Efficacy of Buzzy Device in Reducing Peripheral Intravenous Cannulation Pain Among Children A Comparative Randomized Controlled Trial

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Abstract

Objective: to discover the effects of Buzzy device in Reducing Peripheral Intravenous Cannulation-Related Pain Among School Age Children.

Methods: A comparative and prospective randomized controlled trial was employed. The study was carried out on 150 school-age children who had peripheral intravenous cannulation. Patients were divided into two groups randomly: the Buzzy device group (n = 73) and the control group (n = 77). Immediately after the PIVC procedure, the patients were asked to rate their level of pain by using the Wong-Baker Faces Pain Scale.

Results: There are statistically significant differences in pain intensity between the Buzzy device, and the control group (P-value=.000). The Buzzy device group experienced a reduced pain intensity compared to the control group (mean difference 2.22). Additionally, there were middle pain scores observed in the control group (mean difference 3.73) compared to the Buzzy device group.

Conclusions: When compared to control groups, the Buzzy device was found to be successful in lowering pain levels associated with peripheral intravenous cannulation.

Recommendation: To properly employ non-pharmacological methods, such as the Buzzy device, to lessen pain in patients undergoing PIVC procedures, healthcare professionals especially nurses should be trained. Teaching nurses these techniques is a key component of nursing practice.

Keywords: Intravenous cannulation; Pain Management; Buzzy device.

فاعلية جهاز بزي في تقليل آلم القنية الوريدية الطرفية عند الأطفال: تجربة منضبطة معشاه

المستخلص:

الأهداف: اكتشاف تأثير جهاز بزي في تقليل الألم المرتبط بالقنية الوريدية الطرفية عند الأطفال في سن المدرسة.

المنهجية: تم استخدام تجربة عشوائية مستقبلية مقارنة معشاه، أجريت الدراسة على ١٥٠ طفالً في سن المدرسة خضعوا للقنية الوريدية الطرفية. تم تقسيم المرضى إلى مجموعتين عشوائيًا، (مجموعة جهاز

بزي عدد =٧٣) و(ومجموعة التحكم عدد = ٧٧). ومباشرة بعد إجراء القنية الوريدية الطرفية، طلب من المرضى تقييم مستوى الألم لديهم باستخدام مقياس وونغ–بيكر للألم.

النتائج: هناك فروق ذات دلالة إحصائية في شدة الألم بين جهاز بزي والمجموعة الضابطة ٠.٠٠ =.P–value شهدت مجموعة جهاز بزي انخفاض مستوى الألم مقارنة بمجموعة التحكم (متوسط الفرق ٢.٢٢) بالإضافة إلى ذلك، لوحظت درجات ألم متوسطة في مجموعة التحكم (متوسط الفرق ٣.٧٣) مقارنة بمجموعة جهاز بزي.

الاستنتاجات: عند المقارنة بمجموعات السيطرة، وجد أن جهاز بزي فعال في خفض مستويات الألم المرتبطة بالقنية الوريدية الطرفية.

التوصيات: لاستخدام الأساليب غير الدوائية بشكل صحيح، جهاز بزي، لتقليل الألم لدى المرضى الذين يخضعون لأجراء القنية الوريدية الطرفية، يجب تدريب المتخصصين في الرعاية الصحية وخاصة الممرضات. يعد تعليم الممرضات هذه التقنيات عنصرا أساسيًا في ممارسات التمريض .

الكلمات المفتاحية: القنية الوريدية: تدبير الألم: جهاز بزي

1.Introduction

Pain remains the most complex, disturbing, and challenging sensory-emotional event in children's lives despite developments taking place in the health field around the world. The way a kid perceives pain is influenced by a variety of factors, including their age, developmental stage, cognitive capacity, communication style, past experiences with pain, and pain beliefs. Adverse events resulting in chronic, severe pain might lead to physiological and behavioral issues. If the pain is not reduced or completely resolved at this time by appropriate treatments, it may lead to long-term neurological and behavioral problems [(1).] For more than three decades, the significance of treating children's pain has been well acknowledged. Because of the immaturity of their neural systems, it was formerly believed that newborns and early children could not feel pain or remember painful events However, nowadays, there is a wealth of research that supports the detrimental and long-term effects of pain [(2)]. Each year, approximately 1.2 billion PIVC are globally inserted. It is widely acknowledged that this procedure can cause pain, which in turn can negatively affect cognitive function due to the ensuing discomfort and anxiety [(3)]. Healthcare professionals have a responsibility to ensure that every patient receives the most suitable infusion therapy using the most appropriate device and site, in the most suitable environment, and at the correct time [(4)]. The World Health Organization (WHO) and pediatric medical associations emphasize the importance of improving the approach to managing pain in children in medical settings, including emergencies. Intravenous procedures are among the most

