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The Effect on Pain of Buzzy® and ShotBlocker® during the Administration of Intramuscular Injections to Children: A Randomized Controlled Trial

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Purpose: To investigate the effect of Buzzy® and ShotBlocker® on reducing pain induced by intramuscular penicillin injections in children. **Methods:** This was a randomized controlled study. A total of 150 Turkish children aged 7~12 years who presented to our pediatric emergency clinic and met the inclusion criteria were recruited. The children were randomly assigned to each group (control=50, Buzzy®=50, ShotBlocker®=50). Data were collected using an information form, the State-Trait Anxiety Inventory for Children, Visual Analog Scale, and Faces Pain Scale-Revised. **Results:** The children in the control group had significantly higher pain scores during the penicillin injection than the children in the ShotBlocker® and Buzzy® groups. The children in the Buzzy® group had significantly less pain than the children in both the ShotBlocker® and control groups (p<.001). **Conclusion:** Buzzy® was more effective compared with ShotBlocker® in this study.

Key words: Pain; Child; Cold Temperature; Vibration; Intramuscular Injection

INTRODUCTION

Pain is defined as an unpleasant emotional and sensorial feeling that arises from any part of the body, progresses with possible tissue damage, and overlays all past experiences of individuals [1]. Pain can be felt after surgical operations and also during intramuscular (IM) injections. As an important part of parenteral therapy, the administration of IM injections is a common nursing function, and these are frequently used in clinical practice. Even though IM injections are considered a simple technique, they can cause very serious complications if inappropriately administered. It is reported that the majority of these complications are caused by lack of knowledge and the use of inappropriate techniques [2]. During procedures such as IM injections, which cause pain and discomfort in children, timely and efficient pain management increases the tolerance against pain in future administrations [3,4]. Thus, healthcare professionals who administer injections have important responsibilities.

Pharmacologic and non-pharmacologic methods are used for pain management in children. Non-pharmacologic methods are non-invasive and inexpensive methods with no adverse effects and are included among the independent functions of nurses [4]. When selecting the non-pharmacologic methods, it is required to consider a child's age, cognitive competence, culture, behavioral factors, coping skills, personal differences, and pain type [1,5]. Buzzy® and ShotBlocker® have been reported to be two effective

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devices in reducing pain. Buzzy® is a vibrating device with an optional ice pack. It decreases the perception of pain through local skin stimulation using the effect of cold and vibration [3,6]. ShotBlocker® is a small, flat, yellow, horseshoe-shaped plastic tool that is non-invasive. It decreases the perception of pain by applying pressure on the skin via its points, temporarily blocking the pain signals [3,6,7].

These simple and easily applicable devices which are effective in reducing the pain, will be used by health professionals to prove their effectiveness in different invasive applications and to determine their superiority against each other. Determining the effectiveness and interdependence of these methods will contribute to reducing the problems related with painful applications for children, their families, and health professionals.

METHODS

1. Purpose

The aim of this randomized controlled study was to evaluate two methods (Buzzy® and ShotBlocker®) used to reduce pain during IM injections in children.

2. Participants

The study was conducted in children aged 7~12 years who presented to the Pediatric Emergency Clinic for an IM injection of procaine penicillin between September 2014 and February 2015. The exclusion criteria were as follows: presence of a disease causing chronic pain, neurodevelopmental disorders, analgesics use within the last 6 hours (expert opinion was received), history of fainting during injection, and learning disabilities.

Power analysis was performed using the Power (v3.1.7) program to determine the sample size in the study. Accordingly, in the calculation made with an error margin of alpha 1.0% and power of 99.0%, it was predicted that at least 48 patients were required in the groups. When it was considered that patient losses could occur, the number of patients was increased to 50 children for each group. In order to determine which child would be assigned to which group, numbers from 1 to 150 were divided randomly into 3 groups using a computer-based program without number repetition. Thus, the sample consisted of 150 children (*Buzzy®=50; ShotBlocker®=50; control=50*); none of the children rejected participation in the study between the aforementioned dates.

