pISSN 2320-6071 | eISSN 2320-6012

Original Research Article

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20233036

A study to evaluate the effectiveness of local cold application on pain response during intravenous cannula insertion among children 6-12 years admitted in selected hospitals at Indore

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Received: 21 August 2023 Revised: 14 September 2023 Accepted: 15 September 2023

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ABSTRACT

Background: Hospitalized children commonly experience pain and anxiety as the most prevalent adverse stimuli. One of the most alarming and distressing causes of pain and anxiety that is frequently reported is venipuncture. The objective of this study was to evaluate the impact of cold and thermomechanical stimulation on pain and anxiety levels experienced by pediatric patients during intravenous (i.v.) cannulation.

Methods: This study aimed to assess the efficacy of cold and thermo mechanical stimulation in reducing anxiety and pain experienced by children during intravenous (i.v.) cannulation through a prospective case-control design. Children age 3-12 years and requiring i.v. cannulation were included. Children's level of anxiety and pain was assessed using the children's fear scale (CFS) and Wong-Baker faces pain scale (WBFS).

Results: Mean scores of the self- reported procedural level of pain were less in the intervention group as compared to the control group $(2.80\pm1.86, 7.47\pm2.40)$. Median of procedural pain level showed a significant difference between the intervention and control group at p<0.001, inferring that the cold and thermomechanical strongly resulted in a reduction of perception of pain during the cannulation procedure.

Conclusions: The research provided evidence in favor of the cold and thermomechanical as a promising non-pharmacological intervention for pain reduction during the process of intravenous cannulation.

Keywords: Anxiety, Children, Cold, Intravenous cannulation, Pain, Thermomechanical stimulation

INTRODUCTION

According to the International Association for the study of Pain (IASP), pain is characterized as an adverse sensory and emotional encounter that is linked to real or potential harm to bodily tissues. The phrase "pain: as the fifth vital sign" was coined by the American Pain Society with the intention of enhancing awareness regarding pain assessment, particularly among healthcare professionals, specifically nurses. The underlying justification is that if pain were evaluated with the same level of significance as other vital signs, it would be more likely to receive optimal treatment. The perception of pain is subjective

and can vary among individuals. It is influenced by social learning and personal experiences. Furthermore, the experience of pain is multifaceted and encompasses various factors. In Silkman's work in 2008, an exploration was conducted on the intricate nature of pain, encompassing various dimensions such as physiological, sensory, behavioural, socio-cultural, cognitive, and affective aspects. The physiological dimension encompasses the patient's subjective perception of pain as well as the body's response to the stimulus. The sensory dimension pertains to the subjective perception pain quality and intensity. This dimension encompasses the patient's subjective perception of pain,

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including its location, intensity, and quality. The behavioural dimension pertains to the verbal and nonverbal behaviours exhibited by patients in response to pain. The social-cultural dimension pertains to the impact of the social context and cultural background on an individual's experience of pain. The cognitive dimension pertains to the beliefs, attitudes, intentions, and motivations associated with pain and its management. The affective dimension pertains to the subjective experience of pain, encompassing feelings and emotions associated with it.³

Venepuncture is a frequently encountered medical procedure among hospitalized children, with a significant number of children undergoing this procedure, resulting in substantial distress. Children who are in need of needle sticks, such as intramuscular injections, intravenous catheters, and blood sampling, perceive this procedure as intimidating and a notable cause of discomfort.^{4,5}

The annual usage of peripheral intravenous catheters in the United States is estimated to be around 200 million. Additionally, findings from the Scottish National Prevalence Survey indicate that approximately one in three hospitalized patients in the UK have at least one peripheral venous catheter in place. Assessing pain in pediatric patients presents a complex task for healthcare professionals, particularly nurses. In order to effectively manage pain, it is imperative to first conduct a thorough assessment of the pain. The pain assessment process commonly incorporates three fundamental dimensions, namely self-report of pain intensity, behavioral reactions, and physiological reactions.

The process of pain assessment involves the systematic evaluation of the individual's self-reported pain experience, along with an examination of the various factors that either alleviate or worsen the pain. Additionally, the assessment also includes an analysis of the individual's response to pain treatment interventions. The way individuals respond to pain exhibits significant variation, influenced by a multitude of physical and psychological factors. These factors include specific diseases and injuries, the individual's overall health, their pain threshold, levels of fear and anxiety, as well as their cultural background.⁷

