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Applying Cryotherapy and Balloon Inflation Technique to Reduce Pain of Arteriovenous Fistula Cannulation among Children Undergoing Hemodialysis

*Gawhara Gad Soliman Ebrahim¹, Gehan EL Nabawy Ahmed¹, Ayman Hammad², NashwaHamdy², Riham Eid²

¹Pediatric Nursing Department, Faculty of Nursing, Mansoura University, Egypt

²Pediatric Nephrology Unit, Mansoura University Children's Hospital, Mansoura University, Egypt

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Abstract: Children undergoing hemodialysis are exposed to stress and pain from approximately 300 punctures per year to their arteriovenous fistula (AVF). Relief their pain sensation improves their acceptance of the procedure and consequently improves their quality of life. **Aim:** The study aimed to investigate the effect of cryotherapy and balloon inflation on reducing pain of arteriovenous fistula cannulation among children undergoing hemodialysis. A quasi-experiment design was performed. **Setting:** The study was conducted in the hemodialysis unit in Mansoura University Children's Hospital. **Subjects:** All available children (n = 45 children) undergoing HD with AVF for a period of 3 months at the previously mentioned setting. **Tools:** Four tools were used for data collection: A Structured Interview Sheet, Physiological Measurements Tool, Pain Behavioral Observational Checklist and Numerical pain rating scale. **Results:** There is a highly statistical significance difference between mean scores of observed behavioral response to pain and pain intensity among hemodialysis children across pre intervention, cryotherapy and balloon inflation before and immediately after AVF punctures. **Conclusion:** The study concluded that, cryotherapy and balloon inflation have a positive effect on reducing pain of arteriovenous fistula cannulation among children undergoing hemodialysis. **Recommendations:** Cryotherapy and balloon inflation should be utilized as a routine care in the routine care for hemodialysis children to relieve needle puncture pain.

Key words: Cryotherapy, balloon inflation, pain, arteriovenous fistula cannulation (AVF), children, hemodialysis (HD)

INTRODUCTION

Hemodialysis (HD) is the most important and frequently used alternative therapy with the arteriovenous fistula (AVF). It is as a gold standard for HD children with vascular access, they exposed monthly to an average of ten AVF punctures to live with hemodialysis or until a successful renal transplant. Therefore frequent exposure to punctures with using large, gauge needles lead to pain sensation and stress among children and their families (Alhani, 2010), which have negative effects on their health and functional abilities. So, the priority of HD children care is pain management during AVF (BéfaNotoKadou et al 2014). Moreover, proper pain management led to lower hospital costs and decrease length of hospitalization (Ball, Bindler & Cowen, 2012).

There is no unique and appropriate method for relieving the pain in the children undergoing hemodialysis when inserting a needle into an AVF. So the nurses must be aware of pharmacological or non-pharmacological pain management approaches (Al-Mutairi et al 2009). However, some of pharmacological procedures supposed to have negative effects on the function of AVF and is not useful for all children. Therefore, recent research focusing using non-pharmacological methods for children pain relief (Aydin, Sahiner & Ciftci, 2016). In addition, nurses eager to know about effective and easy methods of pain relief such as Cryotherapy.

Cryotherapy is one of the non-pharmacological methods done by using of cooling to lower the temperature over the painful area and reduce the velocity of nerve conduction in

C and A delta fibers, therefore the transmission of pain signals slowed. It is easy to learn and can be used to relieve various symptoms in a wide range of patient care settings. It is being a natural treatments modality, simple, non-invasive and has absolutely no side effects (Shali, 2012).

On the other hand, distraction method is the most non-pharmacological approach widely used for pain relief during painful medical procedures for children. This approach is a cognitive and behavioral method used with children to limit their brain capacity to focus the attention on stimulation and divert their focus on a distracting task, and then little is left for attending to painful stimulation (Sadeghi et al 2013; Uman, et al, 2013; Inal & Canbulat, 2015). So the nurses prefer to use this approach to control and reduce pain sensation for children (Inal & Kelleci, 2012).

Distraction is a cost-effective method used to reduce distress and pain sensation during insertion of needles for children (Bagnasco et al 2012). Inflating a balloon is one of the important distracting approaches, which has more advantages than other methods, such as easily applied, simple and cheap materials and preparation and saving the time (Mutlu & Balci, 2015). Besides it is a distracting method, it has a physiological effect, which causes a venous return reduction with increased intrathoracic pressure to activate cardiopulmonary and sinoaortic baroreceptor reflex arcs has an antinociceptive effect, resulting in pain relief. Therefore this method can facilitate the health care providers' work with children (Gupta et al 2006).

