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Original article

Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis

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ABSTRACT

Objective: To evaluate the effectiveness of cryotherapy in managing the pain at the puncture site of Arterio-Venous Fistula (AVF) among children undergoing maintenance hemodialysis (HD).
Methods: A one-group pre-post quasi-experiment was performed in two HD centers affiliated with Cairo University. The experiment involved 40 children with AVF undergoing HD. Before puncturing, cryotherapy was applied using 2 cm–3 cm pieces of frozen distilled water in a plastic bag. Pain was assessed subjectively and objectively in two dialysis sessions before and after cryotherapy. A part from a physiological assessment of vital signs, pain was assessed using the Wong–Baker Faces Pain and the Observed Pain Behavior rating scales. All research ethics were applied.
Results: HD had a median duration of four years, while cryotherapy had a median application time of 8.8 min. The Wong–Baker Faces Pain score and almost all observed pain behaviors significantly decreased after cryotherapy. Significant improvements were observed in respiratory rate before and after needle puncture and in oxygen saturation after needle puncture. A lower skin dryness was observed after cryotherapy (12.5%) than before cryotherapy (52.5%; $p < 0.001$).
Conclusions: Cryotherapy can effectively reduce the venipuncture pain among children with AVF undergoing maintenance HD. However, the confounding effects of distraction and the non-randomized design used must be both considered when interpreting the findings. This study recommends the use of cryotherapy in managing needle puncture pain. Further research must adopt a randomized trial design with a placebo to support further the benefits of this procedure.

1. Introduction

Children with arteriovenous fistula (AVF) and undergoing maintenance hemodialysis (HD) are exposed to an average of 10 AV fistula punctures a month, which is expected to continue for the rest of their lives [1]. These punctures are associated with pain and stress among children and their families [2], and are characterized by the use of large gauge needles [3]. Unrelieved continuing pain may have untoward effects on the health, functional abilities, and quality of life of children [4]. Properly managing the pain from these punctures is associated with shorter hospital stays and lower hospital costs [5]. Freedom from pain is a right of children and must be considered in nursing practice [6].

Understanding the physiology of pain, its influencing factors, and effective management can help nurses individualize their care plans for these children [7]. The lack of pain knowledge presents an important barrier to proper pain management [8]. Given that the perceptions of children toward pain are greatly influenced by environmental and psychological factors, the adoption of psychosocial strategies, education, parental support, and cognitive–behavioral nursing interventions may effectively reduce their anxiety and distress [9]. Therefore, as advocates for children, nurses are compelled to minimize the emotional and physical effects of painful procedures. They must also become aware of the different approaches to procedural pharmacological or non-pharmacological pain management [10]. Moreover, pain management becomes highly effective when the presence of pain is anticipated and when the right of children to pain control is acknowledged [5].

Cryotherapy, or the use of cooling, is a non-pharmacological pain relief technique that has been used for centuries [11]. Cryotherapy lowers the temperature over the painful/inflamed area of

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the skin [12] to reduce the velocity of nerve conduction in C- and A-delta fibers, thereby slowing the transmission of pain signals [13]. Despite being simple, non-invasive, and safe, the effectiveness of this technique, especially as an independent nursing function, lacks strong evidence. Therefore, the effectiveness of cryotherapy in relieving pain from AVF puncture was demonstrated during HD [1]. Conversely, a systematic review concluded that cryotherapy could effectively reduce pain among adults, but its effectiveness among children remains unknown [14]. Therefore, future studies must examine the effectiveness of cryotherapy in reducing pain among the pediatric population.

1.1. Aim of the study

This study aimed to evaluate the effectiveness of cryotherapy in managing pain at the puncture site of AVF among children undergoing maintenance HD.

1.2. Research hypotheses

The application of cryotherapy before AVF puncture among children undergoing maintenance HD can lead to the following:

1. lower Wong–Baker Faces Pain Rating Scale scores compared with pre-application scores;
2. lower Observed Behavior Pain Rating Scale scores compared with pre-application scores; and
3. better physiologic measures of stability compared with pre-application scores.