1) Research hypotheses

(1) Hypothesis 0 (H^0): There is no difference in the pain levels between children who received Buzzy® and ShotBlocker® and children who did not receive any intervention to relieve pain during the IM penicillin injection.

(2) Hypothesis 1 (H^1): Children who received Buzzy® during the penicillin injection had less pain than the children who did not receive a pain-relieving intervention.

(3) Hypothesis 2 (H^2): Children who received ShotBlocker® when undergoing a penicillin injection had less pain than the children who did not receive a pain-relieving intervention.

(4) Hypothesis 3 (H^3): Children who received Buzzy® during the penicillin injection had less pain than the children who received ShotBlocker®.

3. Measures

In the study, we used an information form that included a total of 9 questions about the descriptive characteristics of the children and their families (parents' educational level, age, sex) and the injection procedure (past and present experience), the State-Trait Anxiety Inventory for Children (STAIC) to determine the anxiety of the children, and the Visual Analog Scale (VAS) and Faces Pain Scale-Revised (FPS-R) to evaluate the pain.

1) State-trait anxiety inventory for children

The STAIC was developed by Spielberger et al. to measure the anxiety levels of children aged 9~12 years and was adapted into Turkish by Ozusta in 1995 when its validity and reliability was studied. The inventory is a 3-point Likert scale that consists of 20 items aimed at evaluating the emotions related with anxiety-like tension, irritability, and unrest. The highest possible score in the inventory is 60, and the lowest score is 20. High scores signify a high level of anxiety, whereas low scores indicate low levels of anxiety [8]. Approval was received from Ozusta before the study in order to administer the inventory in children aged 7~8 years and the reliability value was determined as α=.83 for children aged 7~12 years.

2) Pain measures

VAS comprises a 10-cm line (0~10 cm or 0~100 mm). Zero signifies "no pain" and 10 signifies "worst pain". Children are asked to mark the point that signified the severity of their pain. VAS is described as easily comprehensible and applicable for children aged 7 years and over. Its validity and reliability have been proven [4,9]. In the present study, VAS was used to evaluate the children's pain in the 1st and 5th minutes after the procedure.

FPS-R consists of six facial expressions rated from 0 to 10 according to the presence and level of pain. This scale is based on a valid and reliable personal expression in children during painful situations. In school-aged children (aged 4~12 years), the FPS-R is felt to be the most valid and reliable measure of acute pain because an understanding of words or numeric values is not needed [4,10]. In the study, FPS-R was used to evaluate the children's pain in the 1st and 5th minutes after the procedure.

ShotBlocker® is a small, flat, yellow, horseshoe-shaped plastic tool that is non-invasive, appropriate for every age group, and does not have the characteristics of a medication or adverse effects (Figure 1). ShotBlocker® has short, blunt points that provide contact with the skin on one side, and a hole that exposes the injection site in the middle of the tool. It is used by being held on the skin surface during injection. The pointed surface of the tool is placed on the administration area immediately before the injection [7]. The points on its surface do not penetrate the skin, but cause stimulation as per the gate control theory of Melzack and Wall, which is thought to exist in relation to pain. The suggested mechanism of action of ShotBlocker® is that the pressure applied by the points of the tool stimulates the faster nerve endings of smaller diameter. This stimulation temporarily blocks the pain signals during the injection and reduces the pain by closing the gates to the central nervous system [11,12].

Buzzy® was developed by a pediatrician, Dr. Amy Baxter, and is an 8×5×2.5 cm device with a plastic battery and a vibration motor that is non-invasive and used for pain control in adults and children (Figure 2). A cold ice pack is placed under Buzzy®. It is placed 3~5 cm above the injection site for 15~30 sec (in this study, we waited for 60 sec and kept it in place during the injection with the approval of the device developer because a painful penicillin injection was administered) before and during the procedure, making local cold application and vibrations. One should be sure about the definite contact of Buzzy® with the skin. The ice pack is kept in a deep freezer and placed in the device before the procedure. After the procedure is completed, the ice pack is wiped with 70.0% alcohol, and kept and chilled again in the deep freezer.