The Study Significance:

Insufficient pain management for HD children led to many negative outcomes. Venipuncture is one of the most frequently a painful medical procedure is doing for HD children. So they are anxious about repeated venipuncture, and their comfort with this procedure is an important issue for long-term compliance with the treatment. Nurses have an important role to use proper methods to relief pain and stress during needle procedures. So they required to continuous training to improve their awareness and practice of using non-pharmacological methods such as distraction and others that may reduce children pain. Therefore, this study aimed is to investigate the effect of cryotherapy and balloon inflation on reducing the pain of AVF cannulation among children undergoing hemodialysis.

The study aim:

The study aimed to investigate the effect of cryotherapy and balloon inflation on reducing pain of arteriovenous fistula cannulation among children undergoing hemodialysis.

Research hypothesis:

The application of cryotherapy and using of balloon inflation expected to decrease the pain of arteriovenous fistula cannulation among children undergoing hemodialysis.

Methodology:

Study Design:

A quasi-experiment design was used in this study.

Setting:

The study was conducted in the hemodialysis unit in Mansoura University Children's Hospital.

Subjects:

All available children (n = 45 children) undergoing HD with AVF for a period of 3 months at the previously mentioned setting and fulfilled the following criteria:

- Aged 8-18 years, oriented, able to talk and can deal with the modalities used in the study
- Free from any other physical illness.

Exclusion criteria:

- Children had analgesic during the days of data collection.
- Children with fever and neurological disorders.
- Children with chronic diseases which required frequent withdrawal blood samples.
- Children with previous history of fainting.

Tools

Four tools were used for data collection

Tool I: A Structured interview Sheet was developed by the researchers after reviewing related literature and previous studies relevant to the problem (Alhani et al 2010; Hassan et al 2012 and Attia & Hassan, 2017). It included:

a. Demographic data about child, such as, age, sex, birth order, level of education and residence.

b. Medical history of children, such as, duration of disease, duration of dialysis, number of dialysis sessions per week, duration of session, AVF side, duration of AVF and presence of abnormal AVF signs.

Tool II: Physiological Measurements; which included: measuring blood pressure, heart and respiratory rates.

Tool III: Pain Behavioral Observational Checklist:

An observational checklist was used to assess the child's behavioral response to AVF puncture pain. It was developed by Eshak (2008), to collect the following data: crying, facial expression, body movements, and verbal expression.

Tool IV: Numerical pain rating scale:

This scale was developed by McCaffery et al, (1989). Score level of pain intensity; zero it means no pain, 1 to 3 means mild pain, 4 to 6 means moderate pain, and 7 to 10 means severe pain.

Pain Management Modalities:

- Cryotherapy (cold therapy) applied in acupressure point: Three-to-four pieces of ice in a plastic bag with a small towel was placed on the web between the thumb and index finger of the opposite hand (contralateral arm) of AVF sites. This procedure was started ten minutes before the puncture and was continued throughout the puncturing procedure (approximately two minutes).
- Balloons inflation: Each child was asked to inflate balloons during the venipuncture procedure.

Validity and Reliability:

A Structured Interview Sheet and Pain Behavioral Observational Checklist were tested for their content validity by a jury of five experts in the pediatric nursing field. Reliability was ascertained by Cronbach Alpha and it gave an internal consistency of $\alpha = 0.86$ and $\alpha = 0.90$ for A Structured Interview Sheet and Pain Behavioral Observational Checklist respectively which was acceptable.

Data collection:

Pilot study:

A pilot study was carried out on five children to test the applicability of the tools. No modification was needed. These five children were excluded from the subjects.

Procedure:

- At the initial meeting, each child in the previous setting was interviewed individually at the beginning of the HD session in HD unit to collect the demographic data and medical history using Tool I- Part I. The questions were directed to each child in a simple Arabic language and the answers were recorded immediately. The time spent to fill the sheet was about 5-10 minutes for each child.
- Each child was assessed for three consecutive HD sessions (one week) without applied any intervention as a base line after that each pain management modality was applied for three consecutive HD sessions (one week) for each child. The children received the pain management modalities as follows: balloon inflation then cryotherapy (cold therapy) applied in acupressure point.
 - a. Balloon inflation: It was applied as follows:
 - The child was asked to inflate balloons 2 seconds prior to puncture and continue during the venipuncture procedure.
 - b. Cryotherapy (cold therapy) applied in acupressure point: It was applied as follows:

