Using Buzzy, Shotblocker, and Bubble Blowing in a Pediatric Emergency Department to Reduce the Pain and Fear Caused by Intramuscular Injection: A Randomized Controlled Trial

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CE Earn Up to 5.5 Hours. See page 593.

Contribution to Emergency Nursing Practice

- The current literature on pain associated with intramuscular injection in pediatric patients indicates that several nonpharmalogic methods—including Buzzy, ShotBlocker, and bubble blowing—are effective in reducing pain and fear in the pediatric emergency department.
- This article contributes study results indicating that the Buzzy system helped reduce children's pain when undergoing intramuscular injection. Emergency nurses caring for children could receive in-service training about the significance of pain relief and the effectiveness of easily usable and cost-efficient methods.
- The key implication for emergency nursing practice found in this article is that nonpharmacologic pain management methods can be used to decrease pain and fear in children during painful procedures in emergency departments.

Abstract

Introduction: Procedural pain in general, and intramuscular (IM) injection pain in particular, is one of the most distressing and painful health care experiences for children. Pharmacologic and nonpharmacologic methods are used as forms of pain control for children undergoing acute painful interventions in emergency departments.

Methods: This study was a prospective, randomized controlled trial. The sample consisted of children aged 5 to 10 years old who required IM injections. Children were placed in 4 subgroups through randomization, using a computer program: the Buzzy (MMJ Labs. Atlanta, GA) group (n = 40), the ShotBlocker (Bionix Development Corporation, Toledo, OH) group (n = 40), the bubble-blowing group (n = 40), and the control group (n = 40). Immediately before and after the injection, the children, their parents, and an observer were asked to evaluate the child's level of fear. The Oucher scale was also employed by the observers, children, and parents immediately after the procedure to assess the level of pain in the children in each group.

Results: No statistically significant difference was determined between the control and intervention groups in terms gender, age, previous pain experienced with injection, the parent who was with the child, the parent's age. A significant difference was found between the intervention and control groups in terms of levels of pain and fear during IM injection. Pain and fear were notably less in the group of children receiving the Buzzy intervention.

Discussion: The Buzzy intervention should be used when children are undergoing IM injections to reduce their levels of pain and fear.

Key words: Buzzy; ShotBlocker; Bubble blowing; Intramuscular injection; Pain and fear; Pediatric emergency department

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Introduction

Pediatric patients in the emergency department often require unforeseen procedures leading to pain, distress, and anxiety.[1] Routine ED procedures include intravenous (IV) insertions, central venous port access, urethral or angiocatheter insertions, and intramuscular (IM) or subcutaneous injections.[2] IM injections are a routine, painful, but common part of many pediatric ED visits.[3]

In 2001, the American Academy of Pediatrics and the American Pain Society released a joint policy statement about pediatric pain. It recognized that children's pain is often inadequately assessed and set out proposals to minimize pediatric procedural pain.[4] The reasons for pediatric oligoanalgesia were said to result from a general lack of understanding of pediatric pain, time restrictions in busy emergency departments or offices, an unawareness of children's developmental stages and their relationship to pain, and worries about the use of prophylactic or therapeutic pharmacologic treatments for children.[4,5] Many articles have been published about various pharmacologic and nonpharmacologic methods of reducing IM injection pain. Research on this topic has examined procedures that might have the potential to limit pain caused by IM injection.[3,6-15] Nonpharmacologic techniques that have been found to have an effect in decreasing acute pain have included distraction, guided imagery, hypnosis, and cognitive behavioral therapy.[16-18] Distraction is frequently used by both parents and health care professionals to limit the experience of procedural pain. Distraction works on the basis of the belief that by moving a child's focus onto something attractive and engaging, their capacity to pay attention to painful stimuli is reduced, thereby alleviating pain, distress, or anxiety.[19] Within the field of pediatrics, distraction techniques have often been defined as cognitive and behavioral strategies employed to draw a child's focus away from distressing stimuli.[20]

