating pain during vibration stimulus, allows for cold packs to be placed next to the skin. As hypothesized by the gate-control theory, vibration therapy interferes with pain receptors at the site of injection leading to a reduced perception of pain [31; 32]. Participating research assistants and nurses reviewed a brief instructional video on the device prior to conducting the data collection. The author offered the parent and child the opportunity to hold the device, turn on vibration, and practice application. Immediately before the first venous access attempt, the nurse applied the device 5 to 10 cm proximal to the dorsum of the hand site. If the IV insertion was not successful at the first attempt, the child was excluded from the study. Children were asked to concentrate on the sensations of the "BUZZY" rather than look at the needle insertion.

### 2.3.4. Distraction Cards

The distraction cards consisted of 5 x 8 cm visual cards with various pictures and shapes. The children were given the opportunity to examine the cards, and then the researcher asked the children about what they could see on the cards. Distraction with the cards began immediately prior to venipuncture and continued until the procedure had been completed.

### 2.3.5. Balloon Inflation

The children were asked for their choice of balloon color. They were asked to inflate the balloon once to assess the suitability of balloon inflation. They were given balloons after venipuncture started and asked to inflate it during the

application. Their parents were asked before the procedure about latex allergy condition and no case was detected,

### 2.3.6. Standard Care (Control Group)

The children in this group were allowed to keep their family nearby. The routine venipuncture procedure was applied and the level of pain resulting from the applied procedure in each child was assessed by the self-report as well as the parent and observer reports, using the Faces Pain Scale-Revised (FPS-R).

## 2.4. Procedure

Before the procedure, a pediatrician made clinical decision for phlebotomy, hospital policy followed for venipuncture procedure and pediatric nurses caring for the patient carried out the procedure. Children and their parents were informed about the purpose and content of the study by the researcher and the nurses involved in the study. Interested parents and children signed a consent form and children signed assent forms. Prior to randomization, the researcher explained the pain and anxiety measures and both parents and children indicated that they understood how to use the measures. Recruited children were assigned to one of four groups of study: vibration group was composed of children to whom the Buzzy was applied, Distraction cards, balloon inflating and standard care (control group). Participants then received the distraction intervention according to their group allocation. Unsuccessful 1<sup>st</sup> venipuncture attempted was withdrawn from the study. All groups were allowed to be held, soothed, comforted, and distracted by both the nurse and parent, as would have been normally done. All data were collected and recorded by participated nurses and research assistants.

## 2.5. Statistical Analysis

All statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL, USA) version 21.0 for Windows. Descriptive statistics were reported using both mean and SD. Statistical significance was set at  $p$  less than .05. Parametric data such as the level of pain in children was compared with one-way analysis of variance.

## 2.6. Ethical Considerations

The study was approved by the hospital's Institutional Review Board. The aim and method of study were explained to the children and their parents. Informed consent was obtained from the parents of each participated child and oral assent was also obtained from children of seven years and above. They were also notified that they could leave the study at any time without having to explain their reasons.

## 3. Results

For three months, 18,220 children were attended to the emergency department of one hospital. Of these, 2,159 (11.8%) received venipuncture, and 631 were aged between 7 and 12 years old, of whom 238 received venipuncture during

the recruiting days (two fixed days per week). Out of these, 201 children had inclusion criteria and a total of 180 of these were included in the study (12 were not included because of

parents did not consent and 9 due to protocol violations (i.e., pre-treatment scales were not completed) (figure 2).



Figure 1. The Buzzy and distraction cards.

