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Vibration and Cold Sensation Can Reduce Pain in Children during Venipuncture

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Abstract **Original Research Article**

Needle-related procedures, such as intravenous (IV) cannulation, are a major source of pain and distress for hospitalized children, often leading to long-term consequences like needle phobia, heightened pain sensitivity, and traumatic memories. Effective, rapid, and affordable methods are needed to manage this pain. The Buzzy device, a vibrating cold device based on the Gate Control Theory, combines cold and thermomechanical stimulation to block pain signals and increase pain thresholds. This study aimed to assess the effectiveness of the Buzzy device in reducing pain and anxiety levels in children undergoing peripheral IV cannulation. This prospective, randomized study compared the effectiveness of the Buzzy device (vibrating cold device, VCD) and topical lidocaine (TL) in reducing pain during IV cannulation in children aged 3-18 years. Pain levels were assessed using the FPS-R and FLACC scales, while caregiver and nurse satisfaction were evaluated through surveys. Exclusion criteria included critical illness, local infection, or conditions affecting sensation. This study included 120 children randomized into two groups: 60 received the VCD and 60 received TL. Both groups were comparable in demographics and prior IV experiences, though the VCD group had higher pre-procedure FPS-R scores ($p<0.001$). The VCD group showed significantly fewer venipuncture attempts, lower FLACC scores, and shorter procedure durations ($p<0.001$). Caregivers and nurses reported higher satisfaction with the VCD method regarding pain relief, comfort, and likelihood of reuse or recommendation ($p<0.001$). No side effects were observed in either group. This study demonstrated the effectiveness of the Buzzy device in reducing pain and anxiety during IV cannulation in children aged 3-18 years. Compared to topical lidocaine, the Buzzy device resulted in fewer venipuncture attempts, lower FLACC scores, and higher caregiver and nurse satisfaction. Its affordability, ease of use, and efficacy make it a valuable tool for routine pediatric care.

Keywords: Buzzy Device, Pain Management, Pediatric IV Cannulation, Needle-Related Procedures, Caregiver Satisfaction, Nurse Satisfaction.

INTRODUCTION

Nowadays, the treatment modalities of diseases are highly developed and many intravenous treatment options are available for hospitalized patients. Healthy children not only receive multiple immunizations during childhood but also undergo fluid and drug therapies as well as peripheral nutrition through intravenous (IV) access when they are ill. However, needle-related procedures, including venipuncture, remain the primary cause of pain and distress for children during their hospitalization. Studies have shown that infants and children who experience repeated painful procedures often develop heightened sensitivity to pain, abnormal pain responses, impaired cognitive and motor development, needle phobia, and lasting traumatic memories that may persist into adolescence and adulthood [1]. Additionally, the stress experienced by the child can also cause significant anxiety and distress for their parents and health care providers during invasive procedures.

Pain from intravenous cannulation has been identified as the second most significant source of discomfort, following the pain or distress caused by the underlying medical condition [2]. Inadequate management of pain and distress during needle procedures can lead to severe needle phobia, which typically develops in early to middle childhood and may persist into adulthood [3]. Furthermore, needle fear contributes to vaccine hesitancy and non-compliance with medical treatments. Due to these potential negative

consequences, there has been a growing focus on recognizing and preventing needle-related pain and distress. Various physical, psychological, and pharmacological interventions have been proposed to combat with the anxiety and pain during intravenous cannulation. Examples include making reassuring statements, relaxation training, deep breathing, hypnosis, distraction techniques (e.g., music, cartoons), blowing bubbles, acupuncture, anesthetic creams, and application of heat or cold [4]. However, no single method or approach has achieved universal approval due to limitations such as effectiveness, cost and application duration.