Auditory or visual distractions (e.g., touching, singing, reading, playing games, blowing bubbles, or vibration or massage[17,21,22]) have shown to be effective over many years, both in helping children to cope with medical procedures and also to limit and diminish memories of the treatment.[23] The use of vibration involves 2 cortical areas that register perceptions of touch and pain.[24] The vibration activates analgesic mechanisms that reduce pain.[25] It has been suggested that an important aspect of vibrotactile analgesia is linked to A-β-mediated afferent inhibition of dorsal horn nociceptive neurons.[26] One specific device that can assist health care staff in distracting patients is the Buzzy system (MMJ Labs, Atlanta, GA), which is widely available. Buzzy is a small plastic instrument, consisting of an ice pack and a vibrating motor. It is fitted to the child's arm immediately above the administration site by using a velcro strap. The ice and the vibration function jointly to distract the child from the insertion of the needle and any subsequent pain by overloading the nerve endings with cold and vibration; these affect the pain receptors.[27] Studies have demonstrated that the device mitigates the pain related to IV insertion, IM injection, phlebotomy, and venipunctures, as well as improving the child's cooperation.[6,7,23,25,28-31] The Buzzy is cost effective and can be easily reused if properly cleaned for each new patient.[27]

Interventions should ideally be relatively noninvasive and have the ability to be administered rapidly to improve pain control. One device that is not yet approved by the Food and Drug Administration, but is undergoing testing, is the ShotBlocker (Bionix Development Corporation, Toledo, OH), a drug-free plastic device that is placed directly on the skin before the injection. It does not require any preparation or waiting time and has no known side effects. The device has several short blunt contact points that are pressed directly onto the skin before the injection; there is hole in the center where the injection is administered. The contact points do not puncture the skin and provide the stimulus for the gate theory, a pain pathway postulated by Melzack and Wall.[32] They suggested that both small- and large-diameter peripheral nerve fibers conduct pressure and pain stimuli to the central nervous system, where a gate mechanism then modulates the pain signal.[32,33] The ShotBlocker's postulated mechanism of action is that applying pressure to the skin excites the faster, smaller-diameter fibers. This stimulation shuts the gates to the central nervous system, putting a temporary block to the slower pain signals of the injection. Theoretically, this easy-to-use, noninvasive device should reduce the pain linked to IM injections. The ShotBlocker has been shown to be effective at decreasing the pain in IM injections and vaccinations in preschool children[3,12] but was not found to have an effect on acute pain in immunization in another study.[34]

Methods used to decrease fear and pain during the administration of IM injections should be inexpensive, reusable, widely available, easily cleanable, and easy for both adults and children to tolerate. There have been no previous studies comparing the effectiveness of the Buzzy, ShotBlocker, and bubble blowing in reducing pain during IM injections.

Methods

This study was a prospective randomized clinical trial that evaluated and compared 3 nonpharmacologic methods to reduce pain of IM injection on pediatric patients (5 to 10 years of age) in the pediatric emergency department of a hospital.

SETTING AND SAMPLE

A randomized controlled trial was conducted to compare Buzzy (the combination of cold and vibration), ShotBlocker (a small, flexible, drug-free plastic device), bubble-blowing techniques, and no intervention in ameliorating children's fear and pain when undergoing IM injections in the pediatric emergency department of a hospital. The study sample comprised children aged 5 to 10 years who were undergoing intramuscular injection and their parents. G*Power (v3.1.9.2) was deployed to determine the sample number. According to Cohen's effect size coefficients, the approximate number of subjects was calculated as 40 for each group with a Type 1 error probability (significance level) of .05, 80% power for bivariate tests (Type II error probability of 20%). Children were placed in 4 subgroups through randomization carried out using a computer program: Group 1 was the control group, consisting of children receiving no pain relief intervention (n = 40); in group 2, a plastic ShotBlocker was used when they were being injected (n = 40); group 3 children were distracted with bubble blowing during the injection (n = 40), and group 4 children were given external thermomechanical stimulation (Buzzy) (n = 40) (Figure 1).

Inclusion criteria included children 5 to 10 years of age who were patients in a pediatric emergency department receiving IM injections. In addition, it was necessary that children be accompanied by parents or family members. Patients were excluded from the study if they had been given local anesthetics, if there was pathology or skin infection at the site of injection, if they had diseases or significant traumas requiring immediate evaluation (Glasgow Coma Scale [GCS] score < 15 and/or being hemodynamically unstable), showed signs of developmental delay, had chronic illnesses (eg, asthma, allergy, dermatitis, diabetes, sickle cell disease, cystic fibrosis), if they had altered sensorium or neurosensory deficit at the site of injection, or if developmental delay prevented the pain scale from being completed.