painful procedures in pediatric medicine [5]. The control of pain is an essential part of providing care. Therefore, it has been deemed the fifth vital sign by the American Pain Association [6;7]. The nurse should use techniques to lessen the fear, pain, and anxiety that are generally connected to venipuncture procedures to minimize the patient's discomfort [8]. Buzzy helps prevent pain and divert attention while youngsters are receiving injections. The purpose of Buzzy is to "distract the nerves" and numb the skin to "reduce pain on contact. Based on the gate control theory, the Buzzy device's mechanism interrupts nociception by stimulating big fiber and inhibitory neurons with cold and vibration [9].

2. Methodology:

2.1 Study design

This study used a prospective randomized controlled trial. The researchers have used it to evaluate the effectiveness of a buzzy device in reducing pain related to peripheral venous cannulation among school-age children.

2.2 Sample and Sampling

The study is conducted at pediatric hospitals in Mosul city which is the only specialized hospital for pediatric care. To get reliable data and a representative sample, a basic random sample strategy (lottery method) was applied in this scientific investigation (150) Patients with a documented order for an intravenous cannulation were systematically targeted after a thorough examination by the ED physician. The sample was divided into (73) children in the buzzy device group and (77) in the control group.

2.2.1 Sample Size Calculation

The sample comprised (150) school-age children's patients. These patients were divided into two groups, the Buzzy device and the control group. The minimum sample sizes were calculated using apriori sample sizes for student t-tests. as in Table (1).

Parameter of calculation the minimum sample size	Selected Values
Anticipated effect size (Cohen's d):	0.5
Desired statistical power level:	0.8
Probability level:	0.05

-For a one-tailed hypothesis, the minimum total sample size is: 102
-Each group's minimum sample size (one-tailed hypothesis): 51

-For a two-tailed hypothesis, the minimum total sample size is: 128
-Each group's minimum sample size (two-tailed hypothesis): 64

2.2.2 Inclusion Criteria

Guardians of subjects aged 6 to 12 who agreed to volunteer for study. Having undamaged hand skin does not cause life-threatening disease, while the intravenous cannula was introduced solely to the right and left hands. No difficulties in communication, including hearing, vision, and speech, that may significantly influence the quality of the gathered data and the progress of the study owing to the difficulty of establishing good communication and mutual understanding.

2.2.3 Exclusion Criteria

included those with significant local infection or cellulitis at the planned IV cannula insertion site, as well as those with skin problems such as burns, rashes, open wounds, abscesses, or boils. These circumstances might affect the intended course of therapy, raise the risk of infection exacerbate the disease, and affect how well the intravenous cannulation is inserted.

2.3 Intervention

A nurse from the emergency department was selected., who had 12 years of expertise performing PIVC on all children in the study. The wings were kept in the refrigerator before the procedure and removed a few minutes before being placed on the skin. The nurse held the child's hand to assess the veins. Once the child and nurse were ready, the frozen wings were inserted into the back of the buzzy through fixed elastic bands. The researcher then placed the Buzzy device on the patient's skin (3–5 cm) above the planned catheterization site, and secured it with a custom tourniquet. Continuous vibration was activated by a manual switch approximately 40-60 seconds before venipuncture. Immediately after the procedure, the child was shown a Wong-Baker pain scale to determine pain level.