Due to the inherently subjective nature of pain, it is imperative to employ a valid scale that takes into account various factors such as the child's age, cognitive abilities, type of pain, and contextual circumstances when measuring pain. It is important to note that there is no universally applicable scale that can effectively assess pain in all children across various pain types. Self-report facial scales are commonly employed for assessing pain intensity in children aged 3 years and above, despite existing concerns regarding the interpretability of the results. The facial expressions encompass a spectrum that spans from a countenance displaying happiness to one exhibiting sorrow and tears. Each face is assigned a

numerical rating ranging from 0, indicating "no hurt", to 10, indicating "hurts worst". 8,9 The measure also demonstrates satisfactory psychometric properties in terms of reliability and validity. Additionally, it is characterized by its ease of use and efficiency. Notably, consistent findings indicate that children, parents, and practitioners exhibit a preference for this particular facespain scale in comparison to alternative options. 10 The alleviation of pain is a fundamental necessity and entitlement for all children. To ensure effective pain management, healthcare practitioners, including nurses, must be open to employing various interventions in order to attain the most favorable outcomes. Pain-reducing methods can be broadly classified into two distinct non-pharmacologic categories: interventions pharmacologic interventions. Whenever feasible, it is recommended to utilize both pharmacologic and nonpharmacologic approaches. Non-pharmacologic interventions serve as alternatives to analgesics and encompass behavioral-cognitive techniques such as distraction, relaxation, biofeedback, thought stopping, positive self-talk, guided imagery, as well as biophysical interventions like massage, pressure, transcutaneous electrical nerve stimulation (TENS), and application of heat and cold.¹¹⁻¹³ The application of cooling methods, including cold water, spray, air, ice cubes, and frozen gel packs, is commonly employed to alleviate discomfort and mild pain resulting from various causes, such as acute soft-tissue injury, injections, nerve blocks, the insertion of intravenous catheters, and laser therapy. A limited number of local side-effects and no systemic side-effects have been documented in the literature.14 Nonpharmacological pain management, which involves the integration of nursing actions and therapeutic techniques, has been shown to reduce costs and mitigate potential adverse effects associated with the administration of medications and invasive interventions. 15

METHODS

Study design and period

It was a prospective case-control design that took place from January 2022 to June 2023, i.e. 18 months.

Source of data

Data was collected from department of pediatric nursing, Sri Aurobindo Collage of Nursing, SAU University, Indore.

Sample size

120 patients were enrolled, 90 were males and 30 females.

This study aimed to assess the efficacy of cold and thermo mechanical stimulation in reducing anxiety and pain experienced by children during intravenous (i.v.) cannulation through a prospective case-control design.

The present investigation encompassed individuals who were admitted to the pediatric units of a tertiary care hospital. The participants were obligated to satisfy the established eligibility conditions: i) children between the ages of 3 and 12, ii) patients who need intravenous cannulation, iii) patients who are experiencing their first intravenous cannulation procedure. The exclusion criteria utilised in this study were as follows: i) individuals who exhibited break or abrasion on the skin in the area where the device was intended to be positioned, experienced nerve damage in the afflicted limb, suffered from acute or chronic disease, or had neurodevelopmental delay, ii) individuals experiencing persistent pain resulting from an injury or medical condition, individuals who have consumed any pain-relieving medication within the past six hours, and individuals who have previously fainted during a procedure involving needles; and iii) individuals who have previously been exposed to a device that combines both cold and vibration approaches.

Children's fear scale (CFS)

The method employed to assess the degree of anxiety in children prior to and during intravenous cannulation is a standardized visual cartoon scale. face aforementioned 5-point scale encompasses a range of facial expressions that depict varying degrees of fear, ranging from complete absence of fear (0) to a slight sense of fear (1), followed by a slightly heightened level of fear (2), a further increase in fear (3), and culminating in the highest level of fear (4). The study evaluates the self-reported anxiety levels of children undergoing i.v. cannulation. Participants were directed to observe a set of facial expressions and select the one that best represents their level of fear during the needle insertion. Additionally, the video footage captured during the process was assessed by another registered nurse to further evaluate anxiety levels. The tool underwent a translation process to facilitate comprehension for selfreporting purposes in the local language. Subsequently, its reliability was evaluated using the inter-rater method, yielding a correlation coefficient of 0.75.

Wong-Baker faces pain scale (WBFS)

The employment of a standardized visual cartoon face scale tool is common practice in evaluating the level of pain experienced by children during intravenous cannulation procedures. The pain intensity scale consists of six points, each represented by a facial expression indicating varying degrees of pain. These points range from no pain experienced at all (0), to a slight sensation of pain (2), a slightly increased level of pain (4), a further increase in pain (6), a significant amount of pain (8), and finally, the most intense level of pain (10). The study evaluated the self-reported pain intensity experienced by children during i.v. cannulation. Participants were

directed to observe a series of cartoon expressions and select the one that best represented the level of pain they felt during the needle insertion. Additionally, the video footage captured during the process was utilized to assess pain levels by an independent observer. In order to enhance comprehension and facilitate self-reporting, the descriptions of the instrument were translated into the local language. Subsequently, the reliability of the tool was evaluated using the inter-rater method, yielding a correlation coefficient of 0.90. The identification of individuals requiring intravenous cannulation was determined by their prescription for intravenous medicine and infusion. The participants were escorted to a designated procedure room where they underwent the process of cannulation. They were positioned in a supine posture while ensuring continuous communication and visual observation with the nursing staff present in the procedure room. One trained nurse provided vein assessment by holding the child's hand, while another registered nurse prioritized patient safety.