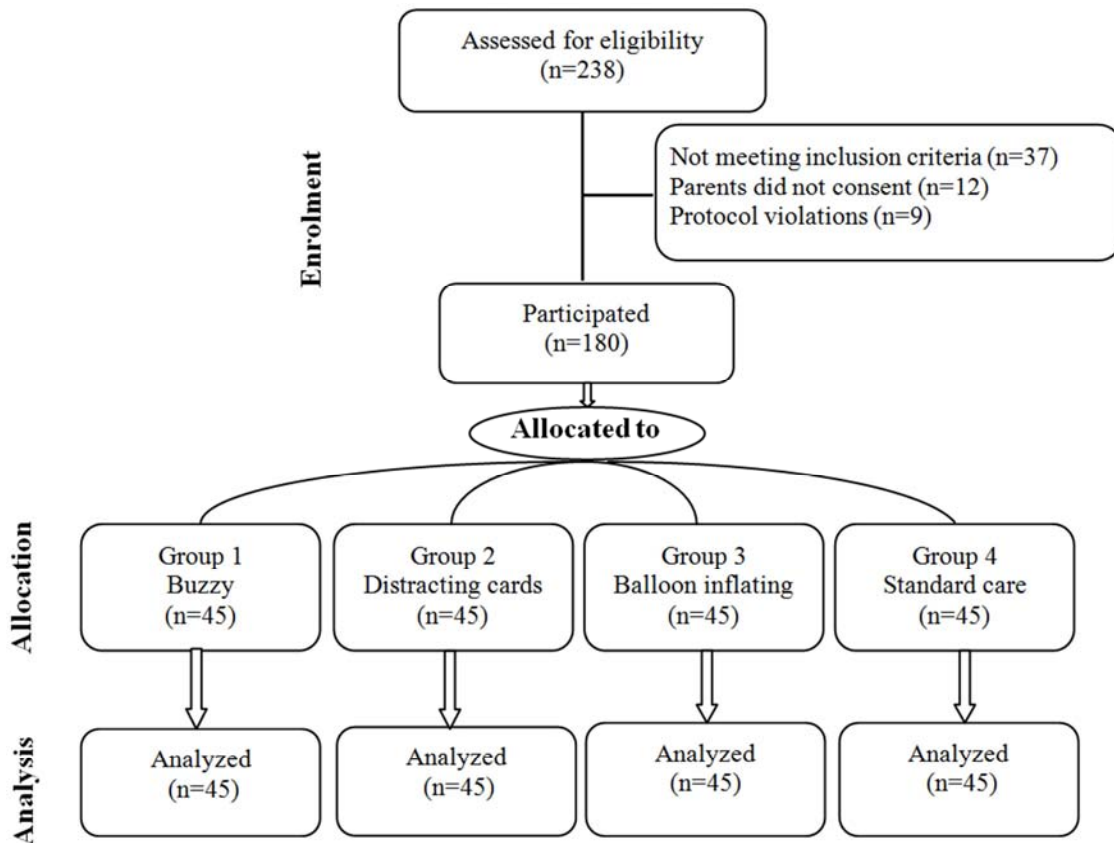


Figure 2. Diagram showing the flow of participants.

Participants' demographic and baseline clinical characteristics are reported in table 1. There were no statistically significant differences between the groups. The mean (SD) age was  $9.3 \pm 1.9$  years and 51.2% of the participants were female. Reasons for participants' admission to ED were divided into trauma (23.3%), respiratory (22.8%), fever (24.4), gastrointestinal (23.9%), and (5.6%) for other conditions. Most of children (86.1%) had no history for hospitalization and 77.8% of them did venous access for IV catheterization. Twenty-four percent of the participants had at least one previous IV cannulation.

Comparison of procedural pain scores among study groups was presented in table 2. The pain level was evaluated based on self-report, parent report and observer report. The pain levels of children showed statistically significant differences between the groups in the self-, observer- and parent-reported procedural pain ( $p = 0.012$ ,  $p = 0.036$ ,  $p = 0.014$  respectively). The Buzzy group had the lowest pain levels according to self-report ( $1.90 \pm 1.34$ ), parent report ( $1.37 \pm 1.70$ ) and observer -report ( $1.75 \pm 1.71$ ) among all groups.

*Table 1. Baseline characteristics of participating children (n=180).*

Variable	Buzzy group (n=45) n(%)	Distraction cards group (n=45) n(%)	Balloon inflating group (n=45)n(%)	Control group (n=45) n(%)	Total (n=180) n(%)	P-value
<b>Age (mean ± SD)</b>	8.9 ± 2.2	9.1 ± 2.1	9.9 ± 1.8	9.3 ± 1.2	9.3±1.9	0.14
<b>Gender n(%)</b>						
Male	21(46.7)	19(42.2)	23(51.1)	25(55.6)	88(48.8)	0.71
Female	24(53.3)	26(57.8)	22(48.9)	20(44.4)	92(51.2)	
<b>Causes to ED admission</b>						
Trauma	13(28.9)	14(31.1)	3 (6.7)	12(26.7)	42(23.3)	0.62
Respiratory	9 (20.0)	10(22.2)	12(26.7)	10(22.2)	41(22.8)	
Fever	12(26.7)	4(8.9)	15(33.3)	13(28.9)	44(24.4)	
Gastrointestinal	8(17.8)	17(37.8)	9(20.0)	9(20.0)	43(23.9)	
Other	3(6.7)	0(0)	6(13.3)	1(2.2)	10(5.6)	
<b>Site of venous access,</b>						
Hand	35(77.8)	40(88.9)	31(68.9)	32(80)	138(76.7)	0.43
Antecubital fossa	9(20.0)	3(6.7)	8(17.8)	6(13.3)	26(14.4)	
Forearm	1(2.2)	2(4.4)	6(13.3)	7(15.7)	16(8.9)	
Other	0(0)	0(0)	0(0)	0(0)	0(0)	
<b>Previous hospitalization</b>						
Yes	2(4.4)	10(22.2)	5(11.1)	8(17.8)	25(13.9)	0.61
No	43(95.6)	35(77.8)	40(88.9)	37(82.2)	155(86.1)	
<b>Type of venous access</b>						
Blood draw	13(28.9)	11(24.4)	6(13.3)	10(22.2)	40(22.2)	0.31
Cannulation	32(71.1)	34(75.6)	39(86.7)	35(77.8)	140(77.8)	
<b>Previous venipuncture (for last 3 months)</b>						
Yes	9(20.0)	14(31.1)	10(22.2)	11(24.4)	44(24.4)	0.12
No	36(80.0)	31(68.9)	35(77.8)	34(75.6)	136(75.6)	

