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Pawandeep Kaur
Lecturer, Guru Gobind Singh College of Nursing, Barnala, Punjab, India

Navjot Kaur
a. Assistant Professor, College of Nursing, Dayanand Medical College and Hospital, Ludhiana, Punjab, India (During Study)
b. Assistant Professor College of Nursing, AIIMS, Deoghar, Jharkhand, India (Present affiliation)

Corresponding Author:
Navjot Kaur
A. Assistant Professor, College of Nursing, Dayanand Medical College and Hospital, Ludhiana, Punjab, India
B. Assistant Professor College of Nursing, AIIMS, Deoghar, Jharkhand, India

Effectiveness of using external cold and vibration on level of pain among children

Pawandeep Kaur and Navjot Kaur

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Abstract
Introduction: Pain is one of the most misunderstood, under-diagnosed, and under-treated/untreated medical problems, particularly in children. One of the most challenging roles of medical providers serving children is to appropriately assess and treat pain.
Objective: To assess the effectiveness of external cold and vibration on level of pain during intravenous cannulation among hospitalized children.
Study Design: A quasi-experimental research design was used.
Participants: Total 60 children in the age group of 4-12 years.
Intervention: External cold and vibration via "buzzy" one minute before, during and till one minute after the procedure.
Outcome: Level of pain measured with standardized FLACC behavioral assessment scale
Results: both the groups were homogenous in terms of socio demographic variables such as age, gender, religion, birth order, informer and socioeconomic status of parents with $p>0.05$. The mean pain score during IV cannulation in experimental group was lower (1.37±1.829) than control group (1.50±1.480) and this difference was statistically non-significant ($p >0.05$). One minutes after IV cannulation procedure, the mean pain score in experimental group was 0.00±0.00 while in control group was 0.07±0.254 ($p>0.05$).
Conclusion: The study findings revealed that external cold and vibration does not reduces the level of intravenous cannulation procedural pain significantly in children.

Keywords: Procedural pain, cannulation, hospitalized children

Introduction

Pain in hospitalized children

Pain is an unpleasant sensation that can range from mild, localized discomfort to agony [1]. The international association for the study of pain further states that pain is "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage," (IASP revised definition of pain) Pain is one of the most misunderstood, under-diagnosed, and under-treated/untreated medical problems, particularly in children. One of the most challenging roles of medical providers serving children is to appropriately assess and treat pain [2]. The hospitalization of a child can cause severe anxiety and stress in the parents as well as children [3]. Children with serious medical conditions are exposed to frequent painful diagnostic and therapeutic procedures (eg, bone marrow aspirations, lumbar punctures, and wound dressing changes). Furthermore, even healthy children have to undergo significant amounts of painful medical procedures throughout childhood. Vaccinations are the most commonly performed needle procedure in childhood, and pain is a common reason for vaccine hesitancy [4].

Childhood pain experiences

Acute pain is an expected physiological response to a noxious chemical, thermal, or mechanical stimulus, and usually accompanies surgery, traumatic injury, tissue damage, or inflammatory processes. It is self-limiting and typically resolves over days to weeks [5]. Strong painful procedures [6] or mild repeated procedures [7] may permanently modify individual pain processing. Acute injury at critical developmental periods is a risk factor for persistently altered neurodevelopment [8]. During normal development, transmission and pain modulation undergo rapid growth [9] Noxious stimuli during the childhood period may trigger unpredicted long-term epigenetic changes, which affect the brain, neurodevelopment, pain modulation, and pain reactivity into adulthood [7].

Health care professionals who care for children are mainly responsible for abolishing or assuaging pain and suffering when possible. The emotional, cognitive, and behavioral components of the pediatric patient are also important to assess pain and to simplify the management practices [10]. It critically depends on an in-depth understanding of the developmental and environmental factors that influence nociceptive processing, pain perception, and response to treatment during maturation from infancy to adolescence [11].

Assessment of pain

In the pediatric age, it is more difficult to assess and treat pain effectively relative to adults. The lack of ability to notice pain, immaturity of remembering painful experiences, and other reasons are the reflection of the persistence of myths related to the infant's ability to perceive pain [11].