INSTRUMENTS

The instruments used in this study included interview forms, procedural fear (Children's Fear Scale [CFS]), and pain (Oucher) scores.

Interview Form

This form consisted of questions about the sociodemographic characteristics of the child and his or her previous IM injection history. Ten questions were developed by the researchers, based on the literature. Information was obtained from the children and parents, using this form in face-to-face interviews and through observations. The form took approximately 5 minutes (mean time) to fill in.

FIGURE 1

© Buzzy. Figure reprinted with permission.

Children's Fear Scale

Fear of the procedure was evaluated using the CFS. This is a valid and reliable tool for assessing procedural fear in children between 5 and 10 years of age.[35] The CFS consists of illustrations of 5 faces, which are distributed horizontally and evenly. A different degree of fear is represented by each face, with the face to the far left—which has an expression of no fear according to the scale's creators—receiving a mark of 0, and the face on the far right—showing the most serious degree of fear—receiving a mark of 4. Participants reported their degree of fear themselves by making a mark on the horizontal axis. Before the injection, the children were informed how the scale would be used. After confirming that they understood, they were asked to state how scared they were.[35] The CFS has demonstrated 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, when used with children.[35] Cronbach's coefficient alphas ranged from r = 0.70 to 0.83 in this study.

Oucher Scale

The children's perception of their pain was evaluated with the Oucher scale. This a self-reported scale measuring the intensity of pain of children between 3 and 12 years of age and is composed of 2 distinct scales.[36] One scale has a

series of 6 photographs of a child in varying degrees of distress and is to be used for children who are unable to count. In this study, seriation screening items were used to determine the appropriate scale for each subject. Children able to determine the bigger of 2 numbers used the vertical numeric scale (0 to 10) printed next to the images of the faces. The range of scores is 0 to 10 for both scales. Discriminate validity was demonstrated by investigating the relationships between the Oucher and the 2 fear scales for children. The internal consistency (Cronbach's coefficient alphas) was in the range of r = 0.52 to 0.98.[36] Cronbach's coefficient alphas ranged from r = 0.69 to 0.76 in this study.

STUDY PROCEDURES

Block randomization was conducted using the web-based program, Research Randomizer.[37] Sequentially numbered envelopes were prepared before the study began. These were placed in a basket, and the children were asked to select 1 envelope. After informed consent had been obtained, the envelope was opened, and the child was assigned to either the intervention or control group. An interview form was completed by the researcher immediately after the randomization of each child. After the form was filled in, IM injections were administered by 2 trained ED nurses who followed a specifically determined procedure. All injections were completed with a 25-gauge 5/8-inch needle. The nurses were asked to cleanse the area, rubbing gently with an alcohol pad, and not to pinch or rub it before or during the injection.

Immediately before and after injections, the children, their parents, and an observer were asked to evaluate the child's level of fear using the CSF. Pain was assessed using the Oucher scale by the observers, children, and parents immediately after the procedure. While both scales were being administered, care was taken that children, parents, and observers did not see each other's assessments and were not mutually affected. Both scales were given to all children in both groups at the same time using the same method (face-to-face interview). Neither the children, the parents, nor the observers were blinded.

ShotBlocker Group

The ShotBlocker[38] is a small, flexible, drug-free plastic device with several short, blunt skin contact points on the bottom, and a hole in the center through which injections can be administered. It is positioned onto the skin before an injection is made. The nurses were instructed to position the ShotBlocker and ensure that the contact points touched the patient's skin. They were then told to press down firmly and give the injection through the central hole. If more than 30 seconds passed between the ShotBlocker being put in place and the injection being administered, the preparation had to begin again from the start. If nurses deviated from the protocol, the procedure was immediately restarted.