The following steps were used for i.v. cannulation: i) identification of a suitable site (ideally dorsal and antecubital fossa of the hand) and size, ii) a tourniquet was applied proximal to the selected site and cleaned with an alcohol swab, iii) the cannula was inserted at an angle of 10-15 degrees to the skin with the bevel upright, just distal, and along the line of the vein, iv) stylet removed and secured the cannula.

I.v. cannulation procedure was considered successful if blood started running into an i.v. needle. If the cannulation was not successful at the first attempt, then the second attempt was made.

RESULTS

The study's sample consisted of 120 participants, comprising 90 males and 30 females. The average age of children in the intervention group was 8.80±2.90 years, while in the control group, it was 8.10±2.41 years. No statistically significant differences were found between the intervention and control groups in terms of demographic characteristics, as shown in Table 1. Research hypothesis 1: the degree of pain experienced. The pain levels of the two groups are presented in Table 1. The study revealed that the self-reported procedural pain level (mean±standard deviation: 2.80±1.86) and the pain level determined through video analysis (mean±standard deviation: 4.00±2.46) were significantly lower in the intervention group compared to the control group (mean±standard deviation: 7.47±2.40, 7.67±2.57, respectively). Research hypothesis 2: the impact of anxiety levels- the statistical analysis reveals a significant difference between the levels of anxiety before the procedure and during the procedure, with a p value of 0.016 (Table 2).

Table 1: Demographic characteristics of children.

Variables		Case group (n=60) N (%) or M±SD (Min-max)	Control group (n=60) N (%) or M±SD (Min-max)	Fisher's exact test	df	P value
Age (years)		8.80±2.90 (3-12)	8.10±2.41	02.37	04	0.70
Gender	Male	46 (77%)	44 (73%)	00.01	01	1.00
	Female	14 (23%)	16(27%)	00.01		
Site of venous	Dorsal	56(93%)	52 (87%)	00.30	01	1.00
access (in hand)	Antecubital	4 (07%)	8 (13%)	00.30		
Number of	1	56 (93%)	48 (80%)	01.02	01	0.85
attempts	2	4 (07%)	12 (20%)	01.02		
Self-reported procedural pain		2.80±1.86 ^a	7.47±2.40 ^b	-		0.59
Video analyzed procedural pain		4.00±2.46 ^a	7.67±2.57 ^b			0.06

df = degrees of freedom; M = mean; Max = maximum; Min = minimum; n = number; SD = standard deviation. ^aRange score: 0-8; ^bRange score: 2-10.

Table 2: Comparison of the pre-procedural and procedural level of anxiety.

Particular	Median (IQR)	Z-value ^a	p value	
Control group (n=60)			•	
Pre-procedural	0 (0-2)	2.04	0.003*	
Procedural	2 (0-3)	-2.94	0.005**	
Case group (n=60)				
Pre-procedural	0 (0-1)	2.55	0.200	
Procedural	1 (0-2)	-2.55	0.208	

^aWilcoxon signed rank test. *Significant at (p<0.05). IQR = interquartile range

Table 3: Comparison of self-reported and video analyzed the procedural level of anxiety and pain.

Variables		SR	VA	Man- Whitney-U	Z-value	P value
		Median (IQR)		Maii- Willing-U	Z-value	r value
Case group (n ₁ =60)	Anxiety	1 (0-2)	0 (0-2)	416.00	-0.53	0.59
	Pain	2 (2-4)	4 (2-6)	335.00	-1.77	0.07
Control group	Anxiety	2 (0-3)	3 (0-4)	325.00	-1.90	0.06
(n ₂ =60)	Pain	8 (6-10)	8 (7-10)	416.00	-0.52	0.59

Hence, it can be inferred that a significant decrease in anxiety levels was observed in both the intervention and control groups throughout the course of the procedure. A comparison was conducted between self-reported and video-analyzed procedural levels of anxiety. The results indicated that there was no significant difference between the anxiety levels reported by the child and those interpreted from the video. This finding was consistent across both the intervention and control groups, with p values of 0.59 and 0.06, respectively. Furthermore, the study conducted a comparison between self-reported and video-assessed procedural pain levels. The results indicated that the levels of anxiety reported by the child and observed in the video were found to be significantly similar in both the intervention and control groups. The p values for these comparisons were 0.07 and 0.59, respectively, as shown in Table 3.