The various pain assessment tools used to assess pain in children include: The FLACC scale, the observational pain scale, child's facial coding system, Faces Pain scale, etc. FLACC scale: In this scale, children are assessed for face, legs, activity, cry, and consolability. This tool is reliable and valid in assessing pain among children and adults who are unable or unwilling to report pain, it is quick to use and easily reproducible. However, it has not been validated among children with special needs, neonates, or ventilated children [12]. Further, it was developed to assess pain in children who are too young to co-operate verbally. It is a reliable and sensitive scale for assessing procedural pain. Inter-rater & Intra-rater reliability was 0.9 and 0.87 respectively. Sensitivity and specificity were found to be 94.9% and 73.5% respectively [13].

Management of pain

Several interventions like pharmacological and non-pharmacological measures are used to reduce painful experiences in children and to alleviate their distress during a needle prick. Pharmacological drugs provide adequate cutaneous analgesia for a variety of clinical situations. However, most of these formulations have reported adverse reactions [14]. Non-pharmacologic techniques are generally divided into physical and behavioral techniques. Physical techniques used for pain relief include, but are not limited to injections massage, and counter-stimulation. Behavioral techniques include music distraction, cartoon distraction, communication, and blowing into sphygmomanometer tubing [15].

External cold and vibration technique (via Buzzy) is a promising, cost-effective non-pharmacological technique in reducing pain and distress among children undergoing intravenous cannulation procedures. Buzzy is a bee-shaped device with detachable, refrigerable wings which provide external skin cooling and vibration. The efficacy of the buzzy device can be explained by gate control theory [16] and Descending Noxious Inhibitory Controls (DNIC). The gate control theory stipulates that the vibration component of the device blocks the A-delta and C-nociceptive fibers, by stimulating the A-beta non-nociceptive fibers. It activates an inhibitory interneuron and results in a reduction of the pain signal transmitted to the spinal cord. The cold component (prolonged cold application 30-60 sec) stimulates the C-nociceptive fibers and further blocks the A-delta nociceptive pain transmission signal [17]. More specifically, intense cold application stimulates the nociceptive C- fibers and activates the supra-spinal modulation which, in turn, increases the body's overall pain threshold and therefore produces a generalized hypoalgesia at the insertion site [18]. A study conducted in the cancer center of Lebonon (2015) on children between the ages of 4 to 12 years assigned to either an intervention (n=25) or a control group (n=23). Pain scores were significantly lower in the buzzy group of children (mean ± SD 3.04±2.62) as compared to the control group (mean ±SD 4.90±2.22) as assessed by the nurse. Mean pain in the experimental group was 3.50±2.86 and in the control group was 4.95±3.22 as assessed by parents [19].

Effect of child characteristics on pain

Certain child characteristics can affect the behavioral pain perception among children, according to Shrestha, & Jeneta 2018, there is a significant association of age, gender, previous hospitalization, and site of the cannula with behavioral pain response in the experimental group (receiving external cold and vibration) and significant association of gender, type of family, and history of the previous hospitalization with behavioral pain in the control group [20].

The present study is conducted to assess the effectiveness of using external cold and vibration on the level of pain among children undergoing intravenous cannulation and to find out the effect of certain child characteristics on pain perception.

Methods

Design & Sample

Quasi-experimental research (parallel-group, post-test only control group) design was used. The target population included all the hospitalized children between the age group of 4-12 years undergoing intravenous cannulation procedure. A total of 60 hospitalized children admitted in selected pediatric units fulfilling inclusion and exclusion criteria were selected. Random assignment of subjects into experimental group and control group was done. The Slip was picked up and the children were assigned to either the experimental or control group. Out of 60 hospitalized children, 30 children were taken in the experimental group (used cold and vibration via buzzy for 1 minute before, during and till 1 minute after intravenous cannulation procedure, user manual for the device advised to apply it 30 to 60 sec before the procedure and till the procedure lasts, moreover as per gate control theory the cold application for 30-60 sec stimulates the c-nociceptive fibers & blocks the A-delta nociceptive pain transmission signal) and remaining 30 children were taken in the control group (routine intravenous cannulation procedure).

Inclusion criteria for the study were hospitalized children in the age group of 4-12 years undergoing intravenous cannulation on the dorsum of the hand.

