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Effect of Thermomecanical Stimulation (Buzzy®) and Cryotherapy on Children Pain, Anxiety and Satisfaction During Blood Specimen Collection

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Abstract
Internationally, needle procedures are the most common and important source of pain and distress in children. Pain relief during these procedures such as blood specimen collection and vaccination is an important nursing task. The purpose of this study was to determine the effect of Thermomecanical Stimulation (Buzzy®) and cryotherapy on children pain, anxiety and satisfaction during blood specimen collection. The design of this study was quasi experimental. It was conducted at pediatric department in Menoufia University Hospital at Shebin El-kom city-Menoufia Governorate. A purposive sample of 150 children aged 6 - 12 years was used. Three tools were used in this study; Structured Interview Questionnaire; Children Fear Scale (CFS) and Faces Pain Scale-Revised (FPS-R). The results of this study showed that children in the buzzy and cryotherapy groups had lower of pain level (child-reported 0. 96± 1.41, 1.44 ± 1.3 VS observer- reported 1.08± 1.4, 1.24± 1.3 VS parent-reported 1.40 ± 1.4, 1.40± 1.5 respectively) and lower level of anxiety (parent – reported 1.10 ± 0.789, 1.86± 0.64 VS observer -reported 1.34 ± 0.717, 1.58±0.64 respectively) than children in control group. Also, it reflected that children and their Parents who receive Buzzy and cryotherapy were more satisfy (78%, 76% and 90%, 70%) respectively regarding its effect. It was concluded that, children in buzzy and cryotherapy groups had lower levels of pain and anxiety. Also, children and their parents were more satisfied than children and their parents in control group. Therefore, this study recommended that buzzy should be integrated as a part of routine daily care for managing needle puncture pain and anxiety during blood specimen collection.
Keywords: Thermomecanical stimulation (Buzzy), Pain, Anxiety, Satisfaction, Blood Specimen Collection.

1. Introduction

Venipuncture is a devastating medical, emotional and physical problem for both pediatric patients and their families. Phlebotomy, blood taking/drawing from a vein for diagnostic purposes or treatment, is one of the most common procedures in hospital setting. Also, it has been shown to be one of the most frightening and distressing nursing procedures for hospitalized children which affects the experience of subsequent treatment and care. Furthermore, fear of needle stick pain experienced due to medical and nursing procedures in childhood usually continues up to adulthood (Gupta et al., 2014 and Abd El-Gawad & Elsayed 2015).

Medical and various nursing procedures that are applied by using a needle, such as blood specimen collection and immunization which considered the most common and a major source of pain for causes considerable stress and anxiety for hospitalized children and their parents (Sadeghi et al., 2013; Uman et al., 2013, and Canbulat et al., 2014). According to Dowall (2010), blood taking is a stressor and source of painful experience to children admitted to hospital. This procedure may cause children to become fearful of needles and may lead to them becoming uncooperative in their care and associated with behavioral arousal and a stress response consisting of increased blood pressure, heart rate, pupil diameter and plasma cortisol level (James et al., 2012).

The painful experience may lead to patient anxiety when undergoing those procedures again. Therefore, the reduction of the sensation of pain and anxiety involved in the procedure is crucial. This can lead to improved patient cooperation and a smoother process during the procedure. So, all health professionals should know how to assess and manage it when caring for pediatric patients (Cohen et al., 2009; Sadeghi et al., 2013, and Mutlu & Balcı, 2015). To this end, the American Academy of Pediatrics (AAP) and American Pain Society (APS), (2011) recommend that minimizing and relieving pain and stress in minor procedures such as establishing vascular access. Therefore, pharmacologic and non-pharmacologic methods are used for relief pain during medical and nursing procedures. When used appropriately, non-pharmacologic methods can be more effective in reducing procedural pain. Non-pharmacologic methods used in children can be classified in three main groups: supportive methods, cognitive/behavioral methods and physical methods (Srouji et al., 2010 and Krauss, 2016).

The most widely type of non-pharmacological method for pain relief among children during painful nursing procedures is the physical and behavioral methods. Physical methods are based on the gate control theory, which states that nociception from the peripheral to central nervous system is modulated by a gate system in the dorsal horn of the spinal cord (Mohamed, 2017). Stimulating touch and temperature receptors decreases a subsequent painful sensation. Using physical methods that employ cold temperatures or vibration is effective in

providing pain relief during venipuncture (Gupta et al., 2017).

In 1984, Bini et al. reported an interesting phenomenon: the research group induced pain in healthy research subjects using electrical stimulation in order to test whether common maneuvers such as vibration, massage, warming, or cooling would affect subjects' pain experience. Vibration provided the most effective response on its own, however, a combination of vibration and cooling provided the most potent analgesic effect of those investigated, at times completely inhibiting moderate pain. Though impressive pain reduction was observed when cold and vibration were combined (thermomechanical stimulation) (Kearl et al., 2015).

Buzzy device, a vibrating motor with ice pack, combines multiple approaches by supplying cold analgesia, tactile stimulation, and distraction. Buzzy is thought to provide pain relief via gate control theory, by stimulating nerves with cold to "close" the fast pain gate. It is hypothesized that by simultaneously stimulating Aβ mechanoreceptors with vibration, one can also close the fast pain gate via presynaptic inhibition at the dorsal horn; the combination of the two would provide optimal pain relief (Baxter et al., 2009). Studies investigating the use of this device in pediatric populations have also demonstrated superior pain relief in children while confirming the feasibility of its use in a fast-paced care setting (Baxter et al., 2011). Most reports of the device suggest it provides significant pain relief however the majority of these studies completed in pediatric populations focused on children undergoing venous cannulation (Inal & Kelleci, 2012; Whelan et al., 2014; and Moadad, et al., 2016).

