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A study to assess the effectiveness of conventional methods along with balloon inflation vs conventional methods only in reduction of pain and fear during venipuncture in children age group of 5-12 years admitted in paediatric wards of GGSMC & H, Faridkot, Punjab

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Abstract
Introduction: Children are vulnerable to all kinds of illness. Illness and hospitalization are the first crisis that children face. Venipuncture is one of the most painful invasive procedures. Distraction has shown to be an effective non-pharmacological pain management technique.
Aim: The study was intended to assess the effectiveness of conventional methods along with balloon inflation vs conventional methods only in reduction of pain and fear during venipuncture in children age group of 5-12 years admitted in pediatric wards of GGSMC&H, Faridkot, Punjab.
Methods: A quantitative research approach and experimental research design was used to conduct the study. Total 80 patients (5-12 years) were selected who were admitted in the pediatric wards on the basis of inclusion and exclusion criteria and randomly allocated into experimental and conventional group through computerized block design method. Socio demographic data sheet was used to collect baseline information, Wong-Baker Faces Pain Rating Scale and Children's Fear Scale were used to assess the pain and fear level.
Results: Study found that the median of pain score in experimental group was 8 in conventional group was 10. Median of fear score in experimental group was 3 and in conventional group was 4. Mann-Whitney U test was applied for statistical analysis and p value was <0.001 which was statistically highly significant.
Conclusions: This study concluded that conventional methods along with balloon inflation was effective as a non-pharmacological method of reduction/management of pain and fear during venipuncture.

Keywords: Conventional methods, balloon inflation, venipuncture, pain, fear, children 5-12 years of age

Introduction
Wong (2007) [1] described that illness and hospitalization are the first crisis, that children face major stressors of hospitalization include separation, loss of control, bodily injury and pain. Children between the age groups of 4-10 years are concrete, ego centric and magical thinking that limits their ability to understand the events because they view all the experience from their own self referred perspective.
According to the International Association for the Study of Pain, Pain is defined as, ―an unpleasant sensory and emotional experience associated with actual or potential tissue damage [2].
Perception of pain in pediatrics is complex, and entails physiological, psychological, behavioral, and developmental factors. However, in spite of its frequency, pain in infants, children and adolescents is usually underestimated and undertreated. Health care professionals during this setting have a responsibility to scale back pain and anxiety the maximum amount as possible while maintaining patient safety [3].

Fear is a negative emotion that is thought to arise as an alarm to a dangerous or life threatening situation. Medical fears have been identified as a common subcategory of fear in children and, unlike other types of fear, may increase with age. Needle fears appear to be particularly prevalent, many children consider getting a needle to be one of their most feared and painful experiences. Fear can increase pain perception relationships between children's fear prior to needles and their fear and pain during needles [4].

Despite these realities, there is a lack of emphasis on the assessment and management of pain and anxiety in children. There are some of the potential explanations for the neglect of pain relief in paediatric management e.g. Lack of information of children's capability to perceive pain, Lack of expertise of scientific situations wherein pain is perceived, Children's inability to express pain in a particular way [5].

The goal of pain assessment is to provide accurate information about the location and intensity of pain, as well as how it affects a child's ability to function. Pain is linked to physiological, biochemical, behavioural, and psychological changes that can be tracked to a degree [6] Strategies used for management of children's pain is based on a trinity of factors: (a) knowledge of children's ability to experience pain, (b) sensitivity to clinical conditions in which pain may occur, and (c) adequate pain prevention and treatment measures [7] Venipuncture is one of the most painful invasive procedures that is commonly used in hospitalized children. Most children find this behaviour to be traumatic and disturbing because it involves a forced invasion and threats to the child's physical and mental space. Cannula insertion is also difficult in children who are afraid of needles or have had a poor experience with them, anxiety stimulates the sympathetic nervous system, causing peripheral vasoconstriction [8] Distraction is a simple and efficient strategy for diverting children's focus away from degrading stimuli. Distraction, on the other hand, is a broad term that encompasses a wide range of techniques and technologies. Furthermore, it has been shown that calming a child by inflating a balloon is an effective technique for dealing with pain during venipuncture [9] Inflating a balloon is one of the most important distracting techniques, with many advantages over other methods, including ease of use, low-cost materials and planning, and time savings. It's a physiological outcome, which causes a blood vessel come reduction with expanded intrathoracic pressure to stimulate internal organ associate degreed Sino aortal sense organ reflex arcs, which has an antinociceptive effect, resulting in pain relief. As a result, this approach would make it easier for health-care providers to "deal with children [10].

