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Effects of buzzy device and distraction cards on pain relief during intravenous cannulation in children: A Randomized Controlled Trial

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Abstract

Background: Under ethical and legal professional obligations, nurses are required to utilize evidence-based methods to enhance the experience of children during intravenous cannulation. Non-pharmacological pain management techniques are increasingly employed in clinical settings, as they can be implemented without incurring additional costs or requiring extra time. The aim of this randomized controlled trial is to evaluate the effectiveness of a Buzzy device and distraction cards in reducing pain associated with peripheral intravenous catheter (PIVC) insertion among school-aged children.

Methods: A randomized controlled trial study was conducted on 221 school-age children's patients who underwent PIVC in emergency departments. Three groups of patients were randomly assigned using a lottery method: the Buzzy device group (n=73), the distraction cards group (n=71), and the control group (n=77) receiving the standard procedure without any interventions. The children were asked to evaluate the pain level immediately following PIVC using the Wong-Baker Faces Pain Scale. Using SPSS (version 26), the independent t-test, Fisher's exact test, analysis of variance, and chi-square test were used to analyze the data.

Results: Children in the intervention groups experienced significantly less pain during the PIVC procedure compared to those in the control group, with a pain score of 5.45 ± 1.67 (p = 0.0001). There was no statistically significant difference in pain reduction between the two intervention methods: the distraction cards (2.54 ± 1.37) and the Buzzy device (2.43 ± 1.60), both showing effectiveness (p = 0.0001).

Conclusion: The results of this study indicate that both the Buzzy device and distraction cards effectively reduce pain levels during intravenous cannulation when compared to the control group. Furthermore, the two strategies demonstrated equivalent effectiveness in pain reduction, as their outcomes were nearly identical. Therefore, it is recommended that these therapeutic approaches be employed to manage and alleviate pain associated with PIVC.

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Highlights

What is current knowledge?

Buzzy devices are significantly more effective than distraction cards in reducing peripheral intravenous cannulation-related pain in school-age children.

What is new here?

Buzzy devices and distraction cards are almost equivalent in reducing peripheral intravenous cannulation-related pain. More studies are needed to confirm the effectiveness of these methods in reducing peripheral intravenous cannulation pain.

Introduction

Children have a complicated sense of pain, and many medical procedures that involve needles, including venipuncture and vaccinations, are thought to be the most prevalent causes of pain for children. Both immediate and long-term adverse effects are possible with acute pain. Acute effects include a rise in the child's discomfort, the emergence of dread and anxiety, and an intensification of pain perception that results in hyperalgesia. Acute pain's long-term consequences include the possibility of developing chronic pain when nerve stimulation triggers several changed pain pathways that degrade central nervous system functions and cause central sensitization (1-3). Managing children's suffering through medical procedures is difficult (4,5). Children's pain management is difficult because of factors like age, cognitive and communication skills, past pain experiences, and cultural attitudes (6,7). The World Health Organization's Guidelines on the Management of Chronic Pain in Children state that managing pain in children can be complex, and there are not enough high-caliber studies on the best management strategies and treatment interventions for this patient group. Pain management involves pharmacologic and nonpharmacologic interventions that are customized to meet the needs of the patient (8). Non-pharmacologic techniques can effectively reduce procedural pain when applied properly, according to the *American Journal of Nursing Science* (9,10). Current studies concentrate on nurses' use of non-pharmacological techniques to alleviate children's pain (11,12). The distraction method is currently the most popular non-pharmacological technique for relieving children's suffering during traumatic medical procedures (13). Distraction's pain-relieving benefits are explained by the theory that the brain's ability to concentrate on stimulus is limited (14). There are other ways to employ the distraction technique, such as a Buzzy device (15,16). The findings of many randomized trials demonstrate that the integration of Buzzy devices and distraction cards alleviates pain during needle-related procedures such as intravenous cannulation without negatively impacting the blood collection process (17,18). Certain non-pharmacological pain management strategies failed to demonstrate efficacy in alleviating pain in children, leading to knowledge gaps. Employing non-pharmacological methods can reduce the use of medicines and provide children with a sense of autonomy (19,20). Although research on the effectiveness of nonpharmacological pain therapy is limited, it remains safe, noninvasive, and cost-effective (21). The present study purposes to

investigate the efficacy of parallel groups of distracting cards and Buzzy devices in reducing pain related to peripheral intravenous catheter (PIVC) in school-age children and whether the two strategies are equivalent. Our study is important since PIVC is one of the most painful medical procedures performed on school-age children, particularly in emergency rooms, and there is a need for strategies to reduce its pain level. Moreover, this addresses the gap in the studies while offering vital insights into the possible significance of non-pharmacological approaches in enhancing children's outcomes throughout the PIVC procedure.