Benjamin et al., (2016) reported that vibration therapy alone (without cold analgesia) was not effective in reducing immunization pain. However, a recent study of both cold and vibration during blood collection specimen procedure indicated that significant pain and anxiety reduction was achieved per child self-report and observer scores (Yılmaz et al., 2017). While these studies have given some evidence of the device's efficacy, few have focused on thermomechanical stimulation during pediatric blood collection specimen and immunization (Schreiber et al., 2016).

Cryotherapy as a non- pharmacological method for management is not expensive, safe and easy to provide (Jose & Lobe, 2016). It is a pain management that uses methods of localized freezing temperatures to deaden an irritated nerve. Cryotherapy without vibration lowers the temperature over the painful or inflamed area of the skin for reduce the velocity of nerve condition in C- and A-delta fibers, thereby slowing the transmission of pain signal (Abd-Elhady, 2017).

In recent years, the scope of patients' participation in the evaluation of healthcare services has been broadened because patients' experiences and satisfaction are considered to be vital components in the evaluation of healthcare interventions, as well as in assessing the quality of care (Aydin et al., 2016)). Moreover, parents' satisfaction with health care is associated with an improvement in their child's health or understanding medical information. Thus, in this study the level of children and their parent's satisfaction is important that helps to evaluate buzzy utilization.

The nurse have important role in providing right patient care by helping and teaching the pediatric patient how to apply buzzy and cryotherapy Also, nurses should be aware of the use of buzzy and have knowledge and practice to teach pediatric patient the self –application of these therapies that may reduce pain and anxiety impact (Czarnecki et al., 2011 and Aydin et al., 2016). Many studies used only technique of cryotherapy but in this study two techniques were utilized to compare between their effects. Therefore, this study was conducted to determine the effect of thermomecanical stimulation (Buzzy®) and cryotherapy on children pain, anxiety and satisfaction during blood specimen collection **Purpose**

The purpose of this study was to determine the effect of thermomecanical stimulation (Buzzy®) and cryotherapy on children pain, anxiety and satisfaction during blood specimen collection.

Research hypotheses

It was hypothesized that:

1. Children in study group (Buzzy) will have less Procedural pain and anxiety during blood specimen collection than children in control group.
2. Children in study group (cryotherapy) will have reduced Procedural pain and anxiety during blood specimen collection than children in control group.
3. Parents of Children who receive Buzzy and cryotherapy will be more satisfy than parents on control groups.

2. SUBJECTS AND METHOD

2.1. Research design

A quasi experimental design was used.

2.2. Research Setting

This study was conducted at the Pediatric Department in Menoufia University Hospital at Shebin El-kom city. It consisted of three rooms in the 4th flower. Each room consisted of 10 beds.

2.3. Sample

A purposive sample of 150 children was obtained from the previous mentioned setting. They were referred by treating physician for blood test. A simple random sample was used to assign children into Buzzy, crayotherapy and control groups did not receive any intervention (only standard care). Each group equally contained 50 children.

Criteria of sample selection

- ***Inclusion criteria:*** children who were aged 6–12 years and requiring blood tests, first needle stick during this admission, Parent have to attend needle stick. All children should have no cognitive delays.
- ***Exclusion criteria:*** Children were excluded if had previously experienced Buzzy, a break or abrasion on the skin where the device would be placed, a nerve damage in the affected extremity, a medically unstable, chronic illness, any congenital anomalies, congenital infections, central nervous system disease, visual and hearing impairment, used an analgesic within the last 6 hours, they had a history of syncope due to blood specimen collection and they had sensitivity to cold**.**
- **Sample size**

  Sample size has been calculated using the following equation: $n= (z^2 \times p \times q)/D^2$ at CI 95% and power 80%. The study sample size was determined by power analysis based on previous research, with a 1.5 SD for the buzzy and cryotherapy groups and 2.0 for the control group. With a power of 0.80 and an acceptable type I α error size of 0.05, each group required a minimum of 50 individuals.

2.4. Data collection tools: - four tools were utilized for data collection**.**

Tool one: Structured Interview Questionnaire. It was designed by the researchers to collect the data about characteristics of the children as well as parent characteristics data. This tool was divided into three parts:

- **Part one: Social Characteristics of Participating Children.** It included questions about name, age, sex and previous vein puncture for least 3 months.
- **Part two: Social Characteristics of Participating Parents**. It included data about the mother and father age, level of mother and father education.
- **Part three: Physiological Measurements Chart.** It was included a diary for recording child physiological measurements such as pulse and respiration.

Reliability:-

The reliability of tool one was done to determine the extent to which items in the tool were related to each other by Cronbach's co-efficiency Alpha (a=.822) .so it can be concluded that the tool has a high level of reliability.

Tool two: Children Fear Scale (CFS). It was developed by McMurtry et al., (2011). It was used to evaluate the children's level of anxiety. It included five cartoons faces revealing different levels of anxiety. **Face 0:-** a neutral expression (0 = no anxiety), **Face 2:-** mild anxiety, **Face 3:-** moderate anxiety, **Face 4:-** severe anxiety and **Face 5: -** a frightened face (very severe anxiety). The scores ranged from 0-5. The reliability was done using Cronbach's Alpha test (r= 0.96).