1.3. Operational definitions

Cryotherapy: Ice massage by applying 2 cm–3 cm of frozen distilled water inside a plastic bag over two AVF puncture sites until numbness is felt before needle puncture.

Physiologic measures: Respiration, pulse, blood pressure, and oxygen saturation.

2. Methods

2.1. Research design and setting

A quasi-experimental one-group design with pre-post assessment was applied. This study was performed in two centers, namely, the Center of Pediatric Nephrology and Transplantation in Elmonira Children's Hospital and the Center of Pediatric Dialysis in the Specialized Pediatric Hospital. Both centers and hospitals are affiliated with Cairo University.

2.2. Subjects

Forty children with AVF and undergoing maintenance HD were recruited from the two settings via convenience sampling from May 2011 to October 2011. Using the Epi-Info software, the sample size demonstrated a pre-post difference of 0.1 point or higher in the two pain scales with 0.1 point standard deviation at the 95% confidence level, 80% power, and expected 20% dropout. These children were considered their own controls in days 1 and 2 (before cryotherapy) for comparison with post-cryotherapy in days 3 and 4.

2.3. Data collection tools

The data collection tools included the following.

2.3.1. Structured interviews

A structured interview form was constructed to collect child-related data from the parents. The form covered the personal characteristics of the recruited children, including their age, gender, educational level, and residence. The medical history of children was also recorded, including the duration of their disease and co-morbidities, the duration and frequency of their HD, and the condition of their AVF.

2.3.2. Wong–Baker faces pain rating scale

The Wong–Baker Faces Pain Rating Scale was developed as a self-report scale for subjective pain assessment. The scale includes six drawn faces expressing various degrees of pain severity ranging from “does not hurt” to “hurts very much” [15]. These faces are assigned scores from 0 to 10, with a higher score indicating a higher severity of pain [16]. Apart from being simple and acceptable, this scale has high test–retest reliability and convergent validity [17]. The scale has a high reliability with a Cronbach's alpha coefficient of 0.70.

2.3.3. Observed pain behavior rating scale

Based on the Procedure Behavior Checklist Scale [18], the Observed Pain Behavior Rating Scale offers an objective assessment of pain. The scale includes eight observable behaviors (screaming, crying, verbalized pain, verbalized anxiety, verbal stalling, muscle tension, physical resistance, and use of restraint). The intensity of these behaviors is rated on a five-point Likert scale ranging from 1 (“very mild”) to 5 (“extremely intense”). The scale has favorable psychometric properties [19]. The researchers modified the scale to suit the cognitive ability of children; in this case, the behaviors observed to have “occurred” were scored 1, while those that “did not occur” were scored 0. The scores of the eight behaviors were summed to obtain the total score, and a higher total score indicates a higher pain severity. The modified scale has a Cronbach's alpha coefficient of 0.74.

2.3.4. Physiological assessment

The physiological measurements that could be influenced by pain were assessed. These measurements included respiratory rate, pulse, systolic and diastolic blood pressures, and oxygen saturation. Standardized assessment methods were employed.

2.4. Pilot study

A pilot study was performed on 10% of the total sample (four children) to pre-test the data collection tools in terms of their clarity, applicability, and time to completion. Minor modifications were applied before finalizing the tools. The children who participated in the pilot study were excluded from the sample.