Methods

This study utilized a randomized controlled trial with a parallel-group equivalence design that included three arms. The researchers used it to evaluate the effectiveness of a Buzzy device and distracting cards in reducing pain related to PIVC among school-age children.

Setting and samples

The study was conducted at the pediatric hospital in Mosul, Iraq, from July 1, 2024, to October 2, 2024. This hospital is the only facility specializing in pediatric care in the region. To obtain reliable data and ensure a representative sample, a simple random sampling method was employed using a lottery approach. The researcher wrote the codes for the three groups-B for the Buzzy device group, C for the control group, and D for the distraction cards group-on separate pieces of paper, which were then placed inside a container.

To ensure blinding, the participating children randomly selected a paper from a container that contained the code for one of the groups, without being aware of which group they were assigned to. A total of 221 children of both sexes, all with a documented order for intravenous cannulation, were systematically recruited following a thorough examination by the emergency department physician. The sample was divided according to serial number into three groups: 73 children in the Buzzy device group, 71 children in the distraction cards group, and 77 children in the control group (Figure 1).

Inclusion criteria for the study included the following: children aged 6 to 12 years of both sexes, parental consent to volunteer for the study, intact skin on the hands, no life-threatening diseases, the intravenous cannula to be introduced solely in the right and left hands, and no communication difficulties, including issues with hearing, vision, or speech, that could significantly influence the quality of the data collected and the progress of the study due to challenges in establishing effective communication and mutual understanding.

Exclusion criteria included the following conditions that would preclude participation in the study: significant local infections or cellulitis at the planned intravenous cannula insertion site and skin conditions such as burns, rashes, open wounds, abscesses, or boils. These conditions could potentially affect the intended course of treatment, increase the risk of infection, exacerbate the underlying condition, and impact the success of the intravenous cannulation procedure.

Sample size

The minimum sample size for the study was determined through a literature review (4) and comprised 221 school-age children. These participants were divided into three groups: the Buzzy device group (n=73), the distraction cards group (n=71), and the control group (n=77). The sample sizes were calculated using a priori estimates for Student's t-tests, with an anticipated effect size (Cohen's d) of 0.5, a desired statistical power level of 0.8, and a significance level of 0.05. For a one-tailed hypothesis, the minimum total sample size required was 102, with 51 participants per group. For a two-tailed hypothesis, the minimum total sample size increased to 128, with 64 participants per group.

Intervention in distraction cards group

To identify the appropriate vein, an experienced nurse with 12 years of expertise in pediatric venipuncture performed the intravenous cannulation on all children participating in the study. The same nurse began by identifying the suitable vein and sterilizing the skin. Before inserting the peripheral intravenous catheter, the researcher presented a distraction card to the child, encouraging them to focus on solving a puzzle, navigating a maze, or identifying differences in a picture while the nurse inserted the catheter. Other forms of parental or nursing distraction were not allowed. Immediately after the procedure, the child was shown the Wong-Baker pain scale to assess their pain level.