Tool three: - Faces Pain Scale-Revised (FPS-R). It was developed by Hicks, et al., (2001) to assess pain level of the children. It was a 0 to 10 scale consisting of six cartoon faces that range from a neutral expression (0-no pain) to a screaming face (10- very much pain). Score the chosen face 0, 2, 4, 6, 8, or 10, counting left to right, so "0" equals "No pain" and "10" equals "Very much pain". The FPS-R is cited in more than 140 studies and has been accepted as a well-established measure. Children were asked to draw a circle around the face that could best represent the amount of pain they were experiencing, which is then numerically represented. The reliability was done using Cronbach's Alpha test (r= 0.87).

Tool four: - Blood Specimen Collection Satisfaction Evaluation Scale.

In order to assess the level of satisfaction during blood drawing, a scale developed by the researchers was used that consisted of three statements indicating children and their parent's satisfaction level related pain and anxiety relief after Buzzy and cryotherapy interventions. It was range from Unsatisfactory = 0, little satisfactory =1 and very satisfactory =2.

Validity

For validity assurance, four instruments were provided to a jury including three professor of pediatric nursing and two assistant professors of pediatric nursing and two assistant professors in pediatrics .The modifications was done to ascertain their relevance and completeness.

2.5. Ethical consideration

A verbal consent was obtained from the children and their parents who participated in the study.

An initial interview was done to inform children and their parents about the purpose, benefits of the study and explain that participation in the study was voluntary and the participants could withdraw from the study at any time without penalty.

2.6. Pilot study

It was carried out on 5 children (10% of the sample) after the instruments were developed and before starting the data collection to test the practicability, applicability and to estimate the needed time to fill the instruments. No necessary modifications were done. Therefore, the pilot study was included in the total sample.

2.7. Procedure

Preparatory phase:-

1- Firstly, the researchers sent email for the company who is responsible for sell buzzy for UK and Ireland in this web site beccy@buzzy4shots.co.uk.and the company gave the website of the buzzy representative in Egypt for researcher http://www.tiarapro.com. The researchers bought the buzzy for about 600 pound.
2- Prior to data collection, a written permission to carry out the study was obtained from the director of each setting after submitting an official letter from the Dean of the faculty of Nursing at Menoufia University explaining the purpose of the study and methods of data collection.
3- Data collection for this study was conducted for a period of 6 months extending from the 1st of November 2016 to the end of April 2017.
4- Children medical files were reviewed by the researcher to determine the list of children who will have blood specimen.
5- The researcher introduced herself to children, their parents and the nurses who shared in collection of blood specimen, explained the purpose of the study and methods of data collection. The device was shown to parents and children prior to enrollment, and children were allowed to touch and turn on the device if they chose (buzzy).
6- After the children and parents agreeing to participate had been ensured, their identifying data were collected on the form, and then they were given brief explanation on the use of the pain and anxiety measures.
7- There were two volunteer nurses with a minimum of five years' experience in pediatric patient care and venipuncture were trained for assisted and conduct of this study. The first nurse was functioned as an observer and the second nurse was performed the venipuncture procedure for all children. The nurses and researchers had no conflict of interest.
8- The pre-procedural anxiety level (from the moment the child knew he/she was going to be punctured) was evaluated for each child by using the 0–4 CFS scale for anxiety through parental, and observer reports. The observer and parents were blinded to each other's responses. Besides, physiological measures (heart rate and respiration rate were assessed.
9- Blood specimen collection sessions were held between 9:00–12:00 AM and 12:00–16:00 PM and performed using a 5-ml injector and a 22-G needle a standard needle and equipment were used on all participants.

Performance phase:

Buzzy Group:

Just before blood drawing procedure, a single researcher was applied the external cold and vibration stimulation via Buzzy 5 to 10 cm above the application area. It was contacted to the skin properly. The cold pack was stayed in a freezer and was mounted on a device before use. The cold application and vibration was started just before the procedure and it was continued until the end of the procedure. If the venipuncture was not successful at the first attempt, the child was excluded from the study. Children were asked to concentrate on the sensations of the "Buzzy" rather than look at the needle insertion. We cleaned the device with 70% alcohol when we switched it to another child. Participating research assistants and nurses reviewed a brief instructional video on the device prior to conducting the data collection.

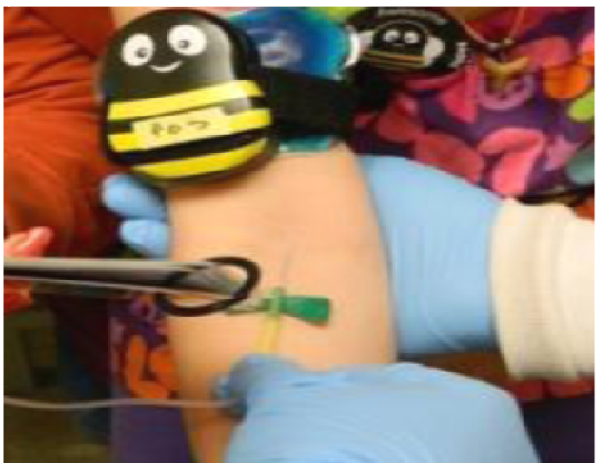

Figure1. Venipuncture Tips. Retrieved from: Home/Buzzy Helps. (2016). How to use BUZZY® in healthcare settings Retrieved from https://buzzy helps.com.

Cryotherapy group: the researcher put olive oil (one or to drops) over puncture sit to reduce the danger of ice burn and made ice massage in circular motion with 2-3 cm ice of a frozen distal water inside plastic bag. Ice massage was done until skin numbness was felt (if frozen ice melted it was replaced).

Control Group: No intervention was implemented before the procedure, and the standard vein entry procedure was used.