2.5. Procedures

The participants were recruited upon receiving their permission. The researchers met the children who satisfied the inclusion criteria as well as their parents in the study settings, gave them a clear and simple explanation of the aim and procedures of the study, and invited them to participate. Those children and parents who agreed to participate signed an informed consent form. The researchers then interviewed the children and their parents individually in the waiting room using the interview form before the dialysis session. Afterward, the researchers explained to the subjects the subjective pain assessment tool, the Wong–Baker Faces Pain Rating Scale, and then trained the children on how to use this scale. The cryotherapy procedure was then explained and

demonstrated to the subjects. The ice (2 cm–3 cm pieces of frozen distilled water) was placed inside a plastic bag. An individualized ice bag was prepared and labeled with the name of each child to prevent cross-infection. An ice sensitivity test was performed on the contralateral site of the AVF to determine whether any child was sensitive to the ice.

During the two dialysis sessions in days 1 and 2 of the intervention, the researchers subjectively and objectively assessed pain using the last three aforementioned data collection tools. The researchers recorded the physiologic measurements of the children before the needle puncture. The AVF puncture sites were sterilized using betadine and following the sterilization protocol of the centers. As the dialysis nurse performed the needle puncture, the researchers observed and recorded the behavior of children using the Wong–Baker Faces Pain and Observed Pain Behavior Rating Scales. The physiologic measurements were rerecorded three to five minutes after puncture and before connecting the child to the dialysis machine. The children were then asked to fill the Wong–Baker Faces Pain Rating Scale. The same process was repeated in the next dialysis session. The scores recorded in these two days were averaged and considered as pre-test or control reference values.

During the two dialysis sessions in days 3 and 4 of the intervention, the researchers applied one to two drops of olive oil over two AVF puncture sites to reduce the risk of ice burns. These areas were then massaged in slow, circular, and interrupted motions using the ice bag of each child to avoid skin injury. The massage lasted until the children felt skin numbness, and the molten ice was replaced when necessary. The dialysis nurse performed the needle puncture one to three minutes after the massage and before the skin numbness sensation disappeared. Physiologic measurements and pain assessment were performed similar to the pretest. The children were then asked to complete the Wong–Baker Faces Pain Rating Scale. The researchers cleaned the ice bags with soap and water after use and kept them inside a clean bag in the refrigerator to prevent contamination.

The researchers and the dialysis nurse inspected the AVF puncture site before the needle puncture to detect any local skin reaction from cryotherapy, such as redness, pallor, swelling, thrombophlebitis, or damage. Any observed local skin reactions were recorded. Cryotherapy was initially performed by the researchers, and some children volunteered afterward to perform the procedure by themselves under the supervision of the researchers.

2.6. Ethical considerations

Ethical approval was obtained from the research ethical committee of the Faculty of Nursing, Cairo University. Permissions to use the pain scales were secured from the authors. Informed consents were signed by parents after being informed about their rights to refuse and/or withdraw at any time without providing a reason and without affecting the care that their children are receiving. The children aged between 7 years and 12 years gave their assent to participate, while those aged between 13 years and 18 years provided their written consents. The participants were assured that their information would remain confidential.

2.7. Statistical analysis

The data entry and statistical analysis were performed using the SPSS 20.0 statistical software package. The quantitative data were compared by performing a paired *t*-test for pre-post comparisons. The categorical variables were compared by performing a chi-square test. The Fisher exact test was performed instead when the expected values in one or more cells in a 2×2 table were less than 5. Spearman's rank correlation was used to assess the interrelationships among the quantitative and ranked variables. Statistical significance was set at $p < 0.05$.

3. Results

The children were aged between 8 years and 16 years, with the girls (55%) slightly outnumbering the boys (45%). Two-fifth of these children (40%) were studying in preparatory schools. The duration of their illness ranged between 11 months and 168 months with a median of 74.5 months or approximately 6 years. Slightly more than one-third of these children (37.5%) had an additional co-morbidity (Table 1).

With regard to the treatment of these children, the duration of their dialysis ranged between 4 months and 120 months with a median of 48 months or 4 years. The majority of these children were having two dialysis sessions per week (95%) for three hours (92.5%). The median duration of their AVF was 34 months or slightly less than 3 years. Less than half of these children (42.5%) developed abnormal signs at the site of their AVF (Table 2).