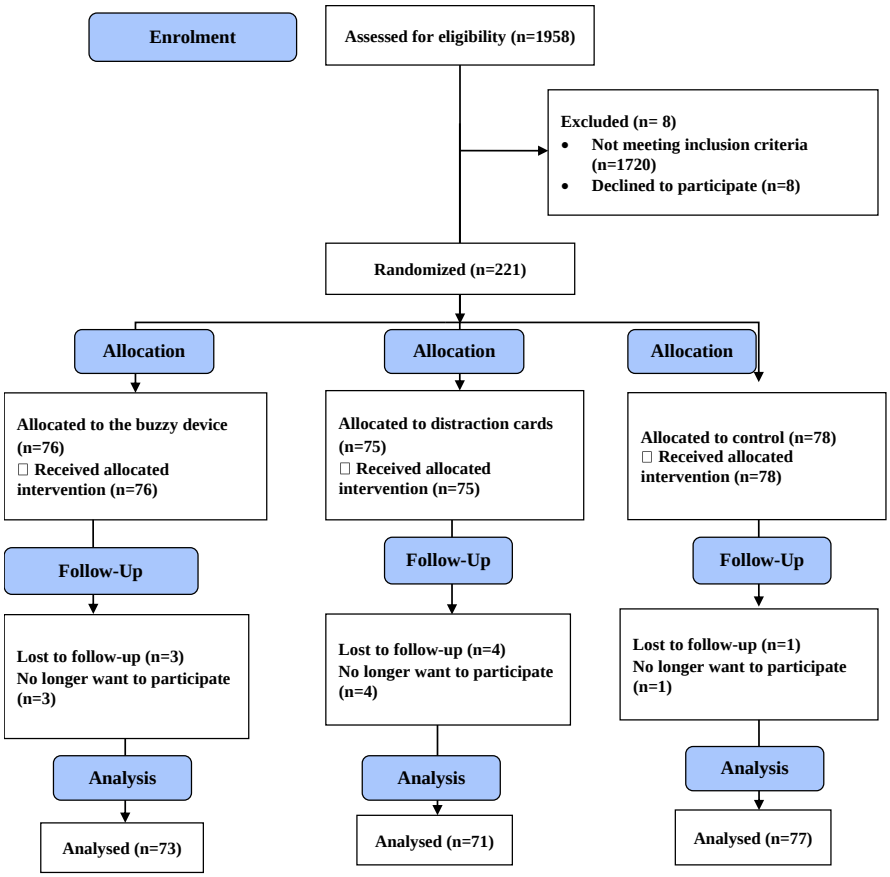

Figure 1. CONSORT flow diagram of participants through each stage of a randomized clinical trial

Intervention in buzzy device group

In this group, the nurse, who has 12 years of experience, also performed PIVC on all children participating in the study. The wings of the Buzzy device were kept in the refrigerator before the procedure and were removed a few minutes prior to being placed on the skin. The nurse held the child's hand to assess the veins. Once both the child and the nurse were ready, the frozen wings were inserted into the back of the Buzzy device using fixed elastic bands. The researcher then placed the Buzzy device on the patient's skin, approximately 3-5 cm above the planned catheterization site, and secured it with a custom tourniquet. Continuous vibration was activated using a manual switch about 40-60 seconds before the venipuncture. Immediately after the procedure, the child was shown the Wong-Baker pain scale to assess their pain level.

Intervention in control group

No specific intervention was conducted in the control group; instead, standard care was provided by the same nurse. Immediately following the procedure, the child was shown the Wong-Baker pain scale to assess their pain level.

Measurement and data collection

The instrument of the study includes Part 1: sociodemographic characteristics (Age, gender, place of residence, order of birth). Part 2: medical information about the child, which involved questions such as the causes for admission, site of cannulation, previous venipuncture in the last three months, and PIVC size.

Wong-Baker FACES® pain rating scale

The most widely used technique for evaluating children's pain is self-report scales. Self-report measures are dependent on the noxious stimuli's sensory, emotional, and contextual characteristics (22). The researcher obtained official approval to use the WBP scale from the concerned authority. The Wong-Baker FACES® Pain Rating Scale is the most often used and recognized self-report pain scale for children. The scale was used to determine the efficacy of the Buzzy device. It consists of six face photos. Each image has a number assigned to it, ranging from 0 to 10, with 0 denoting "no hurt" and 10 denoting "hurts worst." After being shown this scale, the patient was instructed to choose the picture that most closely matched their present level of pain.

Data analyses

Descriptive statistics, including frequency, percentage, mean, and standard deviation, were used to analyze the demographic data. The paired t-test was used to compare means and standard deviations. The ANOVA test and Bonferroni's post hoc test were also applied. The statistical analyses were conducted using SPSS version 26 (SPSS Inc., Chicago, IL, USA).

Results

According to Table 1, the mean age of children in the distraction cards group (8.76 ± 2.06), the Buzzy device group (8.98 ± 2.02), and the control group (8.90 ± 2.00) was reported. Regarding the terms, site of cannulation, cannula size, and cause of admission, there were no statistically significant differences among the three groups. The highest percentage of intravenous cannula insertion sites in the hand for the three groups was n=45. In terms of cannula gauge, size 24 represented the highest percentage across the three groups. According to the cause of admission, the most common cause was "other reasons," with approximately 30% in all three groups.