Blood specimen collection protocol:

- The standard blood specimen collection protocol was carried out in the same way on the children of the buzzy, crayotherapy and control groups as the following:
  - Preparation of the necessary material for the venipuncture.
  - The participant was placed in a supine position.
  - Wearing gloves, the vein for the intervention was assessed by observation and palpation.
  - An automatic tourniquet was attached 12 cm above the intervention site (the buzzy device it already have on automatic tourniquet).
  - The selected site was cleaned with antiseptic solution with a single movement.
  - The needle was held approximately 1 cm below the vein, which was to be entered at an angle of 30º to 45 º to the skin.
  - As the needle entered the vein, the entry angle was reduced to approximately 15 º and the needle was advanced slowly in the vein.
  - A check was made as to whether bloods was entering the phlebotomy set then, aspirate the blood according doctor order.
  - Aspirate the blood according doctor order.
  - The needle position was fixed on the skin according to aseptic principles.
  - When the phlebotomy process was completed, the tourniquet was released, the needle was removed aseptically, and the area was pressed with sterile gauze.
  - The procedure was considered successful if blood started running into the tube in 15 seconds.
- All parents stayed with their children during the procedure.

Evaluation phase:

1. After procedure, the pain levels of children were assessed with self-reports, the parents' and the observer's report. They were asked to rate his/her pain according Faces Pain Scale-Revised (FPS-R) in order to rate pain intensity felt during blood drawing procedure.
2. Re-assessment of anxiety levels during the procedure were assessed via parents and observer reports.
3. Re-assessment heart and respiratory rate after procedure.

2.8. Data analysis

Data was coded and transformed into specially designed form to be suitable for computer entry process. Data was entered and analyzed by SPSS (statistical package for the social science software) version 20 on IBM compatible computer. Graphics were done using Excel program.

Quantitative data were expressed as mean & standard deviation and analyzed by applying t-test for comparison of two groups of normally distributed variables. Qualitative data were expressed as number and percentage (No & %). It was analyzed by using chi-square test (X^2) for 2X2 table. Pearson correlation was used for explaining relationship between normally distributed quantitative variable.

For comparison between the quantitative data at interval for different groups MANOVA-test was used. For comparison between the quantitative data at interval for the same group at different sessions and repeated measures Friedman Test was used for comparison between the quantitative data at interval for both groups that not normally distributed Wilcoxon Test was used.

P-value at 0.05 was used to determine significance regarding:

- P-value > 0.05 to be statistically insignificant.
- P-value ≤ 0.05 to be statistically significant.
- P-value ≤ 0.001 to be high statistically significant.

3. Result

Table 1. Distribution of studied children and their parents according to their characteristics

Items	Control group n= 50)(		Cryotherapy group (n= 50)		Buzzy group n= 50)(		χ^2
	No	%	No	%	No	%	
Age /years $\bar{x} \pm$ **SD**	8.54 ±1.70		8.94 ± 1.65		8.38± 1.77		.98 ns
Gender							1.12 ns
Male	25	50.0	24	48.0	29	58.0	
Female	25	50.0	26	52.0	21	42.0	
Previous venipuncture for last 3 months							
yes	11	22.0	7	18.0	12	24.0	.07 ns
no	39	78.0	43	82.0	38	76.0	
Mother age/years $\bar{x} \pm$ **SD**	31.84 ± 2.713		32.7 ± 2.41		31.88 ± 2.946		.45 ns
Mother education							.19 ns
under secondary	36	72.0	29	58.0	35	70.0	
above secondary	14	28.0	21	42.0	15	30.0	
Father age/years $\bar{x} \pm$ **SD**	39.44± 2.90		40.45 ± 2.45		39.34 ± 2.353		.53 ns
Father education							.20 ns
under secondary	37	74.0	32	64.0	36	72.0	
above secondary	13	26.0	18	36.0	14	28.0	

ns **means non-significant.**

Table 1 shows distribution of the studied children according to their characteristics. In relation to age, the means and standard deviation of children age were 8.38± 1.77, 8.94 ± 1.65 and 8.54 ±1.705 in the Buzzy, cryotherapy and control groups, respectively. There were no statistical significant differences between the three groups at 5% level of statistical significance. Regarding sex, males and females children in were equal in control group (50%) meanwhile more than half of children in the buzzy group were males (58%) and slightly more than half of children in crayotherapy (52%) were female. 22%, 18% and 24% of children in control, cryotherapy and Buzzy, respectively had at least one previous venipuncture. There were no statistical significant differences between the three groups at 5% level of statistical significance. In relation to ages of mothers and fathers this table shows that, mean ages of mothers are 31.84 ± 2.713, 32.7 ± 2.41 and 31.88 ± 2.946 years for mothers of children in control, cryotherapy and Buzzy group, respectively. Meanwhile the mean ages for fathers are 39.44± 2.90, 40.45 ± 2.45 and 39.34 ± 2.353 years for fathers of children in control, cryotherapy and Buzzy group, respectively. There are no statistical significant differences between the three groups at 5% level of statistical significance. According to parents level of education this table reflects that, 72%, 58% and 70% of mothers of children in control, cryotherapy and Buzzy group are under secondary level of education, respectively. While, 74.0%, 64% and 72% of fathers of children in control, cryotherapy and Buzzy group are under secondary level of education, respectively.