An efficient, rapid, inexpensive, and easy-to-use method is essential in clinical settings. Recent studies have reported significant reductions in pain and anxiety in the pediatric population using a combined approach involving cold and thermomechanical stimulation [5, 6]. A commercially developed vibrating cold device (VCD), known as the Buzzy device (MMJ Labs, Atlanta, GA, USA), operates based on the principles of the Gate Control Theory by applying cold and thermomechanical stimulation. This theory explains the effects of cold stimulation and vibration by suggesting that pain signals from the peripheral nervous system are modulated by a gating system in the spinal cord. Non-painful stimuli, such as vibration or prolonged cold, can block pain signals by activating faster non-noxious nerves, while cold may also enhance supraspinal mechanisms, increasing the body's pain threshold. The Buzzy device has previously shown to effectively reduce pain during venipuncture in pediatric population [6-8].

This study aimed to evaluate the impact of external cold and vibration, delivered through the Buzzy device, on pain and anxiety levels in children undergoing peripheral IV cannulation.

METHODS

Children aged between 3 to 18 years, who were hospitalized and required an IV access in the Pediatric Infectious Diseases and Pediatric Surgery wards of our tertiary care hospital, were prospectively recruited. Patients were randomized based on the order of admission into two groups: one received the vibrating cold device (VCD), while the other received topical lidocaine (TL). Critical patients, children with local infection or abrasions at IV insertion site or those with neurological or other disorders (e.g., Raynaud disease) causing decreased sensation in the extremity were excluded. Participation in the study required informed consent from both the patient and their caregiver, and the study was approved by the local ethical committee.

Data collected included the patient's age, gender, main complaint, caregiver's identity and age, use of any analgesic medication in the previous 24 hours, history of any previous IV cannulation, time since the last IV cannulation, and the pre-procedure Faces Pain Scale-Revised scale (FPS-R) scores. The FPS-R scale consists of six facial expressions, scored from 0 to 10, with higher scores indicating greater pain. Children were asked to select the facial expression that best presented their pain level.

Nurses with at least one year of experience in pediatric IV placement participated in the study. For patients in the TL group, topical lidocaine was applied to potential IV sites at least 30 minutes before the procedure. For the VCD group, the nurse applied the cold pack to the IV site and activated the vibration device 15-30 seconds before IV insertion, keeping it in place until the IV cannula was secured.

Post-procedure, data on the insertion site, procedure duration, number of attempts, and FLACC (Face, Legs, Activity, Crying, Consolability) scores were recorded. The FLACC scale assesses acute pain in children by assigning a score between 0 and 2 across five categories, with higher scores indicating greater pain.

After the intervention, both the nurses performing the IV cannulation and the caregivers completed a survey to evaluate their satisfaction with the Buzzy device. A Likert scale was used for responses. Caregivers were asked about their satisfaction with the IV insertion, the likelihood of reusing the method, and willingness to recommend it to others. Nurses were asked whether the method effectively managed pain, whether it interfered with IV insertion, and whether they would recommend it to patients and families.

In the study "Cold Vibration (Buzzy) Versus Anesthetic Patch (EMLA) for Pain Prevention during Cannulation in Children: A Randomized Trial" by Bourdier *et al*., [8], pain scores were 7.2±2.4 in the Buzzy System group (n=302) and 8.5±2.4 in the control group (n=305), with an effect size of d=0.52. Using the G*Power program, the sample size for this study was calculated as d=0.52 for two independent groups, with 5% types I error and 80% power, requiring a total of 120 participants. Sociodemographic data and FPS-R scores were analyzed using descriptive statistical tests. The Shapiro-Wilk test was used to assess the normality of data distribution. Group parameters were compared using the Kruskal-Wallis test, while chi-square and t-tests were applied to parametric data and group characteristics. A p-value of <0.05 was considered statistically significant.

RESULTS

We included and randomized 75 children in each group to account for potential dropouts. Due to

non-compliance by patients and their caregivers (e.g., with treatment protocols or satisfaction surveys), 60 children in each group completed the study and were included in the analysis. Prior to the IV insertion procedures, the groups did not differ in terms of age, gender, use of analgesic medication in the previous 24 hours, history of previous IV cannulation, or duration since the last IV cannulation (Table 1). However, the main complaints of the patients differed between the groups. The number of patients undergoing surgery was higher in the TL group, while complaints such as cough, abdominal pain, and vomiting±diarrhea were more frequent in the VCD group (p<0.001). The median age of the caregivers was higher in the TL group (p=0.01). While the percentage of mothers was similar between the groups, none of the patients in the TL group had a caregiver other than their parents, and none of the caregivers in the VCD group were fathers (p=0.003). Patients in the VCD group had higher median FPS-R scores before venipuncture (p<0.001).