Need of the study

There have been tremendous research advances in the past 15 years in knowledge about children's pain, and strategies for recognizing and managing that pain. However, the clinical care of children in pain remains a challenge [11].

A study suggests that, 63 percent of children (ages 6–17) registered a fear of needles, and there were important links between needle phobia and female sex, as well as increased pain severity during immunizations [12].

It is important that nurses do everything possible to alleviate pain in children undergoing any treatment. Nurses must not only study the literature on the subject but also perform scholarly research at their institutions because the evidence for non- pharmacologic pain relief during venipuncture is mixed. Evaluating non- pharmacologic pain management approaches for children aids in the detection of practical and usable interventions that nurses can use in their practice [13].

The personal experience of the researcher was also the same. To our knowledge and based on the need's assessment, none of the current health care providers training curricula used, prepares health care professionals to manage pediatric pain and fear. During posting in pediatric wards researcher observed that children feel severe pain during painful procedures like Venipuncture and to reduce or to relieve that pain neither a pharmacological nor a non-pharmacological method is used. Moreover, researcher knows the importance of managing the pain and fear to avoid psychological adverse effects in children as well as in parents.

Problem statement

A study to assess the effectiveness of conventional methods along with balloon inflation vs conventional methods only in reduction of pain and fear during venipuncture in children age group of 5-12 years admitted in pediatric wards of GGSMC & H, Faridkot, Punjab.

Objectives of the study

1. To assess the effectiveness of conventional methods along with balloon inflation in reduction of pain and fear during the venipuncture in children admitted in pediatric wards (5-12 years).
2. To assess the effectiveness of conventional methods only in reduction of pain and fear during the venipuncture in children admitted in pediatric wards (5-12 years).
3. To compare the effectiveness of conventional methods along with balloon inflation vs conventional methods only in reduction of pain and fear during venipuncture in children admitted in pediatric wards (5-12 years).

Hypothesis of the study

H_0: There will be no significant difference between conventional methods along with balloon inflation vs conventional methods only in reduction of pain during venipuncture in children admitted in pediatric wards (5-12 years).

H_1: Conventional methods along with Balloon inflation is more effective than conventional methods only in the reduction of pain during venipuncture in children admitted in pediatric wards (5-12 years).

H_0: There will be no significant difference between conventional methods along with balloon inflation vs conventional methods only in reduction of fear during venipuncture in children admitted in pediatric wards (5-12 years).

H_1: Conventional methods along with Balloon inflation is more effective than conventional methods only in the reduction of fear during venipuncture in children admitted in pediatric wards (5-12 years).

Operational definitions

Pain: Pain is an unpleasant sensory and emotional experience felt by children associated with venipuncture and expressed by face expressions and cry.

Fear: Fear is a thought or unpleasant feeling of worry that child get when he/she thinks something horrible is going to happen during venipuncture.

Conventional methods only

It refers to a group in which parents distract the child by talking, holding the child during venipuncture.

Conventional methods along with balloon inflation
It refers to a group in which parents distract the child by talking, holding the child along with act of filling air in balloon used as distraction method during venipuncture.
Children: In this study, children were male or female in the age group of 5-12 years admitted in Pediatric ward of G.G.S Medical Hospital, Faridkot undergoing venipuncture.
Venipuncture: It is the collection of blood from a vein or for an intravenous injection used as a part of medical procedure.
Effectiveness: Effectiveness of conventional methods along with balloon inflation and conventional methods only in reduction of pain and fear among children undergoing venipuncture.