- Ice plastic bag was prepared from crushed three-to-four pieces of ice in a plastic bag.
- The ice bag with a small towel was placed on the web between the thumb and index finger of the opposite hand (contralateral arm) of AVF site for ten minutes prior to puncture and was continued throughout the puncturing procedure (approximately two minutes).
- For each HD session:
 - a. Before AVF punctures, heart, respiratory rates, and blood pressure were measured and recorded for each child using (Tool II).
 - b. During AVF punctures, behavioral responses to pain were observed and recorded for each child using (Tool II and Tool III).
 - c. Immediately after AVF punctures:
 - Each child was interviewed to assess his pain intensity using (Tool IV).
 - Heart, respiratory rates and blood pressure were re-measured and recorded for each child using (Tool II).
 - Comparison of physiological measures, behavioral responses, and pain intensity were done between the base line (pre intervention) and different treatment modalities.
 - The time of each session with every child for each pain management modality was approximately 15-20 minutes.
 - The researchers used to go to Mansoura University Children's Hospital all days of week in the morning and afternoon except Friday as there was no HD sessions on that day.

- The data was collected over a period of 3 months from the beginning of December 2018 till the end of February 2019.

Ethical considerations:

This study was approved by both Mansoura Faculty of Nursing and Faculty of Medicine Institutional Research Board- Mansoura University. Agreement was obtained from the Nephrology Department Board to conduct the study after discussing the purpose and content of the study. And an official permission was taken from the director of the unit after explaining the aim of the study. Each child and/ or parent was informed about the aim of the study and a written consent was obtained. Confidentiality, privacy, anonymity and children' rights to withdraw at any time were ensured to gain their cooperation.

Statistical analysis:

The collected data were coded and entered to the statistical package of social sciences (SPSS) version 19. After complete entry, data were explored for detecting any error and tested for normality by Kolmogorov-Smirnov test. After data analysis, quantitative variables were stated as, frequencies, percentages, mean and standard deviation. Paired sample t-test was conducted for pre-post comparisons for each procedure and repeated measure ANOVA were used for comparing between three main related groups. The categorical variables were compared by performing a chi square test. Spearman's rank correlation was used to assess the interrelationships among the quantitative and ranked variables. The results were accepted to be statistically significant for $p < 0.05$.

RESULTS

Table (1): Distribution of socio-demographic characteristics of the study subjects (n=45)

Characteristics	No	%
Age in year		
▪ 8 < 12ys	20	44.4
▪ 12- 18ys	25	55.6
X± SD	11.62 ± 3.47	
Gender		
▪ Boys	23	51.1
▪ Girls	22	48.9
Level of education		
▪ Primary	26	57.8
▪ Preparatory	19	42.2
Residence		
▪ Rural	21	46.7
▪ Urban	24	53.3
Birth Order		
▪ First	21	46.7
▪ Second	12	26.7
▪ Third	9	20
▪ Fourth	3	6.7

Table (1) presented that 55.6% of children were aged between twelve years and eighteen years with mean age 11.62 ± 3.47 , with the boys (51.1%) slightly outnumbering the girls (48.9%). Less than half of study subjects (42.2%)

were studying in preparatory schools. It was found that less than half of children (46.7%) were the first and more than half of them (53.3%) were from urban areas.

Table (2): Dialysis characteristics of studysubjects (n=45)

Characteristics	No	%
Duration of dialysis		
▪ <5ys	28	62.2
▪ ≥5ys	17	37.8
X±SD	2.98 ± 2.81	
Sessions/week		
▪ 2	2	4.4
▪ 3	43	95.6
X±SD	2.06 ± 0.33	
Session duration (hours)		
▪ 3	6	13.3
▪ 4	39	86.7
X±SD	2.92 ± 0.26	
AV Fistula side		
▪ Right	12	26.7
▪ Left	33	73.3
Duration of AV Fistula		
▪ <5ys	28	62.2
▪ ≥5ys	17	37.8
X± SD	2.98 ± 2.81	
▪ Presence of abnormal AV Fistula signs	31	68.9

Table (2) showed that the disease duration and AV Fistula were <5 years and the mean years was 2.98 ± 2.81 in more than two third of children (62.2%). Nearly all of the subjects (95%)received weekly three sessions for dialysis and each

sessiontime was 3 hours in the majority of children (86.7%). As regard side of AV Fistula, 73.3% of children had AV Fistula in left arm and more than two third (68.9%) of them has abnormal fistula signs.