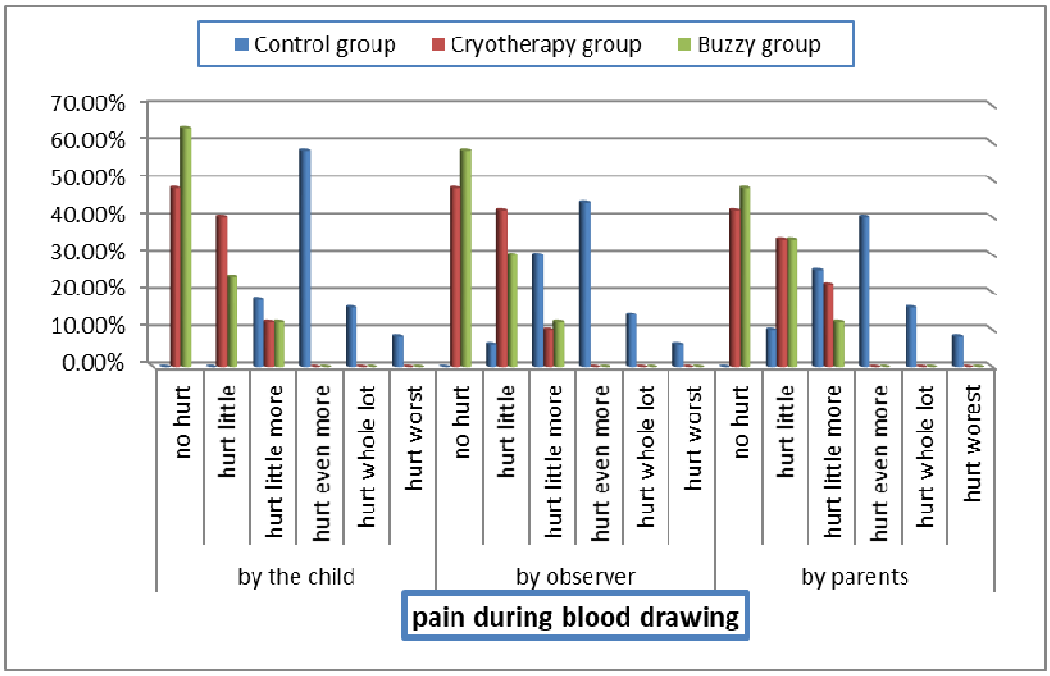

Figure 2. Level of pain among children according child, observer and parents report in each three groups during blood collection specimen procedure

Figure 2 illustrated that more than one third of children in the control group (58%, 44% and 40%) had even more level of pain according child, observer and parents report respectively. Meanwhile, most children in buzzy and cryotherapy groups had no pain according child, observer and parents report.

Table 2. Means of children pain level scores during blood collection specimen procedure according the child, parents and observer- reported in the studied groups

Items	Control group	Cryotherapy group	Buzzy group	**MANOVA**-test	p-value
	$\bar{x}$ ± SD	**$\bar{x}$ ± SD**	**$\bar{x}$ ± SD**		
❖ <u>According to FPS-R</u>					
Child-reported	6.28 ± .61	1.44 ± 1.3	0.96 ±1.41	202.498	.000**
Parent- reported	5.72 ± 2.1	1.40 ± 1.5	1.40 ± 1.4	106.809	.000**
Observer-reported	5.68 ± 1.9	1.24 ± 1.3	1.08 ± 1.4	137.763	.000**

** means highly significant

❖ FPS-R= Faces Pain Scale-Revised (FPS-R)

Table 2 showed means of children pain level scores during blood collection specimen procedure according the child, parents and observer reported in the studied groups**.** it clarifies that there were highly statistical significant differences between the mean of pain scores of the children in studied groups in the child- observer- and parent-reported procedural pain (p<.000). Meanwhile, the findings revealed that the children in the Buzzy group had significant lower pain levels by child-report (0.96 ±1.41), parent report (1.40 ± 1.35) and observer report (1.08 ± 1.4), than the control group.