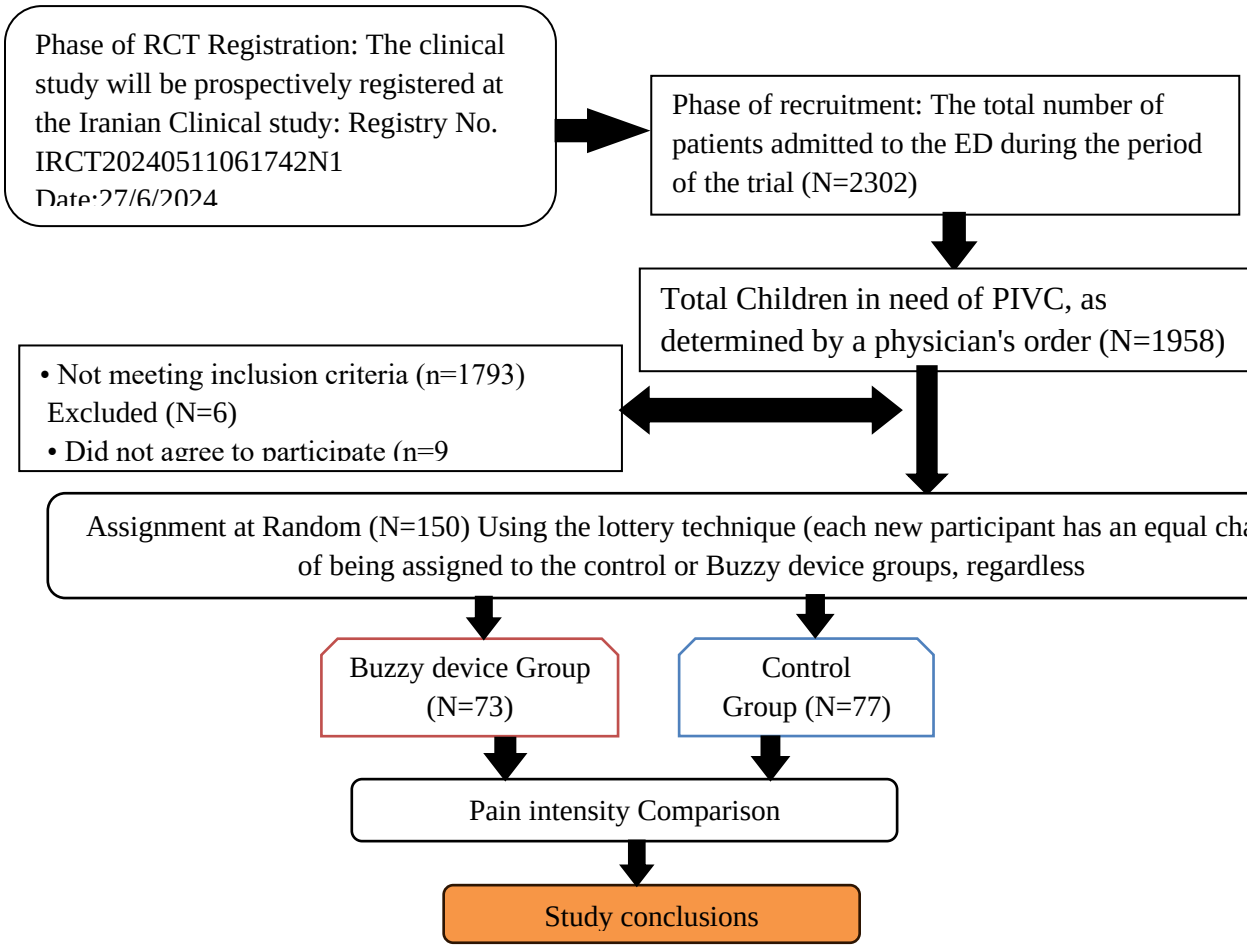
2.4 Data collection and study instruments

The instrument of the study includes **Part 1**: sociodemographic characteristics (Age, Gender, Place of Residence, Order of Birth, and Relation of the guardian. **Part 2:** medical information about the child: - It involved questions such as the reason for admission, Site of venous access, Previous venipuncture for the last three months, PIVC size and site of venipuncture, and Wong-Baker FACES Pain Rating Scale.

2.4.1 Wong-Baker FACES Pain Rating Scale.

The researcher obtained official approval to use the WBP scale from the concerned authority. Wong-Baker FACES The Pain Measure is the most often used and recognized self-report pain scale for children. Six face photos make up this scale. Every 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.

2.1. Study flow algorithm



2.5 Ethical considerations

The project of the study was approved by the ethics committee of the College of Nursing University of Baghdad. The informed consent form was

agreed by the participants. The administrative arrangement was obtained from the Iraqi Ministry of Health, the Ministry of Planning-central Statistical Organization, and the Health Directorate of Nineveh government.

2.6 Data analyses

Descriptive statistics: frequency, percentage, mean, and standard deviation, were used to analyze the demographic data. The paired independent t-test was used to compare Means and SD in the two groups. ANOVA test was used to find the association between demographic variables and the pain level. The significance level was set at p p<0.01in all the tests. The statistical analyses were conducted by SPSS version 26.