The distribution of cannula insertion sites was similar between the groups, and although the procedure duration was shorter in the VCD group, the difference was not statistically significant (Table 2). The number of venipuncture attempts was significantly lower in the VCD group (p<0.001). Patients in the VCD group also had lower median FLACC scores (p<0.001). Caregivers of patients in the VCD group reported higher satisfaction levels compared to the TL group regarding the method, likelihood of reusing the method, and recommending it to others (p<0.001). Similarly, nurses reported higher satisfaction scores with the VCD method in terms of pain relief, comfort during IV insertion, and recommending the method to other patients and families (p<0.001) (Table 2). No side effects were observed in either group during the study period.

Table 1: Demographic and clinical properties of the patients before the procedure

	TL (n=60)	**VCD (n=60)**	**P**
Age, months, median(IQR)	108(80)	127(66)	0.53
Male gender, n(%)	28(46.7)	31(51.7)	0.58
Main complaint of the patient, n(%) Operation Fever Cough Abdominal pain Vomiting±diarrhea Headache	 40(66.7) 8(13.3) 0(0) 6(10) 0(0) 6(10)	 34(56.7) 0(0) 7(11.7) 12(20) 7(11.7) 0(0)	 **<0.001**
Caregiver Mother Father Grandmother, grandfather, aunt, etc	 54(90) 6(10) 0(0)	 56(93.3) 0(0) 4(6.7)	 **0.003**
Age of the caregiver, years, median(min-max)	43(32-50)	41(25-48)	**0.01**
Analgesic medication in previous 24 hours, n(%)	16(26.7)	20(33.3)	0.42
Previous IV cannulation, median(IQR)	1(2)	2(2)	0.07
Duration since the last IV cannulation, hours, median(IQR)	24(24)	72(72)	0.16
FPS-R scores, median(min-max)	0(0-2)	1(0-10)	**<0.001**
IQR, interquartile range; min, minimum; max, maximum; IV, intravenous; FPS-R, Faces Pain Scale-Revised scale			

Table 2: Clinical properties of the patients during and after the procedure and postprocedure outcomes

	TL (n=60)	**VCD (n=60)**	**P**
Location of the canula, n(%) Dorsum of the hand Antecubital region Neck Others	 36(60) 24(40) 0(0) 0(0)	 28(46.7) 32(53.3) 0(0) 0(0)	 0.14
Duration of this procedure, minute, median(IQR)	1(4)	1(1)	0.06
Number of attempts in this procedure, median(IQR)	1(1)	1(0)	**<0.001**
FLACC scores, median(min-max)	2(2-8)	2(0-4)	**<0.001**
Satisfaction scores of caregivers (% of agree/strongly agree) Satisfied with this method Would reuse this method Recommend this method to others	 27(45) 42(70) 23(38.3)	 60(100) 60(100) 60(100)	 **<0.001**
Satisfaction scores of nurses (% agree/strongly agree) The method is good for pain The method did not affect IV insertion Recommend this method to patients/families	 25(41.7) 32(53.3) 30(50)	 60(100) 60(100) 60(100)	 **<0.001**
IQR, interquartile range; min, minimum; max, maximum; IV, intravenous; FLACC, The Face, Legs, Activity, Crying, Consolability scale			