Methodology

Research approach
In the view of the problem a Quantitative research approach was chosen for the present study in order to assess the effectiveness of conventional methods along with balloon inflation vs conventional methods only in reduction of pain and fear during venipuncture in children age group of 5-12 years admitted in pediatric wards.

Research Design
An experimental research design was considered to be appropriate for the present study to answer this practical question of pain and fear management in children.

Research Setting
The present study was conducted in pediatric wards of Guru Gobind Singh Medical Hospital, Faridkot.

Study Population
The target population of the present study consisted of children from 5 year of age to 12 years of age accompanied by a family member and admitted in pediatric wards.

Sample and sampling technique
Sample: Children aged from 5-12 years undergoing venipuncture and admitted in pediatric wards of GGSMC&H, Faridkot, Punjab.
Sample size: A total sample of 80 children (5-12 years) undergoing venipuncture and admitted in pediatric wards were selected, 40 in experimental group and 40 in conventional group
Sampling technique: The subjects were selected on the basis of inclusion and exclusion criteria and randomly allocated into experimental and conventional group through computerized block design method.

Research variables
Independent variable
Conventional methods along with balloon inflation
Conventional methods only

Dependent variable
Pain and fear

Eligibility criteria
Inclusion criteria
1. Children undergoing venipuncture in pediatric ward of GGSMC&H, Faridkot, Punjab.
2. Children in the age group of 5-12 years
3. Children available at the time of sampling.
4. Children who inflate the balloon.
5. Children whose parents are willing to participate and give written informed consent for the same.

Exclusion criteria
1. Children below the 5 years of age and more than 12 years of age.
2. Children who are critically ill and will not able to inflate the balloon.
3. Children with skin infection, scars, psoriasis, eczema at the site of venipuncture.
4. Non-co-operative children.
5. Failed cannulation with first attempt.
6. Any life threating emergency situation.
7. Receiving painkillers before venipuncture.

Description of the final tool
A standardized tool was used to collect the data. The tool used in the study was as follows:

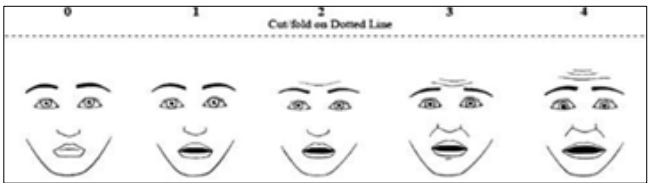
Part 1: Socio demographic data sheet
This profile included code, age, gender, height, BMI (Body mass index), previous hospitalization, previous venipuncture (in 3months), relationship of family members holding the child during venipuncture

Part 2: Information regarding the pain perception of the children measured by the wong-baker faces pain rating scale.

This tool was originally created with children for children to help them communicate about their pain. Now the scale is used with people aged 3 and older, facilitating communication and improving assessment so that pain management can be addressed.

Part 3: Information regarding the fear perception of the children measured by the children's fear scale.

The fear response of the children (5-12yrs) undergoing venipuncture was measured by the children fear scale. These faces are showing different amounts of being scared.



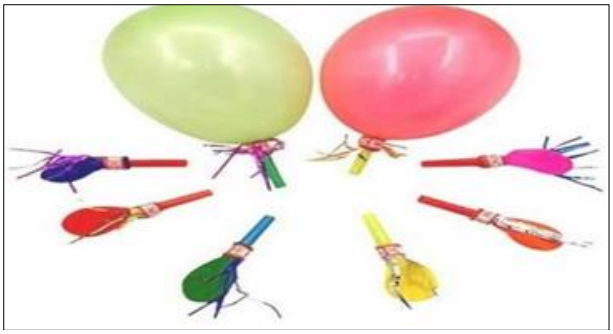
Criterion Measured
Interpretation of scores of Wong-Baker Faces Pain Rating Scale
Score 0 = No Hurt
Score 2 = Hurts little bit
Score 4 = Hurts little more
Score 6 = Hurts even more
Score 8 = Hurts whole lot
Score 10 = Hurts worst
Interpretation of scores of Children's Fear Scale
Score 0 = not scared

Score 1 = a little bit more scared
Score 2 = a bit more scared
Score 3 = scared a lot
Score 4 = most scared possible

Description about intervention

As the study participants were children age group of 5-12 years who were sensitive to get the painful sensations as compared to adults. Balloon inflation was used during venipuncture in order to divert the painful stimuli so as to minimize the painful sensations and fear. Written informed consent was taken from the parents of the subjects and patient information sheet was also provided to them. Researcher first introduced herself to the study subjects and assured that their response would be kept confidential and used only for study purpose.