Table (1) Distributions of Participants' Sociodemographic Characteristics

Variables			types of group		Total
			buzzy device	control	
age of children	6-8 years	No.	40	46	86
		%	26.7%	30.7%	57.3%
	9-10 years	No.	16	17	33
		%	10.7%	11.3%	22.0%
	11-12 years	No.	17	14	31
		%	11.3%	9.3%	20.7%
Total		No.	73	77	150
		%	48.7%	51.3%	100.0%
sex of children	male	No.	39	42	81
		%	26.0%	28.0%	54.0%
	female	No.	34	35	69
		%	22.7%	23.3%	46.0%
Total		No.	73	77	150
		%	48.7%	51.3%	100.0%
order of birth	first	No.	14	22	36
		%	9.3%	14.7%	24.0%
	second	No.	19	21	40
		%	12.7%	14.0%	26.7%
	third	No.	21	14	35
		%	14.0%	9.3%	23.3%
	forth	No.	8	14	22
		%	5.3%	9.3%	14.7%
	more than 4	No.	11	6	17
		%	7.3%	4.0%	11.3%
Total		No.	73	77	150
		%	48.7%	51.3%	100.0%
residency	urban	No.	53	54	107
		%	35.3%	36.0%	71.3%
	rural	No.	20	23	43
		%	13.3%	15.3%	28.7%

Total		No.	73	77	150
		%	48.7%	51.3%	100.0%
Relation of the guardian	father	No.	12	7	19
		%	8.0%	4.7%	12.7%
	mother	No.	7	12	19
		%	4.7%	8.0%	12.7%
	both parent	No.	46	49	95
		%	30.7%	32.7%	63.3%
	other	No.	8	9	17
		%	5.3%	6.0%	11.3%
Total		No.	73	77	150
		%	48.7%	51.3%	100.0%

No: Number, %: Percentage

Table (1) shows that 57% of the participants were in the 6–8 age group, followed by the 9– 10 age group (22%) and the 11–12 age group (20%). According to the sex breakdown, 54% of the children were female and 46 % of them were male. According to the birth order, the percentages were almost equal: first born (24%), followed by second born (26%), third born (23%), and fourth born (11%) in terms of birth order. According to the residency statistics, 29% of the children lived in rural regions, whilst 71% of them lived in urban areas. Finally, about the child's relation to the guardian, the highest percentage was both parents (63%), and the other percentages were almost equal.

Table (2) Discerption of Children's Medical Data

Variables			types of group		Total
			buzzy device	control	
site of canulation	hand	No.	44	47	91
		%	29.3%	31.3%	60.7%
	Antecubital fossa	No.	24	19	43
		%	16.0%	12.7%	28.7%
	forearm	No.	5	11	16
		%	3.3%	7.3%	10.7%
Total		No.	73	77	150
		%	48.7%	51.3%	100.0%
canula size	24 g	No.	45	36	81
		%	30.0%	24.0%	54.0%
	22 g	No.	28	41	69
		%	18.7%	27.3%	46.0%
Total		No.	73	77	150
		%	48.7%	51.3%	100.0%
cause of admission	Respiratory problems	No.	12	13	25
		%	8.0%	8.7%	16.7%
	Gastrointestinal problems	.No	19	23	42
		%	12.7%	15.3%	28.0%
	UTI problems	.No	8	8	16

		%	5.3%	5.3%	10.7%
	fever	.No	12	10	22
		%	8.0%	6.7%	14.7%
	others	.No	22	23	45
		%	14.7%	15.3%	30.0%
Total		.No	73	77	150
		%	48.7%	51.3%	100.0%
Previous Cannulation	yes	.No	13	24	37
		%	8.7%	16.0%	24.7%
	no	.No	60	53	113
		%	40.0%	35.3%	75.3%
Total		.No	73	77	150
		%	48.7%	51.3%	100.0%

F= Frequency, %= percentage

Table (2), shows the hand was the cannulation site in the majority of children (62 %), followed by the antecubital fossa (29 %) and the forearm (11%). Furthermore, (G24) (54%) was the most often utilized cannula size, with 22 g (46%) coming in second. The majority of children were hospitalized for other causes (30%), followed by gastrointestinal disorders (28%), fever (14.7%), urinary tract infections (10.7%), and respiratory causes (16.7%). In addition, 24.7% of the children had previously received cannulation, but a sizable number (75.3%) had never had it.

Table (3). Pain Level According to Types of Group

Types Of Group	No.%	pain level					Total
		no hurt	hurts little bit	hurts little more	hurts even more	hurts whole lot	
Buzzy Device	.No	14	32	24	3	0	73
	%	9.3%	21.3%	16.0%	2.0%	0.0%	48.7%
Control	.No	0	4	28	30	15	77
	%	0.0%	2.7%	18.7%	20.0%	10.0%	51.3%
Total	.No	14	36	52	33	15	150
	%	9.3%	24.0%	34.7%	22.0%	10.0%	100.0%

No: Number, %: Percentage

Table (3) shows that in the Buzzy device group, 14 children reported no pain, 32 reported a little pain, 24 reported a little more pain, and 3 reported hurts even more. Comparison pain levels with the control group, had no children reporting no pain, just 4 reporting a little pain, 28 reporting a little more pain, 30 reporting hurts even more, and 15 reporting a hurts a whole lot of pain.