The cryotherapy duration ranged between 2.5 min and 17.0 min with a median of 8.8 min, while the skin numbness duration ranged between 2 min and 15 min with a median of 7.0 min (Table 3).

A statistically significant decrease was observed in the Wong–Baker Faces Pain Rating Scale scores after cryotherapy ($p < 0.001$), and an absolute mean difference of 0.88 points was observed in these scores before and after cryotherapy. Almost all observed pain behaviors, except for verbal stalling, physical resistance, and use of restraint, demonstrated statistically significant decreases after cryotherapy, while muscle tension and verbalized pain showed the most obvious improvements. The scores of the latter two behaviors decreased by 1.76 points after cryotherapy, and the difference between their scores before and after cryotherapy was statistically significant ($p < 0.001$) (Table 4).

All physiological parameters showed improvements after cryotherapy either before or after the needle puncture. However, statistically significant differences were observed in respiratory rate before ($p = 0.01$) and after ($p < 0.001$) needle puncture and in oxygen saturation after needle puncture ($p = 0.001$) (Table 5).

The Wong–Baker Faces Pain and Observed Behavior Rating

Table 1
Socio-demographic and health characteristics of children in the study sample ($n = 40$).

	Frequency	Percent %
Gender:		
Boys	18	45.0
Girls	22	55.0
Age by years:		
12 and less	17	42.5
More than12	23	57.5
Range	8.0–16.0	
Mean ± SD	11.7 ± 1.7	
Median	12.0	
Education:		
None	9	22.5
Primary	15	37.5
Preparatory	16	40.0
Residence:		
Urban	19	47.5
Rural	21	52.5
Duration of disease (years):		
5 and less	13	32.5
More than 5	27	67.5
Range (months)	11.0–168.0	
Mean ± SD (months)	74.4 ± 43.1	
Median (months)	74.5	
Have co-morbidity	15	37.5

Table 2
Hemodialysis characteristics of children in the study sample (n = 40).

	Frequency	Percent %
Duration of dialysis (months):		
12 and less	7	17.5
More than 12	33	82.5
Range	4.0–120.0	
Mean ± SD	48.0 ± 30.7	
Median	48.0	
Sessions/week:		
2	38	95.0
3	2	5.0
Session duration (hours):		
2	3	7.5
3	37	92.5
Fistula side:		
Right	11	27.5
Left	29	72.5
Duration of fistula (months):		
12 and less	8	20.0
More than 12	32	30.0
Range	4.0–118.0	
Mean ± SD	39.1 ± 28.5	
Median	34.0	
Have abnormal fistula signs	17	42.5

Table 3
Duration of cryotherapy and its sensitivity time among children in the study sample (n = 40).

Time of cryotherapy (min):	
Range	2.5–17.0
Mean ± SD	9.6 ± 3.4
Median	8.8
Duration of skin sensitivity/numbness (min):	
Range	2.0–15.0
Mean ± SD	7.4 ± 3.2
Median	7.0

Table 4
Post-pre-cryotherapy differences in pain sensations among children in the study sample (n = 40).

Pain scores (average of 2 observations)	Post-pre difference		Paired *t*-test	p-value
	Mean	SD		
Wong faces pain	−0.88	0.68	8.18	<0.001*
Observed pain behavior:				
Screaming	−0.14	0.39	2.22	0.03*
Crying	−0.14	0.42	2.05	0.047*
Pain verbalized	−0.46	0.63	4.61	<0.001*
Anxiety verbalized	−0.10	0.26	2.45	0.02*
Verbal stalling	−0.01	0.08	1.00	0.32
Muscle tension	−0.90	0.57	10.01	<0.001*
Physical resistance	0.00	0.00	–	–
Restraint used	0.00	0.00	–	–
Total behavior	−1.76	1.49	7.51	<0.001*

*Statistically significant at p < 0.05.