1. Researcher select the study subjects according to Inclusion/Exclusion criteria and randomly allocated them into Experimental group and Conventional group.
2. The researcher then showed the colour varieties of balloons to the study subject and then allowed to choose the balloon according to their choice.
3. As the procedure for venipuncture started the study subject started to inflate the balloon. Meanwhile the researcher showed both the laminated sheets of 45×30cm
4. With Wong-Baker Faces Pain Rating Scale firstly followed by the Children's Fear Scale.
5. The study subject pointed the finger towards the faces in the laminated sheets with level of pain and fear.
6. The researcher then recorded the data (Demographic data was collected by interview schedule and researcher's assisted approach) and alloweed the study subject to keep the balloon.
7. At the end researcher compared the level of pain and fear between both experimental and conventional group using statistical analysis.



Pic 1: Balloon used in the study

Content Validity

Content validity of the tool was determined by expert's opinion. The tool was given to the Medical and Nursing experts in the field of Pediatrics and language experts in English and Punjabi (consent form). As per the guidance and suggestions from the experts, the suggested amendments were made in the tool.

Tool tryout/reliability of tool

Reliability of tool was estimated by inter-rater reliability method. As the tools used were standardized, no difficulties were faced.

Ethical consideration/approval

Study approval was taken from ethical committee of the University College of Nursing, Faridkot. Keeping in mind the legal rights of the study subjects, only those who were willing to participate were included in the study. Written informed consent was taken from family member of each study subject after explaining them about study, its objectives and its benefits. Confidentiality was maintained throughout the study.

Pilot study

Pilot study was conducted in the month of February. Pilot study was conducted to ensure the feasibility of the study and reliability of the tool. The required changes were made in tool. It was conducted in pediatric wards of Guru Gobind Singh Medical Hospital, Faridkot**.** Also it was found that study was feasible and tool was reliable to carry out final study.

Procedure of data collection

The data collection for the study was carried out from including 80 subjects. A formal permission was obtained from Medical Superintendent, Head of Pediatrics department, Guru Gobind Singh Medical College and Hospital, Faridkot. Study procedure was explained to the study subjects prior to the data collection. They were assured that their responses would be kept confidential and will be used only for research purpose. The demographic profile was filled by investigator by using researcher's assisted approach and interview technique. The time spent on each subject during both groups was 2-5 minutes.

Data analysis

Analysis of data was done in accordance with the objectives. Statistical analysis was performed using SPSS version 20.0 software. Descriptive statistics was performed for sample characteristics (frequency, percentage, median, range and Interquartile range). The inferential statistics calculation (Mann-Whitney U test) was performed. Bar graphs were used to depict the findings, p value at 0.05 was considered statistically significant.

Table 1 (a): Frequency and percentile distribution of children during venipuncture according to selected socio-demographic variables

N=80

S. No	Variables	Experimental group (n=40)		Conventional group (n=40)		Chi-Square & p value		
		F	%	f	%	$\chi 2$	DF	p value
1	**Age (years)**					0.214[a]	2	0.899[NS]
	5-7	13	32.5	14	35.0			
	7-9	06	15.0	07	17.5			
	9-12	21	52.5	09	47.5			
2	**Weight (kgs)**						3	
	10-20	10	25.0	09	22.5	6.244[a]		0.100[NS]
	20-30	11	27.5	18	45.0			
	30-40	10	25.0	11	27.5			