DISCUSSION

Pain is frequently experienced during invasive procedures conducted within a hospital setting, which can elicit fear and anxiety in patients. Specifically, needle anxiety has been identified as a significant factor contributing to worry. 16,17 Anxiety and pain frequently occur during hospitalization, particularly during the process of i.v. cannulation. Undoubtedly, pediatric nurses and healthcare professionals face a significant obstacle when it comes to performing painless cannulation in children. Both the children themselves and their family members express a strong desire for a pain-free experience during the cannulation process. 18-20 The alleviation of anxiety and pain can contribute to improved clinical outcomes.²¹ According to the American Society for Pain Management Nursing, it is recommended that adequate pain management be administered prior to and during any

procedure that may cause pain. 22,23 Therefore, it is recommended to implement measures aimed at reducing pain, particularly non-pharmacological interventions, in order to effectively manage pain and alleviate anxiety levels in pediatric patients. The purpose of this study was to investigate the efficacy of cold stimulation, administered through a device, in reducing pain and anxiety levels among pediatric patients undergoing i.v. cannulation. A total of sixty children were included in the study. The average age of children in the intervention group was 8.80±2.90 years, while in the control group it was 8.10±2.41 years. The majority of the children were admitted with a preliminary diagnosis pertaining to gastrointestinal disorders, accompanied by fever and respiratory issues. The dorsal region of the hand was the most frequently selected site for intravenous cannulation in both groups. The majority of cannulations were successfully completed on the first attempt, although 7% and 20% of participants in the intervention and control groups, respectively, required a second attempt for successful cannulation. According to the findings of Redfern et al and Susam et al, the average pain score reported by children was considerably lower compared to the control group $(3.56 \text{ versus } 5.92, p=0.015).^{24,25}$ However, there was no observable effect on anxiety levels when evaluating the efficacy of Buzzy in the context of vaccination. In a similar vein, the current study found no statistically significant impact of cold and thermomechanical stimulation on anxiety levels in children undergoing i.v. cannulation when comparing the intervention and control groups. Nevertheless, the research conducted by Susam et al and Canbulat et al revealed that the intervention group exhibited a substantially lower level of anxiety (0.58 versus 0.73) compared to the control group (p=0.001).^{25,26} These findings contradict the results of the present study. A comparison was conducted between the median selfreported and video-assessed procedural pain levels among children during i.v. cannulation. The results indicated that the levels of anxiety reported by the kid and those analyzed by video were found to be considerably similar in both the intervention and control groups. Moadad et al and Baxter et al both reported comparable findings, indicating that there was no significant distinction between the median self-reported pain levels (0, p=0.28) and the median behavior observed in children during cannulation (0, p=0.77).^{27,28} Significantly, the present investigation demonstrated a noteworthy reduction in both pain and anxiety levels with the utilization of the aforementioned equipment.

CONCLUSION

The research provided evidence in favor of the device as a promising non-pharmacological intervention for pain reduction during the process of intravenous cannulation. While the gadget did not yield a substantial effect on the procedural anxiety experienced by children, the utilization of both cold and thermomechanical stimulation demonstrates an optimal approach in mitigating pain. The

aforementioned device exhibited characteristics that facilitated ease of use, reusability, time efficiency, and expeditious pain relief, thereby effectively mitigating discomfort experienced by pediatric patients during the process of intravenous cannulation. However, it is imperative to evaluate the prevailing circumstances, such as the limited availability of resources in each institution and the financial implications associated with them. The study's findings suggest that it would be beneficial to establish policies and practices for the utilization of a combination of external cold and thermomechanical stimulation, specifically through the use of a device, therapeutic settings. Additional investigations could be undertaken using a more extensive sample size in order to enhance the validity and credibility of the findings. Research can be conducted to assess the most suitable age for the application of the device. Additionally, it is recommended to conduct research in order to assess the satisfaction of both parents and nurses with the gadget, as well as to evaluate the impact of physiological parameters.

ACKNOWLEDGEMENTS

Owe my heartfelt gratitude and indebtedness to Dr. Prerna Pandey- Professor and HOD (department of pediatric nursing, Sri Aurobindo Collage of Nursing and dean of faculty, SAU University, Indore) for his active help, guidance and valuable suggestions.

Funding: No funding sources Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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Cite this article as: Daya RP, Pandey P, Daya MJ. A study to evaluate the effectiveness of local cold application on pain response during intravenous cannula insertion among children 6-12 years admitted in selected hospitals at Indore. Int J Res Med Sci 2023;11:3785-90.