Scale scores demonstrated a statistically significant positive correlation (r = 0.330). However, neither of these scores was correlated to the personal or medical characteristics of the children or to the duration of cryotherapy or skin numbness (Table 6).

Table 7 shows the effects of cryotherapy on the venipuncture procedure. No differences were observed in the incidence of associated problems before and after cryotherapy. However, the skin dryness after cryotherapy (12.5%) was lower than that before cryotherapy (52.5%), and such difference was statistically significant (p < 0.001).

Table 5
Post-pre-cryotherapy differences in vital signs among children in the study sample (n = 40).

	Post-pre difference		Paired *t*-test	p-value
	Mean	SD		
Respiration (before needle insertion)	−1.19	2.92	2.57	0.01*
Respiration (after needle insertion)	−2.09	3.28	4.03	<0.001*
Pulse (before needle insertion)	−0.95	8.93	0.67	0.50
Pulse (after needle insertion)	−0.41	7.98	0.33	0.75
Systolic BP (before needle insertion)	−0.46	12.15	0.24	0.81
Systolic BP (after needle insertion)	−0.79	11.97	0.42	0.68
Diastolic BP (before needle insertion)	−2.78	9.50	1.85	0.07
Diastolic BP (after needle insertion)	−0.89	9.34	0.60	0.55
O_2 saturation (before needle insertion)	0.11	0.56	1.27	0.21
O_2 saturation (after needle insertion)	0.35	0.85	2.61	0.01*

*Statistically significant at p < 0.05.

4. Discussion

This study examined the effect of cryotherapy on managing the pain at the AVF puncture site among children undergoing maintenance HD. This intervention was associated with significant decreases in both the subjective and objective parameters of pain measurement. These results support the stated research hypotheses.

Applying cryotherapy before AVF puncture significantly decreased the subjective pain scores as measured by the Wong–Baker Faces Pain Rating Scale. These findings reflect genuine feelings of pain that may vary from one child to another depending on their personal factors and previous experiences as suggested in an Italian study [20]. Although the Wong–Baker Faces Pain Rating Scale scores were affected by the age and previous venipuncture experience of children, the authors still recommend the use of this scale in future research.

Consistent with our findings, an Egyptian study assessed the effectiveness of cryotherapy in relieving pain among children and reported significantly lower mean pain scores among children in the intervention group (2.33 + 2.294) than in the control group (6.13 + 2.36) [21].

A quasi-experimental study from Iran demonstrated the effectiveness of cryotherapy in reducing pain sensation through arterial puncture, which is more painful than AVF puncture [22]. Other studies supported the effectiveness of cryotherapy in reducing procedural pains through the application of vibration [23], thereby necessitating further improvements in the use of cryotherapy in pain relief [24].

The changes in pain sensation were also objectively assessed to support the results of the subjective approach for pain assessment. The observed pain behaviors and physiological measurements were both observed, and the findings demonstrated improvements in all observed behaviors. Such improvements were particularly evident in muscle tension and verbalized pain. Other behaviors, such as physical resistance and use of restraint, were not present either before or after the intervention because those children who have been repeatedly exposed to venipuncture have become accustomed to such procedure. Therefore, these children no longer need to be restrained when conducting venipuncture. Consistent with this finding, Volkenant suggested that previous pain experience could lead to improved coping and less behavioral responses to pain [25].

The children undergoing maintenance HD eventually realize the importance of this painful procedure in helping them cope with pain [26]. However, several behaviors, such as muscle tension, may be involuntary, thereby explaining the high and low prevalence of this behavior before and after the intervention, respectively.

Table 6
Correlation between pain scores and children's characteristics (n = 40).