Table (3): Comparison of mean scores of vital signs among hemodialysis children across (pre intervention, cryotherapy and balloon inflation) before and immediately after AVF punctures

Items	Pre intervention				Cryotherapy				Balloon inflation			
	Mean scores of vital signs		Paired t-test		Mean scores of vital signs		Paired t-test		Mean scores of vital signs		Paired t-test	
	X	SD	T	P value	X	SD	T	P value	X	SD	T	P value
Systolic blood pressure (before AVF punctures)	119.13	16.8	3.94	0.000*	124.44	17.05	7.302	0.000*	117.25	14.97	4.619	0.000*
Systolic blood pressure (after AVF punctures)	106.77	16.50			101.62	15.38			102.81	15.39		
Diastolic blood pressure (before AVF punctures)	79.75	11.7	0.941	0.352	83.00	13.50	4.540	0.000*	82.66	13.73	3.731	0.001*
Diastolic blood pressure (after AVF punctures)	77.25	15.59			72.59	12.61			73.48	12.87		
Heart rate (before AVF punctures)	87.56	11.06	1.74	0.089	89.03	11.04	5.513	0.000*	90.29	13.10	3.326	0.002*
Heart rate (after AVF punctures)	90.26	10.68			83.79	8.98			85.28	11.33		
Respiratory rate (before AVF punctures)	22.68	2.67	1.37	0.178	22.75	2.48	5.321	0.000*	23.79	3.26	4.618	0.000*
Respiratory rate (after AVF punctures)	23.21	2.77			21.15	1.83			21.61	1.74		

It was observed from table (3) there is a highly statistical significance difference between mean scores of vital signs among hemodialysis children across (pre intervention, cryotherapy and balloon inflation) before and immediately after AVF punctures.

Table (4): Comparison of mean scores of observed behavioral response to pain among hemodialysis children across (pre intervention, cryotherapy and balloon inflation) during and immediately after AVF punctures

Items	pre intervention		Cryotherapy		Balloon inflation		Repeated measures ANOVA	
	X	SD	X	SD	X	SD	F	p-value
Crying	6.68	1.48	1.15	1.59	1.84	1.62	168.74	0.000*
Facial expression	6.66	1.73	1.24	1.64	1.93	1.63	151.95	0.000*
Body movements	6.62	1.54	1.40	1.68	2.04	1.61	136.97	0.000*
Verbal expression	6.89	1.67	1.32	1.63	1.72	1.65	143.56	0.000*
Total	6.71	1.60	1.28	1.63	1.88	1.62	150.30	0.000*

Table (4) showed that there is highly statistical significance difference in total mean scores of observed behavioral response to pain among hemodialysis children across pre intervention, cryotherapy and balloon inflation during and immediately after AVF punctures. This means that

cryotherapy and balloon inflation has a positive effect on decreasing pain during and immediately after AVF punctures.

Table (5): Comparison of mean scores of pain intensity among hemodialysis children across (pre intervention, cryotherapy and balloon inflation) during and immediately after AVF punctures

Items	pre intervention		Cryotherapy		Balloon inflation		Repeated measures ANOVA	
	X	SD	X	SD	X	SD	F	p-value
Mild pain (Score 1:3)	7.37	0.38	2.15	0.35	3.12	0.38	49.89	0.000*
Moderate pain (Score 4:6)	6.25	0.33	2.53	0.37	2.50	0.29	45.04	0.000*
Severe pain (Score 7:10)	7.87	0.31	2.40	0.35	2.53	0.25	59.88	0.000*
Total	7.16	0.34	2.36	0.36	2.72	0.31	51.60	0.000*

Table (5) indicated that there is highly statistical significance difference in total mean scores of pain intensity among hemodialysis children across (pre intervention, cryotherapy and balloon inflation) during and immediately after AVF punctures. This means that cryotherapy and balloon inflation has a positive effect on decreasing pain intensity during and immediately after AVF punctures.

DISCUSSION

Children undergoing dialysis who receive treatments three sessions weekly and three to four hours each time, they are anxious about repeated venipuncture. So initiating prevention and control measures of pain sensation resulted from medical procedures, lead to physical and psychological benefits for HD children (Alhani et al 2010). Therefore, this study aimed to investigate the effect of cryotherapy and balloon inflation on reducing pain of AVF cannulation in children undergoing hemodialysis.