Table (4) Differences in pain intensity between Buzzy device and control group.

ANOVA					
	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	85.227	1	85.227	126.433	.000
Within Groups	99.766	148	.674		
Total	184.993	149			

df: Degree of freedom; F: F-statistics; Sig.: Significance

The study results show that there was a highly significant statistical difference in pain intensity between the Buzzy device and control group, p-value (0.000).

Table (5). The mean average pain level between the Buzzy device and control groups.

types of group	Mean	N	Std. Deviation	Std. Error of Mean
buzzy device	2.22	73	.804	.094
control	3.73	77	.837	.095
Total	2.99	150	1.114	.091

N= number, M= mean of score, SD= standard deviation

This table makes it easy to see the differences. The pain control group had 77, children. In the absence of any intervention, the subjects' average pain level was 3.73, reflecting the degree of pain they experienced. The Buzzy Device group has 73, individuals. Nevertheless, the Buzzy device group has been shown to reduce pain intensity, as seen by the average pain level of 2.22.**4. Discussion**

This study is significant because it examines how well Buzzy Device can lower pain levels in school-age children undergoing PIVC. The current study included 150 children from Ibn Al-Atheer Teaching Hospital for Children, which covered Nineveh Governorate and neighboring cities. The most common age group visiting the emergency department is (6-8) years. The male and

female genders are equal in number with a slight difference, and the equality of the sample between the two genders may be due to the similarity of the statistics for both males and females. This result is agreed with another study [10]. and according to another study, it showed that (50%) of the study sample is in the age group (6-7) years, and (60%) of them are males [11; 12]. The results of the current study showed that city residents constituted a large proportion of the total sample size, amounting to about 71%, and the proportion of rural reviewers was about 29%. This result is consistent with previous studies that confirmed that urban areas constituted the majority of their study [13]. As for the birth order in the family, the percentages were almost equal for the birth order: first, second, and third (24%,26%,23%), these results disagree with another study in Iraq in 2020 The highest percentage was 40 % for the first child [14]. Regarding the Relation of the guardian during the PIVC procedure, the largest percentage was both parents in both groups, almost equally, 63%. This percentage disagrees with another study, where the mother was the one who guardian the child the most 47% [15].

Regarding the site of cannulation, the highest percentage was in the hand, approximately 60%, followed by the Antecubital fossa28%, and forearm 11%., This result agrees with a similar study, where the highest percentage 69% of cannula sites is in the hand [16]. According to the size of the PIVC used, the percentage was almost equal between gauges 24 and 22, at 54% and 46%. This percentage may agree with a study conducted in Turkey, where the percentage was 54% for cannula size G24[17]. This result is considered normal because we excluded emergency cases or those requiring large volumes of cannula. The study shows different of child's causes of hospital admission The percentage of causes related to the digestive system and other reasons was the highest, approximately 30%, for each one followed by causes related to the respiratory system, at 16%. Our results do not agree with another study conducted in Iraq, where the highest percentage of the reason for admission was respiratory infection, at the highest percentage, 33%. Furthermore, 75% of the children in either of the two groups

had not received a PIVC in the last three months, The results of our study are consistent with the results of another study conducted in Iraq, where most of the participants, 75%, also had no history of cannulation during the last 3 months [(18)]. The results of a randomized trial indicate that the Buzzy® device reduces pain during PIVC, without adverse effects [(19)]. Our results show that the Buzzy device participants had lower pain scores than the control group. In the Buzzy device group, 14 of the children reported no pain, while in the control group, the percentage was 0, and 32 reported hurts little bit of pain, compared to 2. 15 reported hurts whole lot of pain in the control group, while in the Buzzy device group, she was 0, according to Table (3), which shows pain levels according to the type of group. Many RCTs investigate the effect of the Buzzy device on venipuncture pain in children of similar age groups. Our study confirmed the results of those studies on the use of Buzzy devices to reduce pain, as they all confirmed the effectiveness of this method in reducing pain in children during needle-related procedures [(20)]. Our findings indicate that there was a significant difference between the Buzzy device and control groups regarding decreasing the children's pain level during the PIVC procedure. This agrees with other studies that used the Buzzy device and found it active in reducing needle-related pain [(20)].

5. Conclusion

This study showed that the use of the buzzy device effective in reduce pain related to PIVC procedure in children.

6.Recommendation

it may be suggested that health professionals in Iraq incorporate non-pharmacological pain management (buzzy device) into painful nursing procedures. Further follow-up in future trials in this area is recommended.

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