	40-50	09	22.5	02	5.0			
3	**Height (m)**						3	
	1.00-1.20	12	30.0	13	32.5	2.213[a]		0.529[NS]
	1.20-1.40	15	37.5	17	42.5			
	1.40-1.60	11	27.5	10	25.0			
	1.60-1.80	02	5.0	00	0.0			
4	**BMI**						1	0.446[NS]
	Below 18.5	28	70.0	31	77.5	0.581[a]		
	18.5-24.9	12	30.0	09	22.5			
5	**Gender**					0.220[a]	1	0.639[NS]
	Male	25	62.5	27	67.5			
	Female	15	37.5	13	32.5			
6	**Previous venipuncture (in last 3 months)**						1	
	Yes					0.066[a]		0.813[NS]
	No	27 13	67.5 32.5	26 14	65.0 35.0			
7	**Previous hospitalization**						1	
	yes					0.208[a]		0.648[NS]
	no	23 17	57.5 42.5	25 15	62.5 37.5			
8	**Relationship of family members with child during venipuncture**							
	Mother/father	36	90.0	39	97.5		1	0.166[NS]
	Grandfather/grand mother	04	10.0	01	2.5	1.920[a]		

Chi-Square Test: p>0.05; Non-significant

Table 1 (b): Frequency and percentile distribution of Pain score in Experimental group.

N=40

S. No	Score	Experimental group	
		Frequency	Percentage
1	Score 0 (No Hurt)	------	-----
2	Score 2 (Hurts Little Bit)	------	------
3	Score 4 (Hurts Little More)	3	7.5
4	Score 6 (Hurts Even More)	12	30
5	Score 8 (Hurts Whole Lot)	21	52.5
6	Score 10 (Hurts worst)	4	10

Table 1 (b) depicts the frequency and percentile distribution of children during venipuncture according to pain score in experimental group. Majority 21(52.5%) of children had scored 8(hurts whole lot), 12(30%) of children had scored 6(hurts even more), 04(10%) of children had scored 10(hurts worst) and whereas only 3(7.5%) of children had scored 4(hurts little more).

Hence, it can be concluded that majority of children had hurts whole lot during venipuncture and only few children had hurt little more during venipuncture in experimental group.

Table 1 (c): Frequency and percentile distribution of Pain score in Conventional group.

N=40

S. No.	Score	Conventional group	
		Frequency	Percentage
1.	Score 0 (No Hurt)	-------	-------
2.	Score 2 (Hurts Little Bit)	-------	-------
3.	Score 4 (Hurts Little More)	-------	-------
4.	Score 6 (Hurts Even More)	-------	--------
5.	Score 8 (Hurts Whole Lot)	5	12.5
6.	Score 10 (Hurts worst)	35	87.5

Table 1 (c) depicts the frequency and percentile distribution, of children during venipuncture according to pain score in conventional group. Majority 35(87.5%) children of had scored 10(hurts worst) and whereas only 5(12.5%) of children had scored 8(hurts whole lot).

Hence, it can be concluded that majority of children had hurts worst during venipuncture and only few children had hurts whole lot during venipuncture in conventional group.

Table 1(d): Frequency and percentile distribution of Fear score in Experimental group.

N=40

S. No.	Score	Experimental group	
		Frequency	Percentage
1.	Score 0 (not scared)	-------	-----
2.	Score 1 (a little bit more scared)	------	------
3.	Score 2 (a bit more scared)	12	30
4.	Score 3 (scared a lot)	28	70
5.	Score 4 (most scared possible)	-----	------

Table 1(e): Frequency and percentile distribution of Fear score in Conventional group.

N=40

S. No.	Score	Conventional group	
		Frequency	Percentage
1	Score 0 (not scared)	-------	------
2	Score 1 (a little bit more scared)	-------	------
3	Score 2 (a bit more scared)	--------	-------
4	Score 3 (scared a lot)	6	15
5	Score 4 (most scared possible)	34	85

Table 1 (e) depicts the frequency and percentile distribution of children during venipuncture according to fear score of conventional group. Majority 34(85%) of children had scored 04(most scared possible), whereas only 06(15%) of children had scored 03(scared a lot).

