RESEARCH PAPER

Effectiveness of Ice Application in Reducing Venous Puncture Pain in Pediatric Patients: A Randomized Controlled Trial

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ABSTRACT

Background:Venous puncture is a routinely performed invasive procedure within the pediatric health context and is likely to cause pain, fear and anxiety. If procedures such as venous puncture are performed without adequately managing pain, this may result in the development of needle phobia, raising stress levels or cause an avoidance of seeking medical health later in life. Ice application or cryotherapy is a simple non-pharmacological technique that has gained recognition as a method of reducing procedural pain in children.

Objective:The objective of this study was to assess the effectiveness of pre-procedural ice application in reducing pain during venous puncture in children.

Methods:A randomized controlled trial was conducted over a period of four months. This trial was carried out at two hospitals in Punjab, Pakistan. Ninety-four children aged 5 to 7 years were randomly assigned to two groups. 47 children were assigned to the intervention group (ice application group) while other 47 children were assigned to the control group (standard care). The intervention group received ice application at the venous puncture site for three minutes before the procedure. While the control group underwent venous puncture without ice application. Pain intensity was assessed using the Wong-Baker Faces Pain Rating Scale (WBFPS). Pain was assessed both subjectively, by self-reported pain scores from children, and objectively, by observer-based evaluations of video recordings. Data were analyzed using SPSS version 24. Independent t-test and chi-square was applied to the data. A p-value $< .05$ was interpreted as statistically significant.

Results:Pain scores as self-reported by the children showed that the intervention group (ice application) experienced significantly lower score for pain compared to the control group (1.31 ± 1.31 vs. 8.29 ± 1.31; $p < 0.01$). The pain scores as recorded by the observer also showed a significant reduction in pain intensity in the intervention group (1.57 ± 1.12) when compared to that of the control group (8.59 ± 1.37; $p < 0.01$). No statistical differences were observed between the two groups in terms of their age, gender, or previous venous puncture experience.

Conclusion:In children, venous puncture pain can be reduced by pre-procedural ice application, which is an effective, safe, and low-cost intervention. The findings indicate that cryotherapy can be integrated into routine pediatric clinical practice to enhance procedural comfort and patient experience.

Keywords: Ice application, cryotherapy, venous puncture, pediatric pain, non-pharmacological intervention, randomized controlled trial

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INTRODUCTION

Venous puncture is probably the most common procedure undertaken within the health service worldwide and it can be performed for many reasons, e.g. to obtain a blood sample, for the infusion of IV fluids, to administer medications etcetera. Though venous puncture is common,

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there are often great issues associated with pain and discomfort. The problems associated with these phenomena are generally seen in pediatric patients. Children's experience of inadequately managed pain during venous puncture can cause negative and sometimes lifelong emotional sequelae such as fear, anxiety and fear of future health care providers and situations (Parameswaran, 2024; Walther Larsen et al., 2017). Pain is defined by the International Association for the Study of Pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" (Raja et al., 2020b). Pain has been referred to as the 'fifth vital sign', in recognition of its importance in patients' care and it should be managed adequately, as stated by the American Pain Society (Pozza et al., 2021). If pain in children is managed inadequately, they can experience an enduring pain state, a high stress response and a poorer relationship with health care providers. A positive pain experience in children can enhance their recovery rate and satisfaction with their care (Trottier et al., 2022; Ivanova, 2019).

Pain management interventions are divided into pharmacological and non-pharmacological strategies. Pharmacological treatments are popular; however their use can be influenced by factors such as cost, side effects, and fear of dependency and the use of drugs has resulted in great interest in the development of non-pharmacological pain management techniques (Alorfi, 2023). Ice application, known as cryotherapy, is an inexpensive and widely available method, it decreases the conduction of the nerve and thus reduces the pain by reducing the velocity of nerve conduction and inhibiting the afferent pain signals (Yutan et al., 2022). Many researches have illustrated the effect of ice on relieving pain. In one study conducted in Karad India it was found that ice application on the vein for three minutes before puncture decreased the intensity of pain among pediatric patients (Karale and Satve, 2015). A study conducted in Iran, a group using ice application prior to arterial puncture experienced less pain as compared to control group (Bastami et al., 2015); however, another study found that ice application was less effective than vapocoolant spray, during intravenous puncture (Waterhouse et al., 2013). Due to inconsistencies noted between some of these findings further research may need to be done.