Table 1. Participants' demographic characteristics

Variables			Types of groups			Total	p-value
			Distraction cards	Buzzy device	Control		
Age of children	6-8 years	n	38	40	46	124	0.003*
		%	53.5	54.8	59.7	56.1	
	9-10 years	n	19	16	17	52	
		%	26.8	21.9	22.1	23.6	
	11-12 years	n	14	17	14	45	
		%	19.7	23.3	18.2	20.3	
Sex of children	Male	n	33	39	42	114	0.302
		%	46.5	53.4	54.5	51.6	
	Female	n	38	34	35	107	
		%	53.5	46.6	45.5	48.4	
Birth order	First	n	13	14	22	49	0.0001*
		%	18.3	19.2	28.6	66.1	
	Second	n	16	19	21	56	
		%	22.5	26.0	27.3	75.8	
	Third	n	19	21	14	54	
		%	26.8	28.8	18.2	73.8	
	Fourth	n	14	8	14	36	
		%	19.7	11.0	18.2	48.9	
	More than 4	n	9	11	6	26	
		%	12.7	15.1	7.8	35.6	
Residency	Urban	n	45	53	54	152	0.001*
		%	63.4	72.6	70.1	68.8	
	Rural	n	26	20	23	69	
		%	36.6	27.4	29.9	31.2	
	Fever	n	9	12	10	31	
		%	12.7	16.4	13.0	14.0	
	Others	n	23	22	23	68	
		%	32.4	30.1	29.9	30.8	
Previous cannulation last 3 months	Yes	n	16	13	24	53	0.0001*
		%	22.5	17.8	31.2	24.0	
	No	n	55	60	53	168	
		%	77.5	82.2	68.8	76.0	
Total		n	71	73	77	221	
		%	100.0	100.0	100.0	100.0	

* Chi-square test, significancy level at $p < 0.05$

As shown in Figure 2, distraction cards and Buzzy devices were more effective in reducing pain levels than the standard procedure received by the control group during the PIVC procedure.

As shown in Table 2, there are statistically significant differences in pain intensity among the control group (P = 0.0001), the distraction cards group (P = 0.0001), and the Buzzy device group (P = 0.0001).

As shown in Table 3, the Buzzy device and distraction cards both demonstrated statistically significant reductions in pain levels when compared to the control (P = 0.0001 for both). There was no significant difference in the two methods' ability to reduce pain (Mean Difference = 0.048, P = 1.000).

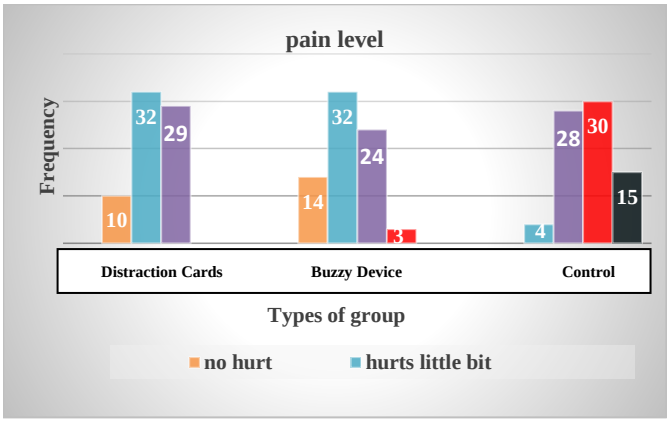

Figure 2. Pain level according to types of groups

Table 2. Differences in Pain intensity among control, distraction cards, and buzzy device groups

One-Sample Test					
Groups	Test Value = 0				
	n	Mean	SD	T	Sig
Control	77	5.4545	1.67446	28.584 *	0.000 *
Distraction cards	71	2.5493	1.37101	15.668 *	0.000 *
Buzzy device	73	2.4384	1.60716	12.963 *	0.000 *

* One-Sample Test -N: Number; SD: standard deviations; Sig.: Significance; T: statistics

Table 3. Multiple comparisons of pain level means in the distraction cards, buzzy device, and control groups using the Bonferroni test

(I) Types of Groups	(J) Types of Groups	Mean Difference (I-J)	Std. Error	Sig.
Distraction cards	Buzzy device	0.048	0.131	1.000
	Control	- 1.460 *	0.129	0.0001
Buzzy device	Distraction cards	- 0.048	0.131	1.000
	Control	- 1.508 *	0.128	0.0001
Control	Distraction cards	1.460 *	0.129	0.0001
	Buzzy device	1.508 *	0.128	0.0001

* Bonferroni test.