This study results shown that, children boys were slightly more than half of studied subjects. In the same context Alhani et al (2010) who found that 66.7% were male. More than half of children age was between 12 and 18 years with mean age 11.62 ± 3.47 . Regarding to level of education, less than half of children were in preparatory schools. It was found that about forty six percent of children were the first and nearly forty five percent of them were from urban areas (table 1). These results agreed with Hassan et al (2012), who presented that the mean children age was 11.72 ± 1.74 years and they ranged between 12 and 16 years. Less than half of children were in preparatory year and were the first or second child while more than half of them live in rural areas.

With regard to dialysis characteristics, the disease duration and AV Fistula were <5 years and the mean years was 2.98 ± 2.81 in more than two third of children (62.2%). Most of children (95%) received 3 dialysis sessions per week and the duration of each dialysis session was 3 hours in the majority of children (86.7%). As regard side of AV Fistula, 73.3% of children had AV Fistula in left arm and more than two third (68.9%) of them has abnormal fistula signs (table 2). These results are not matched with those obtained by Alhani et al (2010) and Attia & Hassan, (2017).

Concerning the cryotherapy and balloon inflation effect on vital signs before and after the needle puncture, the finding of this study showed that, there is a highly statistical significance difference between mean scores of vital signs among hemodialysis children across (pre intervention,

cryotherapy and balloon inflation) before and immediately after AVF punctures (table 3). This means that children physiological measurements improved after cryotherapy and balloon inflation either before or after the insertion of needle. This is in line with Attia & Hassan, (2017) and in more recent Egyptian study, Fathalla & Bayoumi (2018) who found that children in the buzzy and cryotherapy groups had lower mean heart and respiratory rates during and after blood specimen collection.

This study shown that there is a highly statistically significance differences in total mean scores of observed behavioral response to pain and pain intensity among hemodialysis children across pre intervention and cryotherapy during and immediately after AVF punctures (table 4 & 5). These findings are supported with the results of many others studies regarding cryotherapy (Mansy et al 2010; Baxter et al 2011; Çelik et al 2011; Kiran et al 2013) they found and proved that cryotherapy was an effective method used to reduce pain scores at puncture sites of AVF among HD children. Moreover, the findings of many studies supported the results of current study; Bastami, Azadi & Mayel, (2015); Jose & Lobo, (2015) and Alalo, Ahmad & El Sayed, (2016) found that using cryotherapy before AVF puncture significantly reduced the pain scores. And also the study of Fathalla & Bayoumi (2018) who found cryotherapy was an effective method used to reduce pain and anxiety during blood specimen collection. Moreover, the lowered pain scores in this study similar with other studies related to many invasive procedures as Canbulat, Ayhan F & Inal, (2015); Canbulat Şahiner, İnal, Sevim Akbay, (2015); Schreiber, Cozzi, Rutigliano, et al. (2016). Finally, Susam, et al. (2018) proved that cold has an effect in pain reduction during venipuncture in children.

The present study illustrated that there is highly statistical significance difference in total mean scores of observed behavioral response to pain and pain intensity among hemodialysis children across pre intervention and balloon inflation during and immediately after AVF punctures (table 4 & 5). These results supported by Alhani et al (2010), who showed that using distraction program lead to decrease pain resulted from venipuncture among HD adolescents.

The study results are compatible with the results of four earlier studies (Baxter et al (2011); Inal & Kelleci (2012); Whelan et al (2014); Moadad et al (2016) which support using the balloon inflating as distraction approach lead to divert the child attention away from pain stimuli during a

medical procedure, so it is useful for reducing pain and anxiety. Consistent with our results, **Mutlu&Balci,(2015)** found that the using of the balloon inflation and cough trick methods reduce the pain during the procedure of drawing venous blood between 9 and 12 years of age children. Moreover, this study results corresponded with **Sahiner&Bal, (2015);Aydin et al (2016), andTork, (2017)** they found that the distraction methods such as buzzy, distraction cards,squeezing a soft ball and balloon inflating were effect to decrease painlevel among children compared with the control group. In addition, the findings of **Abdolalizadeh et al (2018)** showed that distraction methods can effectively decrease the venipuncture pain.

CONCLUSION

This study concluded that,cryotherapy and balloon inflation have a positive effect on reducing pain of arteriovenous fistula cannulation in children undergoing hemodialysis

RECOMMENDATIONS

Based on the previous findings and conclusion, the following recommendations are suggested:

- Cryotherapy and balloon inflation should be utilized to pain management resulted from needle puncture as a routine care for HD children.
- Cryotherapy and balloon inflation can be used during different painful procedures.
- Application on a larger sample size with different age groups, for a long period and using true experimental design.
- Further research is needed for to apply another non-pharmacological pain management to reduce AVF puncture among hemodialysis children.

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