Cold application and vibration start before the procedure and

Figure 2. Buzzy®.

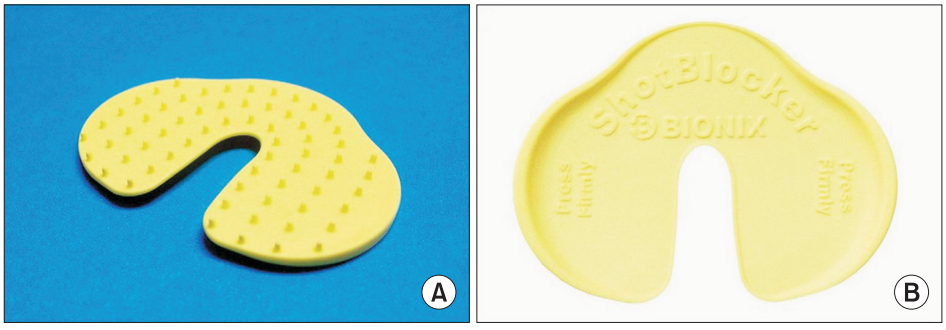

Figure 1. ShotBlocker®.

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continue until the end of the procedure. When vibration is applied, it reduces or relieves the pain by causing numbness, paresthesia, and anesthesia. Cold application reduces the pain by slowing or blocking the conduction in the peripheral nerves, and also via the gate-control mechanism and stimulating sensory receptors [7]. Instruments are used after buying.

4. Procedure

1) Before injection

The parents and their children were informed about the procedures and their written and verbal consents were received. The information form was collected from both parents and children using a face-to-face interview method by the researcher. The STAIC only applied to children.

2) During injection

An injection was administered to the children.

3) After injection

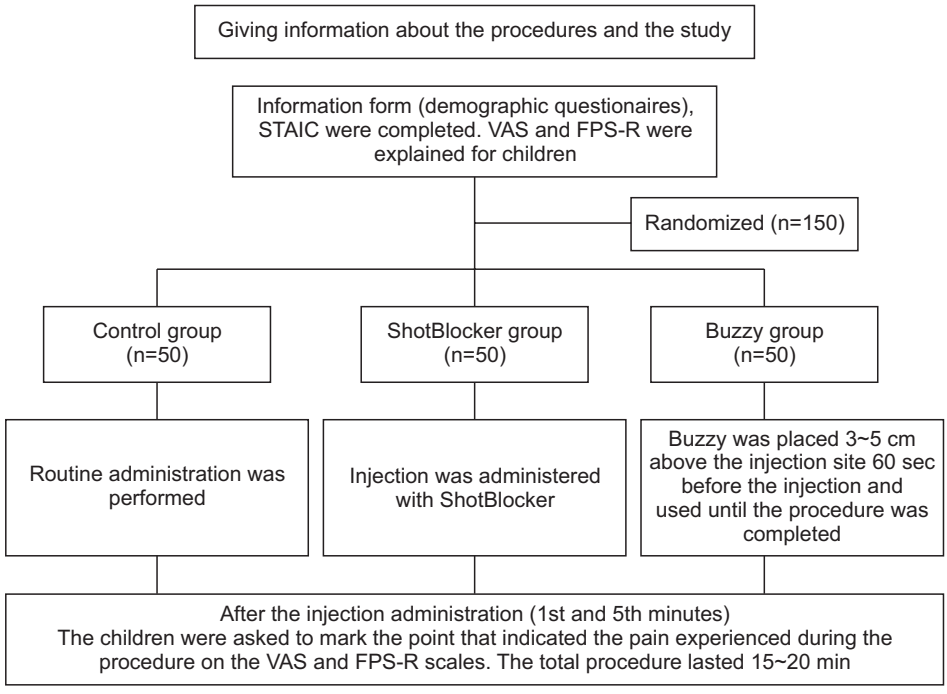
After administering penicillin to the children in the experimental and control groups (1st and 5th minutes), their pain conditions were evaluated using the VAS and FPS-R. The results were recorded on an administration form.