Hence, it can be concluded that most of the children had most scared possible during venipuncture and only few children scared a lot during venipuncture in conventional group.

Table 2: Findings related to effectiveness of conventional methods along with balloon inflation in reduction of pain and fear during the venipuncture.

N=40

Experimental group	Minimum	Maximum	Median	Range	IQR
Pain score	4	10	8	6	2
Fear score	2	3	3	1	1

Table 3: Findings related to effectiveness of conventional methods only in reduction of pain and fear during the venipuncture.

N=40

Conventional group	Minimum	Maximum	Median	Range	IQR
Pain score	8	10	10	2	0
Fear score	3	4	4	1	0

Table 4 (a): Findings related to comparison of conventional methods along with balloon inflation vs conventional methods only in reduction of pain during venipuncture.

N=80

Pain score	Median	Range	IQR	p value by Mann- Whitney U test
Experimental group	8	6	2	0.001**
Conventional group	10	2	0	

Mann-Whitney U test is significant at p value < 0.05 (2 tailed)

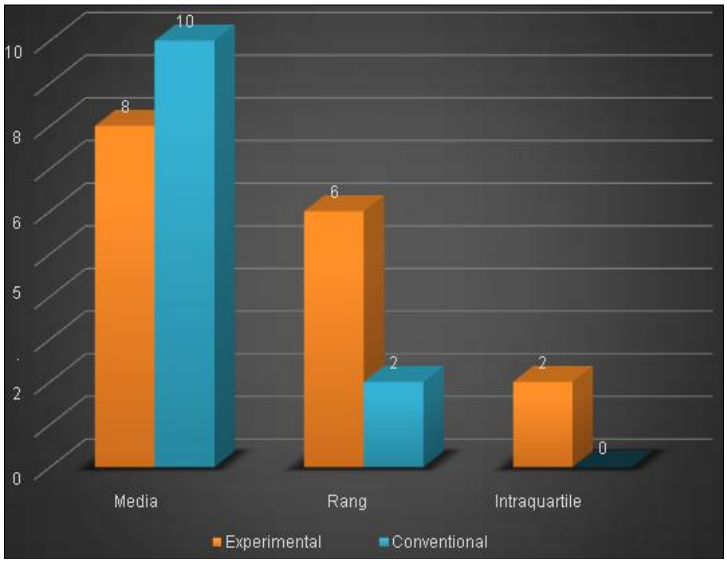


Fig 1: Bar graph showing comparison of pain score in experimental and conventional group.

Table 4 (a) and Fig. 1 revealed that the median of experimental group was 8 with Interquartile range of 2 and median of conventional group was 10 with Interquartile range of 0. Mann-Whitney U test was applied for statistical analysis and p value is 0.001** which is statistically highly significant.

Table 4 (b): Findings related to comparison of conventional methods along with balloon inflation vs conventional methods only in reduction of fear during venipuncture.

N= 80

Fear score	Median	Range	IQR	P value by Mann- Whitney U test
Experimental group	3	1	1	0.001**
Conventional group	4	1	0	

Mann-Whitney U test is significant at p value < 0.05 (2 tailed).