Discussion

In our study, school-age children rated the pain as significantly lower when using the distraction cards and Buzzy device compared with the control. This agrees with several previous studies (23-26) and supports the effectiveness of these strategies in reducing pain levels during the PIVC procedure.

Procedures are frequently performed in the medical field and can be painful throughout life. It is the ethical duty of nurses to care for individuals who are in pain (13,14). According to the American Society for Pain Management Nursing, every patient undergoing a painful procedure has the right to safe and effective pain management during all stages of care (27).

The results of our study indicated that the most common age group visiting the emergency department was 6 to 8 years; age significantly affects pain levels among children.

The number of males and females in the study was nearly equal, with only a slight difference. This balance between the two genders may have contributed to the similarity in the statistical outcomes for both males and females. This finding is consistent with the results of another study (28).

According to another study, 50% of the study sample was in the age group of 6-7 years, and 60% of them were males (29,30). The results of the current study showed that city residents constituted a large proportion of the total sample size, amounting to about 70%, while the proportion of rural residents was about 30%. This variable significantly affected pain levels among the participants. This result is consistent with previous studies that confirmed urban areas constituted the majority of their study population (31). As for birth order in the family, it did not significantly affect pain levels, with the percentages for first, second, and third-born children being almost equal (19%). These results disagree with another study (32).

Regarding the site of cannulation, our results agree with a similar study, where the highest percentage (69%) of cannula sites was in the hand (33). According to the size of the PIVC used, the percentage was almost equal between sizes 24 and 22, at 55% and 45%, respectively. It was not significantly affected by the level of pain. This percentage may align with a study where the percentage was 54% for cannula size G24 (16). The study shows differences in children's causes of hospital admission, with the highest percentages related to the digestive system and other reasons. Our results do not agree with another study conducted in Iraq, where the highest percentage for admission was due to respiratory infection, at 33%. Previous PIVC experiences may affect children's responses, depending on whether their past experiences were negative or if they were able to cope with the stress of the hospital, which significantly impacted the pain level in our study. The results of our study are consistent with the results of other studies (4,34).

Non-pharmacological strategies such as distraction cards and Buzzy devices are effective methods used in medical procedures (24). Our results showed that participants in the distraction cards and Buzzy device groups had lower pain scores than those in the control group, which is in line with multiple studies that demonstrated the superiority and efficacy of Buzzy devices and distraction cards over the standard care procedure in lowering children's needle-related pain and significant differences in pain intensity among groups (23-25). Regarding the study gap, more research is advised on the efficiency of Buzzy devices and distraction cards in reducing infant and toddler pain from intravenous cannulation.

There were several limitations to this study, as it is one of its kind in Iraq. The environment in the emergency room was not ideal, and the crying of other children may have negatively impacted the participants while they were waiting for the PIVC procedure in the same room. Additionally, the number of children participating in the study was limited.

Conclusion

This preliminary study on the use of Buzzy devices and distraction cards found that their application resulted in a reduction of pain in children undergoing PIVC. The findings suggest that Buzzy devices and distraction cards are nearly equivalent in their effectiveness at reducing pain associated with PIVC. Therefore, it is recommended that professional nurses incorporate non-pharmacological pain management strategies into painful nursing procedures. Further research in this area is warranted, including investigations into their effectiveness for other types of injections, such as intramuscular injections.

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Ethical statement

The study received approval from the Ethics Committee of the College of Nursing at the University of Baghdad on April 25, 2024, under approval number 1608. Informed consent was obtained from all participants, and written consent from the parents of young children was secured prior to their involvement in the study. Additionally, verbal consent to participate was obtained from the children themselves. The rights of the participants to withdraw from the study at any stage were upheld, and confidentiality and individual identity were maintained throughout the research process. All ethical principles governing human research were strictly adhered to in this study.

Administrative permissions were obtained from the Iraqi Ministry of Health, the Ministry of Planning - Central Statistical Organization, and the Health Directorate of Nineveh.

Conflicts of interest

The authors declare no conflict of interest regarding the publication of this study.

Author contributions

Both authors contributed to the study's idea and design. MAA helped in data collection and proposal creation. KA and MAA took part in the interpretation and analysis of the data. The article was drafted in collaboration with MAA and KA. The submitted version of this work has been reviewed and approved for publication by all authors.

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