All procedures lasted for approximately 15~20 min for each child. The children were administered the penicillin injection and were told to stay at the hospital for 20~30 min after the procedure; the families agreed to this duration. Figure 3 shows the sample flow and protocol of the study.

In order to conduct the study, written permissions were obtained from the hospital. The study was granted ethical clearance by the Institutional Review Board of the M University (IRB no: 2014-26857650-047) and was undertaken in compliance with the Helsinki Declaration. Before starting the study, the parents and children were informed about the objective, plan, and period of the study, and their written and verbal consents were received.

5. Data analysis

Data were assessed using the Statistical Package for the Social Sciences (SPSS) for Windows, version 22 packaged software, and the Number Cruncher Statistical System (NCSS) 2007 program for statistical analyses (Kaysville, Utah, USA). The data of the study were evaluated using descriptive statistical methods



FPS-R=Faces pain scale-revised; STAIC=State trait anxiety inventory for children; VAS=Visual analog scale.

Figure 3. Sample flow and protocol.

(mean, standard deviation, median, 25.0% percentile, 75.0% percentile, frequency, ratio, minimum, and maximum), one-way analysis of variance and dependent samples t-test in those showing a normal distribution, and Kruskal-Wallis, Pearson's and Chi-square test in those not showing a normal distribution. Significance was evaluated at the levels of $p<.001$ and $p<.05$.

RESULTS

As presented in Table 1, the average age of the children was determined as 8.66±1.77 years in the ShotBlocker® group, 8.98±1.82 years in the Buzzy® group, and 9.12±2.03 years in the control group. The majority of the children were boys [ShotBlocker®=27 (54.0%); Buzzy®=25 (50.0%); control=29 (58.0%)]. The groups had no differences and were homogeneous in terms of these characteristics. There was no significant difference between the mean scores of STAIC before the procedure (ShotBlocker®=38.50±5.47; Buzzy®=37.74±6.07; control=40.16±6.24) ($p>.05$) (Table 1).

The first-minute mean VAS scores of the children in the Buzzy® group were significantly lower than those of the children in the ShotBlocker® and control groups. The fifth-minute VAS mean scores of the children in the Buzzy® group were also significantly lower than those of the children in the ShotBlocker® and control groups. Additionally, the children in the ShotBlocker® group had significantly lower mean scores than those in the control group ($p<.001$) (Table 2).

The first-minute FPS-R mean scores of the children in the Buzzy® group were significantly lower than those of the children in the ShotBlocker® and control groups. The fifth-minute FPS-R mean scores of the children in the Buzzy® group were significantly lower than those of the children in the ShotBlocker® and control groups. Additionally, the children in the ShotBlocker® group had significantly lower mean FPS-R scores in the fifth minute than the children in the control group ($p<.001$) (Table 3).

Table 1. Comparison of Socio-Demographic Characteristics according to Groups (*N*=150)

Characteristics	ShotBlocker® (n=50)	Buzzy® (n=50)	Control (n=50)	Total (n=150)	Test Value	*p*
	M±SD	M±SD	M±SD	M±SD		
Average age (yr)	8.66±1.77	8.98±1.82	9.12±2.03	8.92±1.87	0.82†	.456
Number of penicillin injections	2.78±2.26	2.82±1.85	3.32±2.43	2.97±2.19	2.40††	.301
State-Trait Anxiety Inventory (before the procedure)	38.50±5.47	37.74±6.07	40.16±6.24	38.80±5.99	2.17†	.118
	n (%)	n (%)	n (%)	n (%)		
Sex						
Female	23 (46.0)	25 (50.0)	21 (42.0)	69 (46.0)	0.64§	.725
Male	27 (54.0)	25 (50.0)	29 (58.0)	81 (54.0)		

M=Mean; SD=Standard Deviation.
†One-way analysis of variance; ††Kruskal-Wallis test; §Pearson chi-square test.