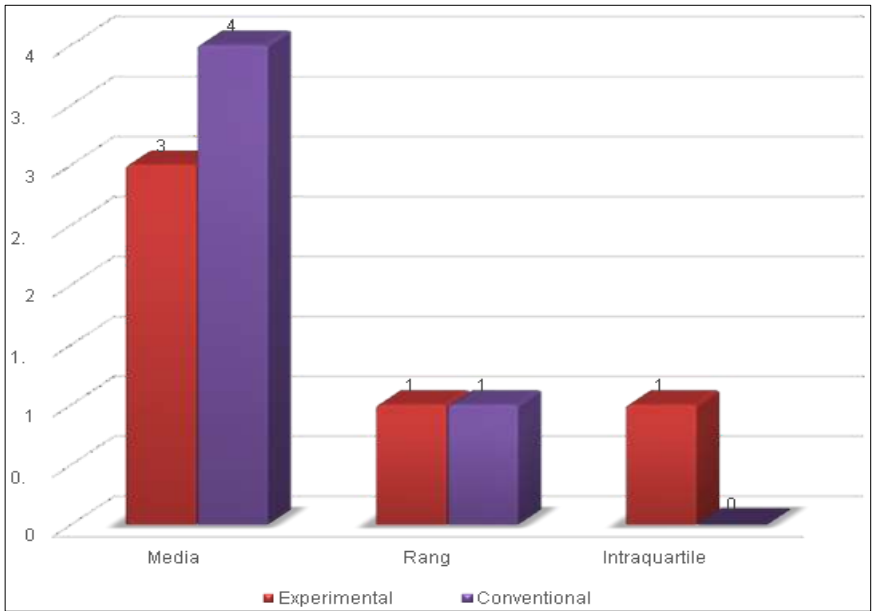


Fig 2: Bar graph showing comparison of fear score in experimental and conventional group

Table 4 (b) and Fig. 02 revealed that the median of experimental group was 3 with Interquartile range of 1 and median of conventional group was 4 with Interquartile range of 0. Mann-Whitney U test was applied for statistical analysis and p value is 0.001** which is statistically highly significant.

Hence, it can be concluded that, children who were using conventional methods along with balloon inflation perceives less pain and fear than children who were receiving conventional methods only. It revealed that level of pain and fear was less in experimental group than in conventional group during venipuncture.

Discussion

These finding were supported by Gupta D *et al.* (2006) [14] that balloon inflation may have a combined effect of Valsalva maneuver and distraction on decreasing the incidence of venipuncture pain. Consistent findings were supported by Mutlu B *et al.* (2015) [15] that pain intensity significantly difference between the control (n = 44) and intervention groups (balloon inflation [n = 44] and cough trick [n = 44], p <.001). The findings were also supported by Sadeghi TA (2010) [16] that balloon inflation is an effective, non-medical, cheap and available method to reduce the pain in children when venous opening procedure is performed. Ebrahem GGS *et al.* (2019) [17] that cryotherapy and balloon inflation have a positive effect on reducing pain of arteriovenous fistula cannulation among children undergoing hemodialysis The findings were also supported by Robabi H *et al.* (2017) [18] that two distraction methods of inflating balloon and watching cartoons could effectively decrease the pain induced by DPT vaccine. These findings were supported by Sahiner NC *et al.* (2016) [10] that self-reported procedural pain levels showed significant differences among the study groups (p=.040).The procedural child anxiety levels reported by the observer showed a significant difference among the study groups (p =.032). These findings were also supported by Aykanat Girgin BA *et al.* (2019) [19] that mean scores for pain and fear after the procedure were lower in all intervention groups compared with the control group (p =.001). Balloon inflation, ball squeezing, and coughing were all effective in reducing pain and fear associated with venipuncture in children aged 7-12 years.

Conclusion

On the basis of the findings of the study, it was concluded that children feel severe level of pain and fear during venipuncture as expressed by Wong-Baker Faces Pain Rating Scale and Children's Fear Scale.

There was highly significant reduction in level of pain and fear when Venipuncture was done with conventional methods along with balloon inflation in comparison to conventional methods only.

Conventional methods along with balloon inflation was effective as a non-pharmacological method of reduction/management of pain and fear during venipuncture. Hence, strategies should be planned so as to implement it in the clinical setting which leads to painless and fearless venipuncture.

Recommendations

1. Further studies can be conducted in future regarding the analgesic and distracting effect of conventional method along with balloon inflation on pain and fear related to other painful procedures.
2. Further researches can be conducted by taking other non-pharmacological strategies (like use of Valsalva manoeuvre, maternal holding and use of guided imagery) as an intervention.

3. The study can be replicated on a large sample to validate and generalize its findings.
4. A multicentre study could be done.
5. A comparative study can be conducted with more than one intervention.
6. A study can be conducted to assess the knowledge and practice of health care professionals on various non-pharmacological measures available for reducing pain and fear during venipuncture.

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