DISCUSSION

In this randomized prospective study, the Buzzy device was shown to provide significant advantages for patients compared to topical lidocaine. However, it remains unclear whether the effectiveness of the Buzzy device stems from its vibration, its cooling effect, or a combination of both, as evidence supports the efficacy of each mechanism. Patients using the device had lower FLACC scores compared to those who received TL before venipuncture in this study. A study by Simoncini *et al*., [6], compared the Buzzy device with no intervention during venipuncture and demonstrated that the device effectively reduced pain in children. Similarly, a recent meta-analysis revealed that the Buzzy device significantly reduced pain responses and anxiety scores compared to no intervention in children under 12 years of age during needle-related procedures [9]. Additionally, self-reported anxiety levels were found to be lower in patients using the Buzzy device compared to those using virtual reality (VR) [9]. Another systematic review and meta-analysis concluded that the Buzzy device was as effective as VR in relieving pain and anxiety during venipuncture [10]. However, some studies have reported conflicting results. In a study by Potts *et al*., [11], the authors compared the Buzzy device with topical lidocaine, as in our study, and found no superiority of the Buzzy device in reducing pain and distress for children undergoing IV catheter insertion. The FLACC scores for both groups were reported to be similar. Similarly, Semerci *et al*., [12], reported that the Buzzy device was ineffective in reducing pain. In another study, the Buzzy device was compared with cold spray for their effects on reducing pain, anxiety, and fear in children during venipuncture [13]. While cold spray was found to be more effective than the Buzzy device, both interventions were more effective than standard care in reducing pain, anxiety, and fear in children.

In our study, we demonstrated that caregivers of patients in the VCD group reported higher satisfaction levels compared to those in the TL group regarding the method, likelihood of reusing the method, and recommending it to others. Additionally, nurses reported higher satisfaction scores with the VCD method in terms of pain relief, comfort during IV insertion, and recommending the method to other patients and families. However, Potts *et al*., [11], found no significant differences between the groups in terms of caregiver or nurse satisfaction. In a recent review of the literature, no definitive conclusions were drawn regarding satisfaction levels when comparing the Buzzy device to virtual reality [10]. Nevertheless, it was observed that the Buzzy device reduced parental and observer-reported pain and anxiety compared to distraction cards [9].

The literature review also indicated that the first puncture attempt success rate for children using the Buzzy device was not significantly different from other interventions. However, in our study, we found that the number of venipuncture attempts was lower in the VCD group compared to the TL group [9]. Although the procedure duration was shorter in the VCD group, we did not observe a statistically significant difference between the groups in this regard. In contrast to our findings, Potts *et al*., [11], reported no significant differences in the success rate of IV catheter insertion on the first attempt. However, they noted that the IV cannulation procedure was completed more quickly in patients using the Buzzy device compared to those using topical lidocaine.

No adverse effects were observed in our study, consistent with the data reported in the literature [9]. Our study demonstrated that the Buzzy device was effective in children aged 3 to 18 years but did not provide data for children under 3 years of age. However, another study that included patients aged between 29 days and 18 years found the device to be effective in controlling pain and anxiety in younger children as well [6].

Our study highlighted the beneficial effects of the Buzzy device during IV cannulation. Existing evidence also supports the effectiveness of the Buzzy device for children undergoing intramuscular injections [14, 15], routine vaccine injections [16], insulin injections [17], and even dental procedures [18]. Some pre-procedural characteristics of the two groups in our study, such as the main complaints of the patients, the median age of the caregivers, and the distribution of caregivers, were different. Although it would have been preferable to have no differences between the groups, randomization of the study prevented this, and these differences were not considered to have a significant impact on the study's results. Patients in the VCD group had higher median FPS-R scores before venipuncture; however, their FLACC scores were lower after IV cannulation. This demonstrates the effectiveness of the Buzzy device.

CONCLUSIONS

The Buzzy device is affordable, easy to use, and suitable for routine use in blood-drawing centers. It also represents a cost-effective and simple strategy for managing routine needle-related procedures in children. Medical interventions are constantly evolving, with new methods being introduced every day. Managing pain during procedures and addressing needle phobia are critical for ensuring patient cooperation. Therefore, new studies, developments, and management strategies will continue to emerge. However, as shown in both the literature and our study, the Buzzy device remains one of the most effective methods available.

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