Exclusion criteria of the study were, children who were critically ill or unconscious, children who were under the effect of sedatives, children receiving more than one prick during intravenous cannulation, and had non-zero pain before the procedure.

Measures

To assess the effect of external cold and vibration (via buzzy) in reducing the level of pain during intravenous cannulation among hospitalized children at pediatric units, the investigator used a structured socio-demographic profile

questionnaire, clinical profile questionnaire, and FLACC-Behavioral Pain Assessment Scale.

Part A (I): Socio-demographic and clinical profile of child

The profile collected basic information related to hospitalized children like their age, gender, religion, informer, birth order as well as educational status, and socioeconomic status of parents ward of admission (Pediatric medicine, pediatric surgery, and thalassemia unit), type of admission, duration of hospitalization, any painful procedure within one hour before cannulation, and history of previous intravenous cannulation and year of experience of health personnel performing intravenous cannulation.

Part B: FLACC- Behavioral Pain Assessment scale (Lewis 2010)

It includes the observation of five parameters i.e. face, legs, activity, cry, and consolability, which indicates behavioral pain responses of the child. The parameters were categorized according to the behavioral response of the child. For each variable, a score of 0 to 2 was assigned. The maximum pain score of the tool was ten and the minimum was zero.

Score	Level of pain
0	No pain
1-3	Mild pain
4-6	Moderate pain
7-10	Severe pain

FLACC Assessment Process

At the time of the procedure, video-recording was done and later it was analyzed. The assessor rated the videos as per the FLACC scale and give scores to each video in both the experimental and control group. Based on those scores it was further analyzed whether the child had no pain, mild, moderate, or severe pain.

Reliability and validity of the measures

The reliability of the FLACC scale was calculated by using the inter-rater method and it was found to be 0.9. Two independent observers (Two pediatric nurses, for a sample of 6 patients in the pilot study) watched the videos and assess the level of pain using the FLACC scale and their observations were used to calculate the reliability by using the following formula:-

$$\frac{\text{No. of agreements}}{\text{No. of agreements} + \text{No. of disagreements}}$$

Ethical considerations

First of all, Approval from the institutional ethics committee was taken and the subject information sheet was provided to the parents in which the purpose of the study was clearly stated in their vernacular language, they can withdraw from the study anytime, the contact information of all the researchers was provided. Informed written consent was taken from the parents of the children. Children were also explained about the procedure and use of buzzy as per their level of understanding.

Plan of data analysis

Chi-square was used to check the homogeneity in the experimental and control group. Chi-square and independent t-test was applied to find out the statistical difference in pain among experimental and control group. For finding out the association of socio-demographic variables with pain among experimental and control group t-test and ANOVA was used.

Results

Socio-demographic characteristics: Both experimental and control groups were homogenous (same) and comparable in terms of age, gender, religion, informer, birth order, education level, and socioeconomic status of parents.

Near about half of children, i.e. 14 (46.6%) in the experimental group and less than one-fourth [7(23.4%)] children in the control group experienced no pain. A mild level of pain was experienced by 11 (36.7%) children in the experimental group as compared to 19 (63.3%) in the control group. Moderate level of pain was experienced by an equal number of children [4(13.3%)] from the experimental group and control group. A severe level of pain was experienced by only 01(3.3% children from the experimental group. At one minute after fixation of IV cannula, the majority of children i.e 30 (100%) from the experimental group experienced no pain as compared the to control group where it was experienced by 26(86.7%). No child from the experimental group experienced a mild level of pain as compared to 4 (13.3%) from the control group. (Table I)

The mean pain score during IV cannulation in the experimental group was lower [1.37(1.829)], than the control group [1.50(1.480)], and this difference was statistically non-significant (p=0.943). At one minute after fixation of IV cannula, the mean pain score in experimental group was lower than control group [0.07(0.254)]. Hence, it can be inferred that cold and vibration were not effective in reducing the mean level of pain among children during the IV cannulation procedure. (Table II)

The association of age, gender, and birth order of children in the experimental group and in control group, with pain was statistically non-significant. (p>0.05)