Buzzy Group

The Buzzy[39] is a reusable device that deploys vibration and cold together and is secured in place using a tourniquet near the site of an injection or venipuncture to reduce the feeling of pain (Figure 1*)*. The Buzzy looks like a handheld, 8 × 5 × 2.5-cm plastic bee with a battery-operated vibrating motor and a mechanism to affix an ice pack underneath it. It is placed 3 to 5 cm above the injection area immediately before the IM injection. It requires that there be sufficient contact with the patient's skin. The cold pack is kept in a freezer and is placed on the device just before use. The cold pack is applied, and the vibrations start 30 seconds before the procedure and continue until it ends. Before being used on another patient, the device was thoroughly cleaned using 70% alcohol. The researcher applied this method to each child in the group.

Bubble-Blowing Group

In this group, the children blew bubbles using a toy containing soapy liquid. This toy produces soap bubbles when someone blows into a part of the apparatus. It was used as a way of distracting children by making them take a deep breath, blow out, and produce soap bubbles while the IM injection was being administered. The researcher applied this method to each child in the group.

Control Group

In this group, a standard IM injection procedure was performed; the children were only told about the injection. No other intervention was given to any of the children in this group, either before, during, or after the IM injection.

ETHICAL CONSIDERATIONS

Permission for the study was obtained from the Ağrı İbrahim Çeçen University Ethics Committee (95531838-050.99/55) via the ethical consent form. The children and their parents were informed about the objective and the method of the study, and it was explained that if they did not wish to be involved, they could withdraw at any time

without stating a reason. Informed written consent including the primary investigator's conflict of interest was obtained from parents; written assent was obtained for patients older than 7 years of age. Participants were assured that the information they provided would remain confidential and not be used for any other purpose. The study fully met all the necessary ethical principles of informed consent, voluntariness, and the protection of the privacy and individual rights of human subjects.

DATA ANALYSIS

Statistical analysis was carried out using the SPSS Statistics software for MS Windows XP (Version 21.0, SPSS Inc., IBM, Chicago, IL). The Shapiro-Wilk test was used to assess whether the data values conformed to normal distribution. The demographic and clinical characteristics of the participants were described using frequency distributions for categorical variables and means/standard deviations for continuous variables. Comparisons of pediatric procedural fear (CFS scores) and pain (Oucher score) for the 4 groups were conducted using analysis of variance (1-way analysis of variance [ANOVA]), and the *post hoc* advanced analysis Bonferroni test for binary comparisons were used for the statistical analyses.

Results

COMPARISON OF THE GROUPS BY SELECTED VARIABLES

Included in the study were 160 children (81 [50.6%] girls and 79 [49.4 %] boys). The mean age of the children was 7.05 ± 1.49 years (range: 5 to 10 years). No statistically significant difference was determined between the control and intervention groups in terms of gender, age, body mass index, previous pain with injection, the parent who was with the child, or the parent's age. There were no significant differences among the study groups immediately before the procedure in terms of self-, parent-, and observer-reported fear (Table 1).

COMPARISON OF PROCEDURAL OUCHER SCORES OF THE CONTROL AND INTERVENTION GROUPS

ANOVA showed a difference among the groups with regard to the children's procedural pain levels with the IM injection. The pain levels in the Buzzy group were significantly lower than the other groups (ShotBlocker, bubble-blowing and control; $P < .05$), whereas the scores in the ShotBlocker and bubble-blowing groups were also lower than the control group (Table 2).

TABLE 1
Comparison of descriptive characteristics of the control and intervention groups (N = 160)

Variables	ShotBlocker group (n = 40)	Buzzy group (n = 40)	Bubble-blowing group (n = 40)	Control group (n = 40)	Difference	P value
Gender, n(%)						
Girl	21 (52.5)	20 (50.0)	18 (45.0)	23 (57.5)	$\chi^2 = 0.729$	0.220
Boy	19 (47.5)	20 (50.0)	22 (55.0)	17 (42.5)		
Age, mean ± SD	7.02 ± 1.77	7.32 ± 1.36	6.95 ± 1.36	7.00 ± 1.45	F = 0.64	0.635
BMI, mean ± SD	19.27 ± 2.36	20.05 ± 2.30	19.22 ± 2.49	19.52 ± 2.70	F = 1.341	0.257
Previous pain with injection (5-point Likert-type scale), mean ± SD	4.02 ± 1.17	4.32 ± 1.16	4.15 ± 1.06	4.20 ± 1.41	F = 5.44	0.358
The parent next to the child, n(%)						
Mother	27 (67.5)	19 (47.5)	24 (60.0)	27 (67.5)	$\chi^2 = 3.643$	0.854
Father	13 (32.5)	21 (52.5)	16 (40.0)	13 (32.5)		
Parent age (y), mean ± SD	35.5 ± 5.31	37.3 ± 5.16	36.1 ± 5.02	34.8 ± 5.12	F = 3.41	0.578
Preprocedural fear scores, n(%)						
Self-reported	1.90 (1.02)	1.88 (1.09)	1.95 (1.14)	1.92 (1.16)	F = 1.435	0.084
Parent-reported	1.93 (1.09)	1.96 (1.05)	2.03 (1.11)	1.95 (1.10)	F= 2.325	0.121
Observer-reported	1.91 (1.06)	1.89 (1.02)	2.01 (1.15)	2.01 (1.09)	F = 2.184	0.261