*Table 2. Comparison of Procedural Pain Scores of Study Groups (n=180).*

Pain Intensity	Buzzy group(n=45)mean ±SD	Distraction cards group(n=45)mean ±SD	Balloon inflating group(n=45)mean ±SD	Control group(n=45)mean ±SD	F-value	P-value
*According to FPS-R						
Self-reported	1.90±1.34	3.17 ±2.13	2.83 ±1.41	4.15±1.29	5.061	0.012
Observer-reported	1.75 ±1.71	1.85 ±1.90	2.30±2.06	3.62 ±1.76	3.372	0.036
Parent-reported	1.37±1.70	2.17 ±1.47	2.53 ±2.71	4.78 ±1.50	6.822	0.014

\*FPS-R= Faces Pain Scale-Revised (FPS-R)

*Table 3. Procedural anxiety scores of the study groups (n=180).*

Procedural anxiety scores	Buzzy group(n=45)	Distraction cards group(n=45)	Balloon inflating group(n=45)	Control group(n=45)	F-value	P-value
*According to CFS						
Observer-reported	0.61±0.19	0.97 ± 1.64	1.19 ± 1.26	3.17± 1.91	1.534	0.13
Parent-reported	1.21±1.12	1.80 ±0.91	1.49 ±0.78	2.04± 1.28	1.174	0.42

\*CFS= Children Fear Scale

Table 3, presented the procedural anxiety levels among the study groups during phlebotomy. No statistically significant difference was found between the children's procedural anxiety levels reported by the observer and parent groups ( $p = 0.13$ ,  $p = 0.42$  respectively). Although the parent- and observer-reported anxiety levels were low in the Buzzy and distraction card groups, they were not found statistically significant. This situation was clinically significant rather than statistically significant.

## 4. Discussion

The American Society for Pain Management Nursing recommends that optimal pain control before and during painful procedures needs to be provided [33]. Making needle

pricks and venous access procedures as pain free as possible is an ethical obligation. Thus, finding an efficient and inexpensive device to decrease needle insertion pain is of paramount importance to health providers caring for children [21, 22]. The present study aim to investigate the efficacy of three interventions (Buzzy, distracting cards and balloon inflating) on mitigating pain and anxiety associated with venipuncture in a group of pediatric patients. There is strong evidence that distraction is a cost-effective technique in reducing pain and distress that children experience during needle procedures [11, 34, 35]. In spite of that, not every distraction methods are effective in reducing pediatric pain where in the recent study, Luthy et al. [36] compared the effects of distraction with DVD and a vapocoolant spray on pain and anxiety levels in children during vaccination and

they found that both methods did not decrease either pain or anxiety. In the current study, children, parents and nurses rated pain as significantly lower when the “BUZZY” was used. This is in line with four earlier studies [3, 6, 22, 37] and supports the use of this simple intervention to decrease the pain during an IV insertion.

Distraction with balloon inflating causes the child to draw his/her attention away from pain stimuli during a medical procedure. Therefore, as a distraction method, balloon inflating might be useful for reducing pain and anxiety during medical procedures. There are several studies in the literature which evaluated the effect of distraction with balloon inflating on pain control [13, 19, 38, 39].

The results of the study which conducted by Mutlu and Balci [13] showed that balloon inflation was effective in reducing pain during venous blood drawing in children, thus providing an effective technique during painful medical procedures. Different from the study of Sahiner and Bal [38] who found that balloon inflation significantly lowered procedural anxiety scores, in the present study, although anxiety levels in group of balloon inflation were lower than in the control group, no statistical significance was found. Even though the results of our study are different from those in the literature, balloon inflation is among the more interesting methods for school-age children [16,40]. In accordance with our results, Aydin et al. [18] recently studied the efficacy of ball squeezing, balloon inflating and distraction cards in decreasing pain and anxiety during venipuncture among school-age children (n=120). They found that these methods did not decrease anxiety. In the current study, the children in the four groups were similar in terms of the factors that might influence pain perception, such as age, sex, and causes to ED admission.

## 5. Limitations

This study has several limitations; On the one hand it is a study in a single center and with a limited number of children, in the other hand is not a blind study due to the characteristics of the intervention. The visual distraction that we used was short of cartoons selected previously by the researcher and may be if the cartoons were selected by the children, the distraction level could be higher. Further studies are needed to evaluate the pain and anxiety reducing effect of these methods for various interventional procedures.

## Competing Interests

The author declare that they have no competing interests

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