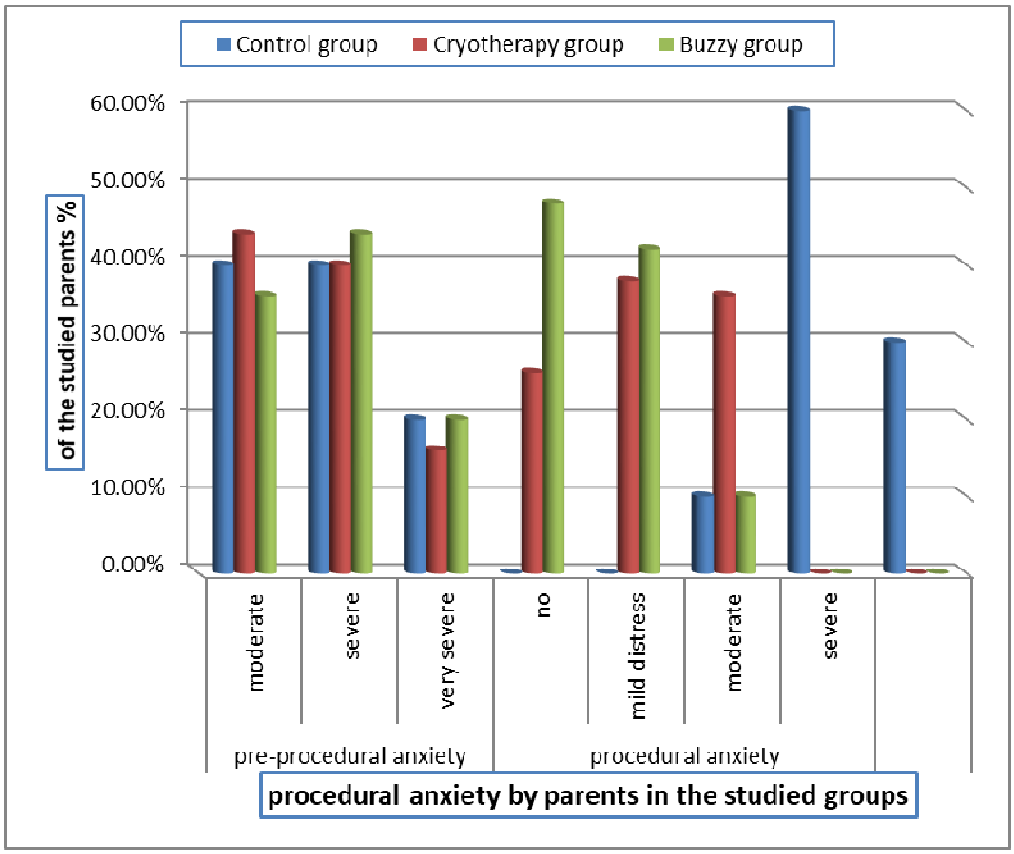

Figure 3. Distribution of Level of anxiety for children according parent-reported in each three groups before and during blood collection specimen procedure

Figure 3 illustrated that more than half of children in the control group (60%) had severe level of anxiety during blood collection specimen procedure according parent-reported**.** Meanwhile, most children in buzzy and cryotherapy groups had no anxiety or mild level of anxiety. In addition, most of children in three groups had moderate to severe level of anxiety according parent-reported before blood collection specimen procedure.

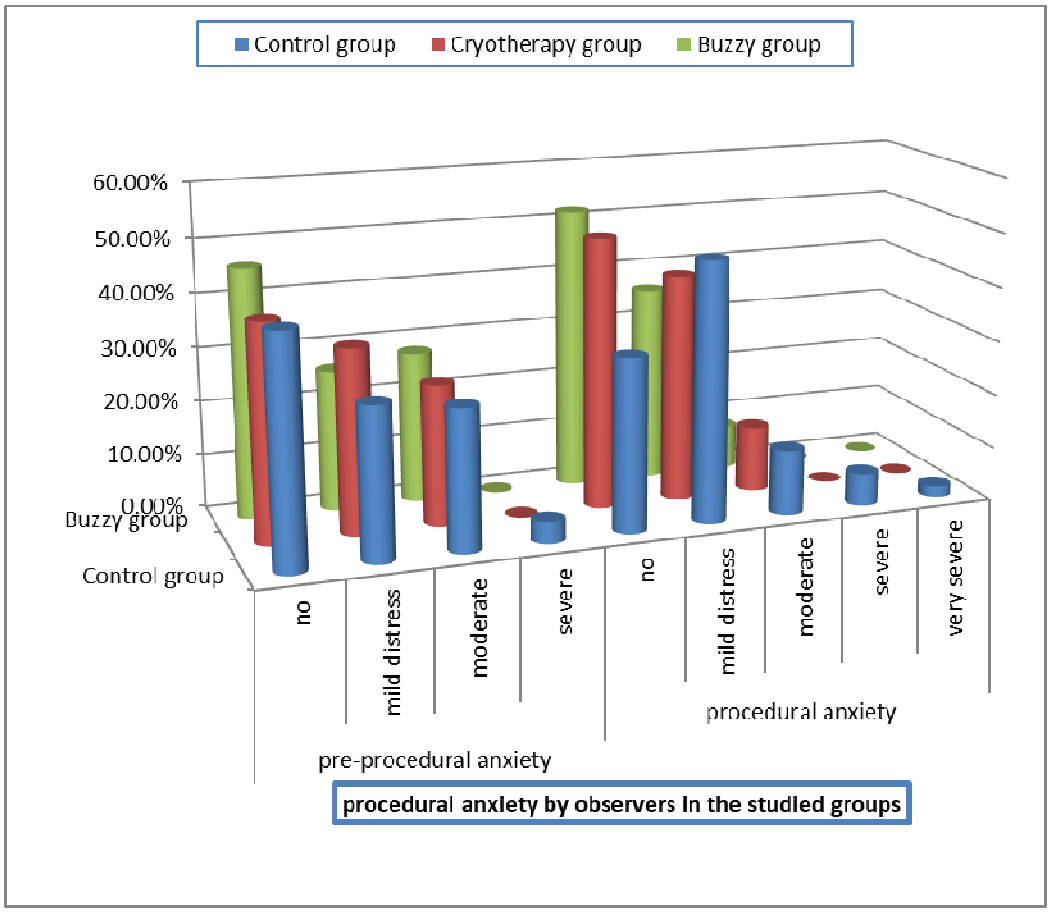

Figure 4. Distribution of level of anxiety for children according observer-reported in each three groups before and during blood collection specimen procedure

Figure 4 illustrated that the 48% of children in the control group had mild level of anxiety during blood collection specimen procedure according observer-reported. Meanwhile, about the half of children (52%, 50%) in buzzy and cryotherapy groups had no anxiety.

Table 3. Mean scores of children anxiety level during blood collection specimen procedure by the parents and observer- reported in the studied groups

Items	Control group	Cryotherapy group	Buzzy group	**MANOVA-test**	p-value
	$\bar{x} \pm SD$	**$\bar{x} \pm SD$**	**$\bar{x} \pm SD$**		
❖ **Parent-reported according CFS:**					
pre-procedural anxiety	2.80 ±0.76	2.70± 0.73	2.84 ± 0.74	.340	.713
procedural anxiety	3.20 ± 0.606	1.86 ± 0.81	1.10± 0.789	195.510	.000**
Wilcoxon Test	-4.066	6.446	-6.737		
p-value	.000**	.000**	.000**		
❖ **observer-reported according CFS:**					
pre-procedural anxiety	2.68 ± 0.794	2.57± 0.76	2.88± 0.659	.171	.843
procedural anxiety	3.12 ± 0.718	1.58 ± 0.64	1.34 ± 0.717	4.284	.000**
Wilcoxon Test	-.331	-1.352	-2.083		
p-value	.741	.176	.037		