	Pain scores			
	Behavior observation		Wong	
	Spearman's rank correlation coefficient	p-value	Spearman's rank correlation coefficient	p-value
Wong score	0.330*	0.04		
Age	0.29	0.07	0.09	0.60
Duration of disease	0.31	0.05	0.04	0.82
Duration of dialysis	0.19	0.25	−0.02	0.92
Duration of fistula	0.20	0.21	0.09	0.58
Site abnormal signs	0.27	0.09	0.14	0.38
Cryotherapy duration	0.00	1.00	−0.25	0.13
Numbness duration	0.04	0.78	−0.28	0.08

*Statistically significant at $p < 0.05$.

Table 7
Post-pre-cryotherapy differences in changing the site of insertions and related difficulties among children in the study sample (n = 40).

Difficulties	Pre		Post		Chi-Square	p-value
	No.	%	No.	%		
Vein change	5	12.5	2	5.0	Fisher	0.432
Artery change	5	12.5	2	5.0	Fisher	0.432
Nurse change	11	27.5	12	30.0	0.061	0.805
Difficult vein insertion	30	75.0	30	75.0	–	–
Difficult artery insertion	30	75.0	36	90.0	3.117	0.077
Dry skin	21	52.5	5	12.5	14.587	<0.001*
Diaphoresis	7	17.5	2	5.0	Fisher	0.154

*Statistically significant at $p < 0.05$.
–Test result not valid.

Therefore, the improvements in the objective parameters of pain assessment support and confirm the changes that have been recorded in the subjective pain assessments.

Consistent with these findings, a study from Australia demonstrated the effectiveness of cryotherapy in improving the scores of behavioral responses to pain associated with AVF puncture [27]. Similarly, an Egyptian study reported a lower incidence of behavioral responses to pain, such as crying, grimacing, contraction of eyebrows, and clenching of fingers, among children exposed to venipuncture after cryotherapy [21].

The physiological parameters demonstrated similar improvements in stability, thereby confirming the effectiveness of cryotherapy in reducing subjective pain. Respiratory rate and oxygen saturation showed the most obvious improvements. The latter is a sensitive indicator of pain because the sensation of pain is associated with stress leading to increased oxygen consumption and lower oxygen saturation. A study from Iran demonstrated that pain relief in neonates was associated with high levels of oxygen saturation [28].

The changes in hemodynamic parameters, including heart rate and blood pressure, before and after cryotherapy were not significant, which could be explained by the fact that these parameters were influenced by many other physical and psychological factors other than pain. In line with this, Hockenberry and Wilson mentioned that the pulse rates of children with end-stage renal disease were extremely responsive to any changes in circulatory volume [29]. In another study, Ricci and Kyle claimed that the changes in physiological parameters were not strongly correlated to pain sensation, but could be highly responsive to other factors, including increased body temperature or physical activity [9].

This study employed a safe intervention without any negative effects on the venipuncture process. However, this intervention significantly decreased skin dryness, thereby leading to difficulties in needle puncture. The decreased skin dryness might be related to the emollient effect of the olive oil drops applied prior to cryotherapy. Moreover, some children preferred to perform the ice bag massage by themselves upon learning the procedure or to assist their colleagues during the process. Such cooperative behavior shown by these children not only reduced their fears of the needle puncture process but also made them enjoy their participation in managing their pain. Nonetheless, such cooperation could have confounding effects because the enthusiasm of children about the process and their participation could distract them from the feeling of pain as shown in studies from Japan [30] and Turkey [31]. This potential effect presents a limitation for this study and can be addressed in future studies by using a placebo group.

5. Conclusion and recommendations

Cryotherapy or ice massage can effectively reduce the sensation of pain from venipuncture among children with AVF and undergoing maintenance HD. This effect was demonstrated through subjective and objective pain assessments. However, the findings from this study must be interpreted in consideration of the potential confounding effects of distraction and the employment of a non-randomized design.

Given the simplicity, safety, and potential benefits of cryotherapy, this study recommends the utilization of this process in managing needle puncture pain. Future studies must adopt a randomized trial design with a placebo to support further the utility of cryotherapy.

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