While undertaking pain evaluation and management, nurses plays a crucial role but several factors like inadequate pain assessment, nurses' heavy workload and lack of standardized non-pharmacological pain management protocol hinder the adequate pain management (Carmona et al., 2019; Seldon, 2017). Improvement in implementation of non-pharmacological methods like ice application will significantly enhance pediatric pain management. This study purpose was to judge and establish a comparison of pain intensity between the group which receive ice application as intervention, and the group that will not receive any interventions other than the regular management during venous puncture.

Methodology

The design used in this study was a Randomized controlled trial (RCT). It aimed to compare pain intensity in children aged between 5 to 7 years old between intervention group receiving ice application and control group receiving standard procedure. The study was carried out in two hospitals of Punjab, Pakistan; namely: “the District Headquarter (DHQ) hospital Sheikhupura and the Tehsil Headquarter (THQ) hospital Muridke”. Duration of study was 4 months (July 2024 – October 2024). “The Advanced Studies and Research Board of the University of Health Sciences Lahore” granted permission prior to the research. It was registered on ClinicalTrials.gov as NCT06089889 and Unique Protocol ID was VPP RCT 001.

The study population comprised children who required venous puncture in the pediatric ward. Ninety-four children were enrolled using non-probability convenience sampling. Sample size was computed by using the formula for comparison of means of two independent groups with 95% confidence level and 90% desired power. Calculated sample size per group was 47 so two groups were formed; group A: intervention and group B: control. Group assignment was done by means of lottery method: each patient chose an opaque sealed card, which assigned to one of the groups. (Figure 1)

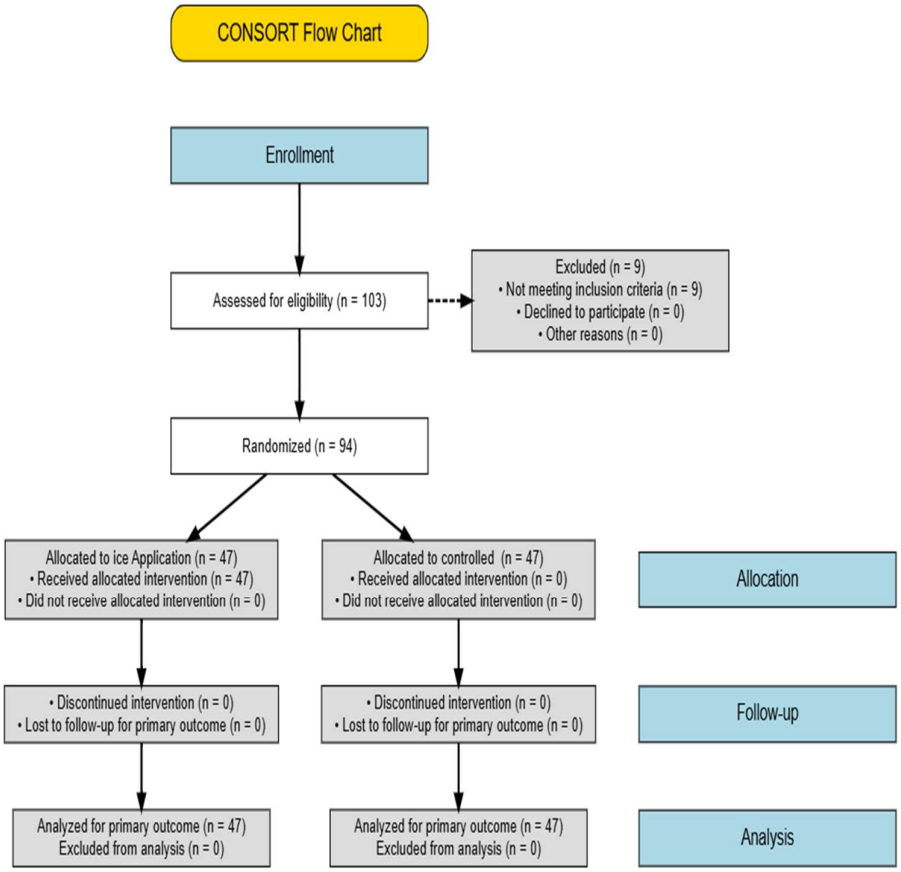

Figure 1: CONSORT Flow Diagram of Participant Enrolment and Allocation.