BMI, body mass index; *SD*, standard deviation.

TABLE 2
Comparison of procedural pain scores between the control and intervention groups

Procedural pain scores according to Oucher	GROUPS				F	P	Paired comparisons†					
	ShotBlocker group 1 (n = 40) Mean (SD)	Buzzy group 2 (n = 40) Mean (SD)	Bubble-Blowing group 3 (n = 40) Mean (SD)	Control group 4 (n = 40) Mean (SD)			1-2	1-3	1-4	2-3	2-4	3-4
Self-reported	4.14 (2.12)	3.87 (1.79)	4.75 (1.74)	6.72 (2.16)	1.54	.02	-	-	*	*	*	*
Parent-reported	4.51 (3.49)	3.18 (2.85)	5.65 (3.26)	6.85 (2.64)	3.63	.03	*	-	*	*	*	*
Observer-reported	4.23 (3.56)	3.09 (3.08)	5.13 (3.15)	6.30 (4.09)	6.21	.01	*	-	*	*	*	*

SD = standard deviation.
* $P < .05$
† Significance levels for Bonferoni test comparing ShotBlocker–Buzzy (1-2), ShotBlocker–Bubble-Blowing (1-3), ShotBlocker–Control (1-4), Buzzy–Bubble-Blowing (2-3), Buzzy–Control (2-4) and Bubble-Blowing–Control (3-4) paired comparisons.

COMPARISON OF PROCEDURAL CFS SCORES OF THE CONTROL AND INTERVENTION GROUPS

As a result of ANOVA, a difference was determined between the groups with regard to the children's procedural fear levels during the IM injection. The fear levels in the Buzzy group were significantly lower than the other groups (ShotBlocker, bubble-blowing and control; $P < .05$), whereas the scores in the ShotBlocker and bubble-blowing groups were also lower than the control group (Table 3).

Discussion

This study investigated and compared the effects of using the Buzzy, ShotBlocker, and bubble blowing for the relief of pain and fear in children experiencing the IM injection in a pediatric emergency department. The children who participated in the study were divided into 4 groups. This research found no statistically significant difference between children in terms of age, gender, body mass index, and preprocedure fear (Table 1). These results suggest that the groups were similar in terms of the demographic variables that may have affected their perception of pain.

In this study, the mean fear and pain scores given by the children, parents, and observer during IM injections were significantly lower in the Buzzy group than in the other groups. There are no previous studies in the literature comparing the use of the Buzzy, ShotBlocker, and bubble blowing for pediatric relief of pain and fear during IM injection. However, more research is being conducted using Buzzy and ShotBlocker in reducing pain in procedures applied to children in the literature. Buzzy is known to be effective in reducing pain during IM injections, IV catheterization,[29] immunization,[6,7] and blood sampling.[30,40,41] The findings of the present study are similar to the literature. Drago et al[3] evaluated the effect of ShotBlocker on pain levels in

TABLE 3
Comparison of procedural fear scores between the control and intervention groups

Procedural fear scores according to CFS	GROUPS				F	P	Paired comparisons†					
	ShotBlocker group 1 (n = 40) Mean (SD)	Buzzy group 2 (n = 40) Mean (SD)	Bubble-Blowing group 3 (n = 40) Mean (SD)	Control group 4 (n=40) Mean (SD)			1-2	1-3	1-4	2-3	2-4	3-4
Self-reported	1.66 (0.53)	1.35 (0.60)	1.88 (0.61)	2.82 (0.66)	4.56	.02	*	-	*	*	*	*
Parent-reported	1.65 (0.44)	1.38 (0.56)	1.93 (0.53)	2.85 (0.74)	6.54	.01	*	-	*	*	*	*
Observer-reported	1.57 (0.53)	1.39 (0.49)	1.74 (0.57)	2.60 (0.70)	7.3	.03	*	-	*	*	*	*