Table 2. Comparison of the First and Fifth-Minute Visual Analog Scale (VAS) Mean Scores of the Children according to Groups (*N*=150)

Scale	ShotBlocker® (n=50)	Buzzy® (n=50)	Control (n=50)	Test Value	*p*
	M±SD	M±SD	M±SD		
VAS (1st min.)	6.36±3.24	3.68±3.05	7.34±3.11	30.06†	<.001
VAS (5th min.)	3.38±2.94	1.68±2.28	4.88±3.24	26.45†	<.001
Mean Score Difference	−2.90±1.59	−2.00±1.67	−2.46±1.69	9.33†	.009
Test Value	−6.06††	−5.47††	−5.81††		
p	<.001	<.001	<.001		

M=Mean; SD=Standard Deviation.
†Kruskal-Wallis test; ††Wilcoxon signed-ranks test.

Table 3. Comparison of the First and Fifth-Minute Faces Pain Scale-Revised (FPS-R) Mean Scores of the Children according to Groups (*N*=150)

Scales	ShotBlocker® (n=50)	Buzzy® (n=50)	Control (n=50)	Test Value	*p*
	M±SD	M±SD	M±SD		
FPS-R (1st min.)	6.24±3.20	3.64±3.10	7.36±3.09	30.64†	<.001
FPS-R (5th min.)	3.24±2.96	1.52±2.23	4.84±3.29	27.17†	<.001
Mean Score Difference	−2.92±1.48	−2.12±1.73	−2.52±1.71	8.79†	.012
Test Value	−6.10††	−5.85††	−5.83††		
p	<.001	<.001	<.001		

M=Mean; SD=Standard Deviation.
†Kruskal-Wallis test; ††Wilcoxon signed-ranks test.

DISCUSSION

The American Academy of Pediatrics and American Pain Society recommend minimization and relief of the stress and pain during minor administrations, such as IM injections and vascular access [5]. Timely and efficient pain control during painful procedures in children increases their tolerance against pain in future administrations [12]. When examining the literature, it is seen that studies have constantly been conducted to decrease complications and increase patient satisfaction in IM injections. These studies also revealed that the injection technique, injection site, nurses' skills, the characteristics of the drug to be administered, and the administration of pharmacologic and non-pharmacologic pain relieving methods are effective in decreasing the pain and stress [2-4].

Many interventions made in the hospital environment cause intense anxiety, particularly in children [13,14]. Previous studies [4,15] also revealed that children in both the experimental and control groups experienced anxiety before the interventions. When examining the mean anxiety scores of children in the ShotBlocker®, Buzzy®, and control groups before the procedure in our study, the children had similar mean anxiety scores and the difference between the groups was not statistically significant (p>.05) (Table 1).

It is reported that IM injections cause the development of severe pain, stress, anxiety, and nosocomephobia in children [16,17]. In the present study, when the 1st- and 5th-minute pain of the children were assessed according to the VAS, Buzzy® relieved the pain the most, and both Buzzy® and ShotBlocker® were effective in relieving the pain compared with the control group. These results indicated that both Buzzy® and ShotBlocker® reduced the children's pain during the penicillin injection and supported the hypotheses 1, 2, and 3 (Table 2).

In a study conducted by Şahin [18] in adult patients who received IM injections, it was determined that Buzzy® was an efficient method for reducing the injection pain and increasing post-injection satisfaction. In the study conducted by Hasanpour et al. [19] in children aged 5~12 years, the authors performed a local cold application on the injection site for 30 seconds for reducing the pain induced by IM injections and reported that the method was effective. Russell et al. [20] determined that Buzzy® and 2.0% lignocaine reduced the pain and injection fear in children aged ≤13 years who were diagnosed with a rheumatic fever and had to receive benzathine penicillin. In the present study, when the 1st- and 5th-minute pain of the children was assessed using the FPS-R, the children in the control group experienced more pain than those in the Buzzy® and ShotBlocker® groups; Buzzy® was more effective in the 1st and 5th minutes compared with both the control and ShotBlocker® groups, and the difference between them was highly significant (p<.001).