The inclusion criteria were children between 5-7 years of age undergoing a venous puncture. The exclusion criteria were chronic illnesses, mentally handicapped and already received local anesthesia at the venous puncture site.

Data collection was carried out by two main tools: a research proforma (for demographic data) and a pain rating scale namely the Wong-Baker Faces Pain Rating Scale (WBFPS). The WBFPS which was a validated tool used a pictorial measurement of the amount of pain ranging from a 0 (no pain) to 10 (worst pain).

The intervention group received ice application at the venous puncture site for three minutes before the procedure, using a frozen water-filled plastic zipper bag. The control group received standard care without ice application. A trained pediatric nurse, blinded to group assignments, recorded facial expressions during the procedure. Pain assessment was performed using both subjective self-reported pain evaluation by the children and objective evaluation by the researcher from analyzing the video recordings.

SPSS version 24 was used for analyzing the data. Descriptive statistics were figured out by computing the means and standard deviations. To check the data normality, the Shapiro-Wilk test was used. Chi-square test was conducted on the demographic variables of two groups. whereas an independent sample T-test was used to compare the means of two groups of children on pain rating scale. Results with a p-value <0.05 were deemed statistically significant.

Ethical approval was obtained, and informed consent was secured from parents/guardians, with child assent. Participants' anonymity and confidentiality were maintained, and they had the right to withdraw at any stage.

Results

A total of 94 children aged 5 to 7 years participated in this study, and randomly assigned to the intervention (n=47) and control (n=47) groups. The participant flow is summarized in Figure 2.

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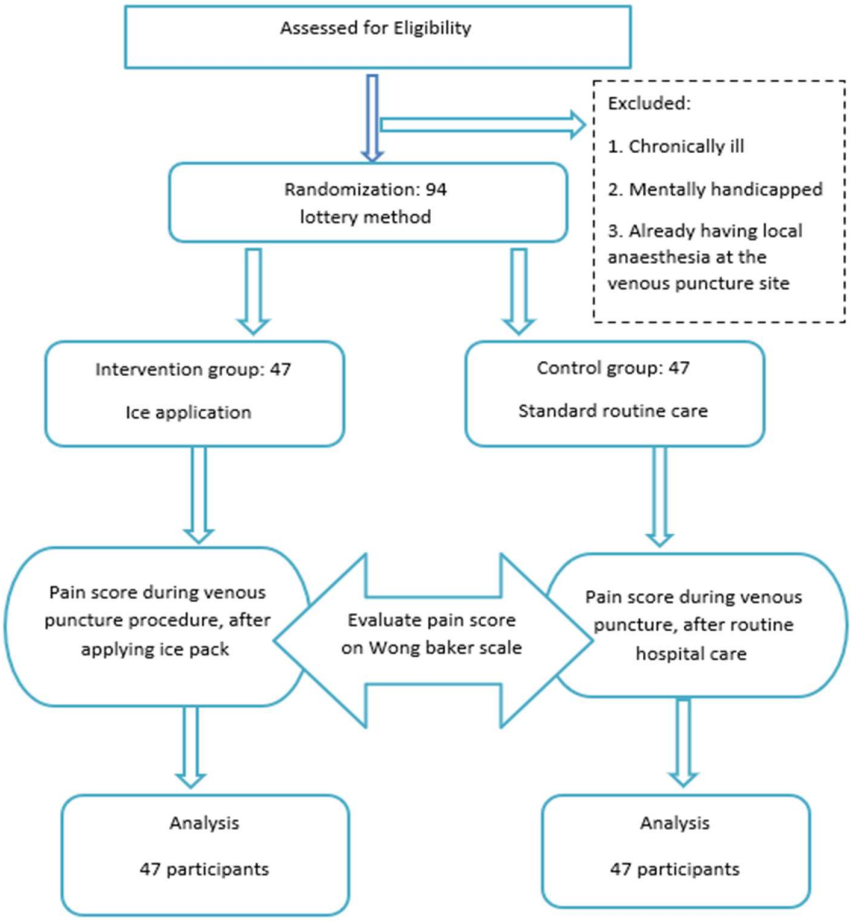

Figure 2: Diagrammed Explanation of Research Work

Demographic characteristics and their group differences are presented in Table 1.

Table 1: Sociodemographic Characteristics and Comparison Between Groups.