Table 1: Comparison of level of pain in experimental and control group N=60

Intravenous cannulation procedural pain assessment time	Group	No pain	Mild pain	Moderate pain	Severe pain	χ^2 value
Zero min (during intravenous cannulation*)	Experimental	14(46.6)	11(36.7)	4(13.3)	1(3.3)	5.467, df =3
	Control	7(23.4)	19(63.3)	4(13.3)	--	$p=0.140^{NS}$
At one min (After fixation of the cannula)	Experimental	30(100)	00	--	--	NA
	Control	26(86.7)	4(13.3)	--	--	

NS =Non significant Maximum pain score=10, Minimum pain score=0; NA= Not applicable

Table 2: Comparison of mean intravenous cannulation procedure pain scores among children in the experimental and control group. N=60

Intravenous cannulation procedural pain assessment time	Group	Mean (SD)	t value	p-value
Zero min (during Intravenous Cannulation)	Experimental	1.37(1.829)	0.3026	0.763^{NS}
	Control	1.50(1.480)		
One min. (after fixation of the cannula)	Experimental	0.00 (0.00)	NA	NA
	Control	0.07 (0.254)		

NS=Non-significant (p>0.05); Maximum pain score=10; Minimum pain score=0; n=30 in each group; NA= Not applicable

Discussion

The mean pain score during and one minute after the IV cannulation in the experimental group was less (1.37±1.829 during IV cannulation, 0.00 ± 0.00 one minute after the IV cannulation) as compared to the control group (1.50±1.480 during IV cannulation, and 0.07±0.254 one minute after the IV cannulation) however, this difference was statistically non-significant (p>0.05).

A study conducted by Redfern, Chen, & Sibrel (2017) on the effect of thermo-mechanical stimulation (buzzy) during vaccination on pain in pediatric patients failed to demonstrate a statistically significant benefit of buzzy for reducing procedural pain. The findings showed that the mean pain score during vaccination in the experimental group was lower (3.18±3.00) than the control group (4.48±3.00) and this difference was statistically non-significant (p>0.05) [21].

Another study conducted by Moadad, Kozman, Shahine, Ohanian, & Badr, (2015) on distraction using buzzy for children during an I.V insertion, in this randomized control trial (RCT), children between the ages of 4 to 12 years were assigned to either an intervention (n=25) or a control group (n=23) in the cancer center of Lebanon. Pain scores were lower in the buzzy group of children (mean ± SD 3.04±2.62) as compared to the control group (mean ±SD 4.90±2.22) as assessed by the nurse. Mean pain in the experimental group was 3.50±2.86 and in the control group was 4.95±3.22 as assessed by parents. This study also failed to demonstrate the statistically significant benefit of buzzy [19]. Statistically non-significant (p>0.05) association was found between selected socio-demographic variables in terms of age, gender, birth order with level of pain among children undergoing IV cannulation in the experimental and the control group.

The study findings are supported by Canbulat, Ayhan, & Inal, (2014) who did a study to assess the effectiveness of external cold and vibration for procedural pain relief during peripheral intravenous cannulation in pediatric patients. The findings showed that all the socio-demographic variables (gender, education, and informer) have no significant relationship with pain scores. The observer reported that p>0.05 [22].

Conclusion

The difference of mean pain score among the experimental and the control group was found statistically non - significant during and at one minute after the I/V cannulation procedure (p>0.05). Therefore the findings revealed that external cold and vibration were not effective in reducing the level of pain among the experimental group during the I/V cannulation procedure and at one minute after the I/V cannulation procedure. Limitations of the study are video recording during the I/V cannulation procedure was distracting the children, it can also have some impact on pain perception. Maximum children recruited in the study were admitted to the Thalassemia unit and observers were not blinded during pain assessment. It cannot be denied that the use of buzzy can be troublesome for some children. They may get disturbed by the sensation. This might have inflated the results. Children were not familiarized with buzzy before the start of the intervention. Only one minute before the IV cannulation procedure they were introduced to buzzy. This study recommends that buzzy is a promising intervention to be used during painful procedures like IV cannulation in children, some of the previous studies showed a significant reduction of pain with the use of this device.

What this study adds: Use of External Cold and Vibration did not reduce the pain perception significantly.

What is already known before: Using various distractions techniques during painful procedures in children help to reduce the perception of pain.

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