SD = standard deviation.
* $P < .05$
† Significance levels for Bonferoni test comparing ShotBlocker–Buzzy (1-2), ShotBlocker–Bubble-Blowing (1-3), ShotBlocker–Control (1-4), Buzzy–Bubble-Blowing (2-3), Buzzy–Control (2-4) and Bubble-Blowing–Control (3-4) paired comparisons.

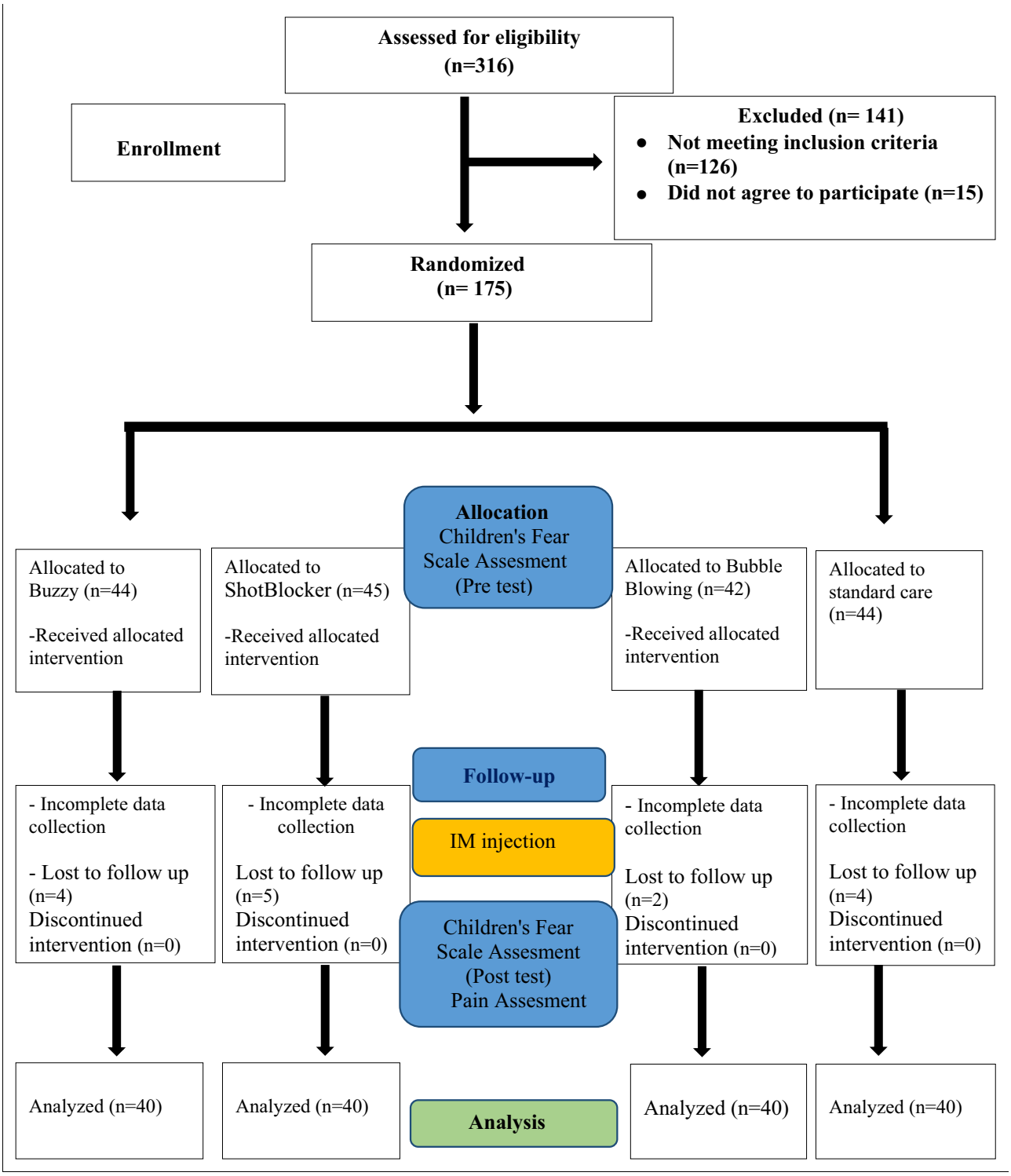

FIGURE 2
CONSORT diagram showing the flow of participants (study enrollment, randomization, and procedures).