❖ CFS= Children Fear Scale ** means highly significant

Table 3 clarifies mean scores of children anxiety level during blood collection specimen procedure by the parents and observer- reported in the studied groups. It reflected that there were highly statistical significant differences between the mean of procedural anxiety level scores of the children in three groups according observer- and parent-reported procedural anxiety (p<.000). The findings revealed that children in buzzy group and cryotherapy had significantly lower procedural anxiety levels by parent (1.10 ± 0.789 and 1.86 ± 0.81) and observer report (1.34 ± 0.717 and 1.58 ± 0.64) than the control group. Meanwhile, there was no statistical significant difference between means of pre- procedural anxiety levels scores reported in three groups by the parent and observer reports.

Table 4 . Means and standard deviation of heart rate and respiratory rate for children in three groups in pre, during and post blood collection specimen procedure in the studied groups

Items	Control group	Cryotherapy group	Buzzy group	Anova - test	p-value
	$\bar{x}$ ± SD	$\bar{x}$ ± SD	$\bar{x}$ ± SD		
pre heart rate	93.82 ± 7.634	94.06 ± 7.826	96.54 ± 0.597	1.467	.234
during heart rate	122.00 ± 3.423	98.62 ± 5.155	98.62 ± 0.781	87.489	.000**
post heart rate	111.98 ± 8.518	96.36 ± 8.463	97.32 ± 9.958	47.242	.000**
Friedman Test	91.600	.418	.505		
p-value	.000**	.519	.604		
pre- respiratory rate	27.98 ± 2.412	27.06 ± 2.543	27.70 ± 1.340	1.401	.250
during respiratory rate	31.64 ± 3.601	28.70 ± 3.903	28.52 ± 2.323	14.890	.000**
post respiratory rate	28.90 ± 2.573	26.28 ± 3.084	27.10 ± 1.471	4.976	.008**
Friedman Test	51.458	2.798	1.926		
p-value	.000**	.098	.149		

** means highly significant

Table 4 shows means and standard deviation of heart rate and respiratory rate for children in three groups in pre, during and post blood collection specimen procedure in the studied groups. It Clarified that there were no statistical significant differences between means of heart and respiration rates before procedure in both groups (P >0.05) and there were highly statistical significant differences means of respiration and heart rates during and after procedure on both groups (p < .001). These changes revealed that children in the buzzy group had lower mean respiration and heart rates than children in the control group during and after procedure.

Table 6. Distribution of children and their parents' satisfactions regarding the effect of Buzzy and cryotherapy in relieving pain and anxiety during blood collection specimen in each studied group

Items	Control group		Cryotherapy group		Buzzy group		χ^2	p-value
	No	%	No	%	No	%		
Parents satisfaction							159.4	.000**
Unsatisfactory	50	100.0%	0	0.0%	0	0.0%		
Little satisfactory	0	0.0%	5	10.0%	15	30.0%		
Very satisfactory	0	0.0%	35	70.0%	45	90.0%		
Children satisfaction							131.6	.000**
Unsatisfactory	45	90.0%	0	.0%	0	0.0%		
Little satisfactory	5	10.0%	11	22.0%	12	24.0%		
Very satisfactory	0	0.0%	38	76.0%	39	78.0%		

** means highly significant

Table 6 shows Children and their parents' satisfactions regarding the effect of Buzzy and cryotherapy in relieving pain and anxiety during blood collection specimen in each studied group. It reflected that children and their Parents who receive Buzzy and cryotherapy were more satisfy (78%, 76% and 90%, 70%) respectively regarding the effect of Buzzy and cryotherapy in relieving pain and anxiety during blood collection specimen than children and parents on control groups.

4. Discussion:

Many researchers have shown the long-term negative effects of early pain experienced in children. Therefore, nurses should be able to manage painful procedures to reduce children anxiety and pain during painful medical procedures. A few studies have investigated the effect of buzzy and cryotherapy on pain reduction. These studies indicated that Buzzy and cryotherapy decreased perceived pain and reduced children's anxiety during medical procedures such as blood specimen collection, immunization, and peripheral intravenous cannulation (Canbulat

et al., 2015). The current study hypothesized that Children in study group (Buzzy) will have less procedural pain and anxiety during blood specimen collection than children in control group, children in study group (cryotherapy) will have reduced procedural pain and anxiety during blood specimen collection than children in control group and Parents and children who receive buzzy and cryotherapy will be more satisfy than parents on control groups.

In relation to hypothesis one: The results of this study suggest that the Buzzy can reduce pediatric pain and anxiety during blood specimen collection and the most effective method was use of external thermomechanical stimulation. This might be due to the gate control theory may offer an explanation for the effect of external thermomechanical stimulation. This theory suggests that pain is transmitted from the peripheral nervous system to the central nervous system, where it is modulated by a gating system in the dorsal horn of the spinal cord. The afferent pain-receptive nerves (A-delta fibers carrying acute pain and unmyelinated slower C fibers carrying chronic pain messages) are blocked by fast nonnoxious motion nerves (A-beta). Prolonged cold stimulates the C fibers and may further block the A-delta pain signal. Another mechanism of sensation of cold is noxious inhibitory controls, which activate a descending supraspinal modulation and raise the body's overall pain threshold (Kakigi & Shinbasaki, 1992). So, Buzzy relieves the pain and stress from any minor sharp aches or stick, including needles, splinters and stings. This finding came in agreement with Canbulat et al., 2015 who conducted a study about "Effectiveness of External Cold and Vibration for Procedural Pain Relief during Peripheral Intravenous Cannulation in Pediatric Patients". He mentioned that Cold and vibration were applied 1 minute before the peripheral IV and continued until the end of the procedure was significantly lower pain and anxiety levels in the experimental group than in the control group during the peripheral IV cannulation.