Variable		Categories	Total (n=94)	Intervention Group (n=47)	Control Group (n=47)	p-value
Age (years)		5–7	94 (100%)	7.6 ± 8.1	5.4 ± 0.5	0.07
Gender	Male	59 (63%)	31 (66%)	28 (56.6%)	0.797	
	Female	35 (37%)	16 (34%)	19 (40.4%)		
Previous Venous Puncture Experience	Yes	75 (80%)	38 (80.9%)	37 (78.7%)	0.797	
	No	19 (20%)	9 (19.1%)	10 (21.3%)		
Caregiver Presence	Father	22 (23%)	13 (27.7%)	9 (23.4%)	0.004	
	Mother	58 (62%)	22 (46.8%)	36 (61.7%)		
	Other	14 (15%)	12 (25.5%)	2 (14.9%)		

There were no statistically significant differences between either group with regard to age, sex, or history of previous IV puncture. Despite this, there was a statistically significant difference between the two groups in terms of the presence of a caregiver (p=0.004), which was found to be more frequently recorded in the control group and noted to more specifically be the mother. See (Graph 1) below.

Graph 1: Demographic Comparison between control and intervention

The main objective of the study was to evaluate the impact of ice application on perceived pain. The self-reported pain scores by children (reported in section 2.4) and observer recorded scores, demonstrated a decrease in pain scores following the application of ice in experimental group (p<0.01) (Table 2).

Table 2: Comparison of Pain Scores Reported by Children and Observer Between Groups

Pain Score Source	Intervention Group (Mean ± SD)	Control Group (Mean ± SD)	p-value
Children's Reported Score	1.31 ± 1.31	8.29 ± 1.31	<0.01
Observer-Recorded Score	1.57 ± 1.12	8.59 ± 1.37	<0.01

Baseline demographics and clinical characteristics of subjects are given in Figure 3. Groups are similar on age, gender and prior history of intravenous insertion. Only caregiver type demonstrated a significant difference in groups (p=0.004), and more mothers were present in the control group.

Graph 2: Baseline Characteristics Forest Plot.

The plot shows odds ratio (for categorical data) or mean difference (for age) with 95% confidence interval. All groups were similar with the exception of caregiver type (p=0.004).

Discussion

There is substantial evidence in the literature that supports this finding and concludes that ice application reduces procedural pain. Pain scores were significantly decreased in the intervention group (a difference of more than 80%) in comparison with control. This decrease in pain score was demonstrated consistently through both objective (observed) and subjective (self-reported) measurement.

This finding is supported by a large amount of literature that demonstrates that ice application decreases procedural pain. Studies by Karale and Satve (2015), Dani et al. (2019) and Ekawaty and Oktarina (2020) all used ice to decrease pain scores in children with consistent results in significant pain score reduction. The mechanism is believed to work by slowing down the conduction velocity of pain fibers through a decrease in metabolic activity, which serves as a topical analgesic effect (Yutan et al., 2022).

There were no differences noted in baseline characteristics of age, gender or experience with the procedure among groups, indicating an internally valid trial and a result caused by the intervention. The only notable difference between the groups was in the type of caregiver present (p=0.004) during procedure, which may have played some role in decreasing pain scores but likely had a minimal effect in relation to the overwhelming magnitude of the difference in pain scores (more than 7 on a 10-point scale). This finding is further supported by the similarity in results between the self-reported and observer reported pain scores.

The practice relevance is illustrated by emphasizing non-pharmacological intervention that can be utilized by nurses to relief pain and discomfort in children. Ice application is cheap, easy to implement and needs no pharmacological drugs or equipment, therefore could be of great advantage in areas with limited resources.

However, the randomized controlled design, standardized pain measurement, and combination of observer and self-reported pain indices improve the validity of the results.

Conclusion

It is clear that applying ice pre-procedure is an effective non-pharmacological method to alleviate pain associated with venous puncture in children. This study showed children who received ice application experienced less pain intensity than those receiving standard care. Cryotherapy is simple to implement and is safe, inexpensive, and easy to use and may be included as a routine intervention to enhance pain and procedural comfort in the pediatric setting. Studies with larger samples sizes and multi-center studies would provide additional information to further support ice effectiveness and utility in pediatric procedural pain management.

Declarations

The authors stated that they don't have any competing financial interests or personal relationships or conflicts that could seem to affect the reported findings in this paper.

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