children undergoing IM njections and found that this method was effective at reducing pain. In a study of 119 preschool children, those children who were given ShotBlocker during IM injections had significantly less pain compared with the control group.[12] In their study, Gundrum et al[11] reported that ShotBlocker was effective in alleviating acute pain in children who received IM vaccination. However, Cobb and Cohen[34] and Mennuti-Washburn[42] reported that ShotBlocker was not effective in alleviating acute pain in children. These conflicting findings may reflect the different age groups of the children evaluated, as well as the different settings, and further investigation is warranted.

Another parameter assessed in the study was fear. There was a significant difference among the children's, parents', and observers' fear-scale scores after the procedure ($P < 0.05$). The Buzzy, ShotBlocker, and bubble-blowing groups had lower fear scores (parent, child, observer) than the control group. The lowest fear was found with children in the Buzzy group. Tork's[40] study of Buzzy drew attention in another direction; balloon inflating for reducing pain and anxiety during blood sampling revealed that the Buzzy group had the lowest pain scores, but there was no difference among the groups in anxiety scores. Redfern et al[6] and Canbulat et al[7] concluded that the effect of Buzzy on the reduction of anxiety in children undergoing immunization had been established, and its routine use was suggested. Nevertheless, it has been determined that Buzzy does not reduce preprocedural anxiety. The findings of the current study are similar to the literature.

Limitations

This study has a number of limitations. First, neither the observers, the children, nor the parents were blinded to the intervention; this may have caused bias in children, observer, and parent assessments. Children may also have had different responses to pain as a result of their physical conditions, emotional states, socioeconomic status, and cultural backgrounds.

Another limitation of the study is the lack of application to the randomized controlled trial registration system, although the ethical approval from the clinical research ethics committee was received before conducting the study. Moreover, 15 children and parents were excluded from the study, as they did not want to evaluate the fear and pain scales after IM injection (Figure 2, incomplete data collection). Although they initially accepted to participate in the study voluntarily, they withdrew from the study because they did not want to devote their time to the re-evaluation of the intervention. These children were not included in the data analysis.

Implications for Emergency Nurses

The Buzzy and ShotBlocker methods can be used to decrease children's pain and fear to painful procedures, such as IM injection, in pediatric emergency departments. Nurses must clarify misconceptions and unsubstantiated fears held by uninformed health care providers. Education of all health care providers is the first step to reducing pain in pediatric patients. Hospital policies should advocate a multidisciplinary approach with the use of pharmacologic and nonpharmacologic methods, combined with quality assurance procedures, to improve management of pediatric pain. Nurses and other health care professionals responsible for children could be taught about the importance of pain relief during in-service training and informed about the effectiveness of easy-to-use and cost-efficient devices such as Buzzy and ShotBlocker. The usefulness of these methods could be demonstrated further in studies of other painful procedures and with different age groups. Parents could be given better information about nonpharmacologic methods that assist in managing children's pain. Management of pain in pediatric patients is both a moral and ethical obligation for health care providers. Nurses should be aware of pain during IM injections and use a method for pain relief accordingly. Nurses need effective pain relief methods that are easily applicable and do not take much time.

Conclusions

The Buzzy method should be used when children are undergoing IM injections to reduce their levels of pain and fear. In addition, using ShotBlocker during the IM injection was found to be less effective than Buzzy; however, they had less pain and fear than the children in the bubble-blowing and control groups. It is recommended that both Buzzy and ShotBlocker be used routinely with children who are undergoing IM injections to decrease the severity of their pain. However, additional studies with larger sample sizes targeting children with developmental delay, different ages, and various cultural groups are necessary for conclusive evidence to be produced.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

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