Moreover, this result was in the same line with Bahorski and Hauber, 2015 who conducted a study about" Mitigating procedural pain during venipuncture in a pediatric population". They reported that mechanical vibration [Buzzy] appears to be as effective as a topical anesthetic in children regardless of age, ethnic group, or sex. It has the advantage of being a fast-acting, cost effective, non-pharmacological preparatory intervention for venipuncture in children. Also, these findings came in agreement with Inal and Kelleci, 2012 who conducted a research about "Relief of pain during blood specimen collection in pediatric patients." The researchers clarified that Buzzy decreased perceived pain and reduced anxiety throughout blood collection, without decreasing the effectiveness of the procedure.

Moreover, this result was consistent with Baxter and Cohen, 2011 who conducted a research about "An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department." added that Venipuncture success was more likely with Buzzy. Cold and vibration significantly decreased pain while improving procedural success. Also, Whelan and Kunselman, 2014 added that locally applied vibration appears to be a well-accepted technique to minimize discomfort that may facilitate the procedure. In addition, this finding was consistent with Baxter, 2009 who conducted a research about **"**External Thermomechanical stimulation versus vapocoolant for adult venipuncture pain: pilot data on a novel device**."** They showed thatThe Buzzy device prototype significantly reduced pain (p=.035) while vapocoolant spray did not.

The present finding illustrated that external thermomechanical stimulation using Buzzy were found effective in anxiety reduction during blood specimen collection. This might be due the child to draw his/her attention away from pain stimuli during a medical procedure. Therefore, as a distraction method, buzzy might be useful for reducing pain and anxiety during medical procedures. The use of a device such as this one also may provide a way to decrease anxiety for future procedures. This result came in agreement with Sahiner, 2015 who mentioned that significantly lower pain and anxiety levels in the experimental group than in the control group. Also, they found anxiety was also reduced by 70% on average during the immunization in the group using Buzzy.

Also, this result came in the same line with Russell, 2014 who conducted a research about **"**Reducing the Pain and Anxiety of Intramuscular Benzathine Penicillin Injections in the Rheumatic Fever (RF) Population of Counties Manukau". In this study, 405 RF patients receiving 4 weekly injections were offered lidocaine and/or Buzzy for pain management. The authors concluded that after 5 months, 43% continued to use Buzzy.

In relation to hypothesis two, cryotherapy in our study was found an effective method of pain and anxiety reduction in during blood specimen collection. This result was consistent with Abd El Aziz (2013) who conducted a research about "Effect of Cryotherapy on Pain Intensity at Puncture Sites of Arteriovenous Fistula among Adult Patients Undergoing Hemodialysis at Tanta University Hospital" and concluded that cryotherapy was effective in reducing AV fistula puncture pain. Thes finding were in in the same line with Mansy et al., (2010), who found that there was a statistical significant difference between cryotherapy group and control group. This was attributed to the effect of cryotherapy application on pain management. Also Movahedi et al., (2006), clarified that local application of ice decrease pain and distress that was associated with venipuncture.

In this study, the present findings showed that children in the buzzy and cryotherapy groups had lower mean heart and respiratory rates during and after blood specimen collection on control group. These finding consistent with Saliew and Preechawai, 2010 who conducted a study about "Evaluating the effects of ice

application on patient comfort before and after botulinum toxin type injections." Thy summarized that Buzzy was effective in reducing heart and respiration rates of children. This can be explained as the combination of cold and vibration may have a sedating effect leading to activation of the parasympathetic nervous system which leads to stimulating the Vagus nerve to slow down the heart rate and slowing respiration.

In relation to hypothesis three, parents and children who receive Buzzy and cryotherapy had satisfied than parents on control groups regarding the effect of Buzzy and cryotherapy in relieving pain and anxiety during blood collection specimen. Patient satisfaction is an important measure in evaluating the quality of service given (Uzun, 2001; Yıldız and Erdo_gmus¸, 2004). Reducing the feeling of pain experienced during phlebotomy also affects children and their parent satisfaction. The findings of this study indicated that the level of satisfaction scores of children and their parent of the buzzy and cryotherapy groups were higher than those of the children and their parent of the control groups. This result is thought to be because those in the buzzy and cryotherapy groups felt less pain and anxiety during the procedure than control group children. This result came in agreement with the Roberta, (2018) & Inal, & Kelleci, (2017) who mentioned that the Buzzy device has demonstrated improved pain ratings and patient satisfaction scores, with the majority of parents endorsing their preference for its future use.

5. Conclusion

Based on the findings of the present study, the following are concluded:

1. Children in the study group (buzzy) had lower pain and anxiety than children in control group who received routine hospital care.
2. Children in the study group (cryotherapy) had lower pain and anxiety than children in control group who received routine hospital care.
3. Parents and children who receive Buzzy and cryotherapy had satisfied than parents on control groups regarding the effect of Buzzy and cryotherapy in relieving pain and anxiety during blood collection specimen.

Recommendations

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

- The use of external thermomecanical stimulation by cooling vibration device called buzzy and cooling only (cryotherapy) should be integrated as a part of routine daily care for managing needle puncture pain and anxiety during blood specimen collection.
- Application on a larger sample size and for a long period to ensure generalizability of the results.
- Further research is needed for assessing buzzy effects on the pain and anxiety reduction during other procedures and when compared to placebo.

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