In a single-blinded study, it was found that Buzzy® was an effective method in reducing the pain induced by intramuscular injections and increasing the post-injection satisfaction [21]. Sahiner and Bal [22] reported that among children aged 7 years who were vaccinated, the children for whom Buzzy® was used had a lower level of pain and anxiety than those in the control group. Studies conducted on children revealed that Buzzy® reduced the pain during blood sampling, intravenous, and immunization injections [6,23-25]. These results show that the aforementioned methods are effective in reducing the pain in children

owing to their physiologic effects and these methods' distraction. In a study conducted for the purpose of examining the effect of ShotBlocker® on pain in IM vaccinations administered to preschool children, 93.2% of the children in the ShotBlocker® group and 51.7% of the children in the control group had "mild pain" [26]. Similar results were obtained in the study of Gundrum et al. [27]. In our study, the mean FPS-R scores of the ShotBlocker® group in the 5th minute were significantly lower than those of the children in the control group (p<.001). When the difference between the mean FPS-R 1st- and 5th-minutes scores of the children in all groups was examined, it was found that there was a significant difference associated with the ShotBlocker® group and the score difference of the children in this group was higher than that of the children in the Buzzy® group (Table 3). These results supported the findings obtained using the VAS, and the fact that both scales showed parallel results verified the finding.

In the present study and other studies [22,24,26], it was shown that both Buzzy® and ShotBlocker® were effective in reducing pain. Thus, the use of these devices, especially in very painful injections such as penicillin injections, is thought to be effective in reducing children's pain, creating more comfortable working conditions for the healthcare professionals, and preventing undesired conditions in children, such as needle phobia and nosocomephobia.

In our study, even though Buzzy® (1st and 5th minutes) and ShotBlocker® (5th minute) were more effective in reducing the pain compared with the control group, Buzzy® was more effective in reducing the pain compared with the ShotBlocker® and control groups. A study in which ShotBlocker® was used to reduce the pain induced by IM injections in children [12] determined a decrease in the pain scores of children according to the evaluations of nurses and caregivers; however, but there was no difference according to the evaluations of the children. It was observed that ShotBlocker® was not effective in reducing the pain in children aged 4~12 years [28] and 2 months-17 years [29] who used ShotBlocker® during immunization. Considering the fact that penicillin is a very intense drug, which causes pain that spreads through the leg [30], it could be presumed that the children who received Buzzy® felt less pain than the children in the ShotBlocker® group due to the cold and vibration effect. The devices are not paid by the health insurance; however, they can be obtained if approved by the hospital administrators. Also, in our hospital, nurses could apply these devices to children independently, without a doctor's order. Therefore, after the study these devices were given to the hospital by the researcher for use.

We recommend that further studies are conducted concerning the efficiency of ShotBlocker® in reducing pain induced by IM injections in children.

CONCLUSION

The strengths of the study are as follows: the experimental (ShotBlocker®, Buzzy®) and control groups were assigned in a randomized way; the children who participated in the study did not see each other during the procedure so the children were not positively or negatively affected by the intervention; two different, easily comprehensible self-reporting pain scales with a high validity and reliability were used to determine the pain levels; all measurements obtained from the children were made using only tools (Buzzy® and ShotBlocker®); this is the first study in Turkey and worldwide to examine the effect of Buzzy® and ShotBlocker® at the same time in the reduction of pain experienced by children during penicillin injection; both methods have been patented (Buzzy® and ShotBlocker®) and they were used in the same group for the first time; all measurements and injections administered to the children were made by a single researcher who has 11 years' nursing experience; and both methods used to reduce the pain could be easily applied.

Limitations: A single researcher stayed with the children during the intramuscular injections, and later assessed the self-reported pain in children after the procedure. Having one person administer the intervention and evaluate the results may have induced bias in the children's answers.

In line with our results, it is recommended to use primarily Buzzy® and secondly ShotBlocker® for reducing pain during painful pediatric procedures, such as IM injections. In addition, further evidence-based studies are needed, which should be conducted in different painful interventions and different age groups, to support the efficiency of these methods.

CONFLICTS OF INTEREST

The authors declared no conflict of interest.

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