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Effect of Thermo-Mechanical Stimulation on Pain Associating Venipuncture among Children with Leukemia

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Abstract
Background*: Pain has been reported as a significant problem for children with leukemia as they regularly experience pain as a result of the disease, side effects of treatment and painful procedures associated with medical management. Children often perceive invasive medical procedures as worse than the disease itself for which they are being treated. So, it is reasonable to address their pain by incorporating non-pharmacological intervention as thermo-mechanical stimulation. Thermo-mechanical stimulation is a non-pharmacological technique that reduces venipuncture pain by combining vibration, cold therapy and distraction.* ***Aim:*** *The aim of this study was to determine the effect of thermo-mechanical stimulation on pain associating venipuncture among children with leukemia.* ***Research Design****: A quasi- experimental research design was used.* ***Setting****: The study was conducted at the Outpatient Hematology/Oncology Unit of Alexandria University Children's Hospital at Smouha.****Subjects****: A convenience sampling of 80 preschool children with leukemia who were visiting the previously mentioned setting for blood sampling or receiving chemotherapy. The study subjects fulfilled the following criteria: age ranged from 3 to 6 years,free from sickle cell disorder and did not receive any analgesics before venipuncture.* ***Tools****: Three tools were used to collect necessary data, namely; Children's Characteristics and Medical History Tool, Children's Physiological Parameters Record and FLACC (Face, Leg, Activity, Cry and Consolability) Pain Assessment Tool.* ***Results****: The main study findings showed that 80% of children in the study group were relaxed and comfortable during venipuncture compared to none of children in the control group. Furthermore, more than half of children in the control group (55%) exhibited severe pain during venipuncture compared to none of children in the study group. On the other hand, all of children in the study group were relaxed and comfortable after venipuncture compared to only 7.5% of children in the control group. Meanwhile, more than two-thirds of children in the control group (67.5%) exhibited moderate pain after venipuncture compared to none of children in the study group. High statistical significant differences were found between the study and control groups regarding the total pain score during and after venipuncture.* ***Conclusion****: It can be concluded that thermo-mechanical stimulation was effective in reducing pain responses during and after venipuncture among children with leukemia.* ***Recommendation:*** *The main recommendation of the current study was incorporating thermo-mechanical stimulation as non-pharmacological pain relief measure for children with leukemia in the Outpatient Oncology departments.*

Keywords: *thermo-mechanical stimulation; Cold therapy; Vibration; Venipuncture; Pain; Leukemia.*

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I. Introduction

Leukemia is the most common malignancy in early childhood. It is cancer of the hematopoietic (blood forming) system which occurs when immature white blood cells that are produced in the bone marrow keep multiplying [(1, 2)]. The most frequent presenting signs and symptoms of leukemia are a result of bone marrow infiltration [(3)]. The three main consequences are anemia from decreased red blood cells, infection from neutropenia, and bleeding from decreased platelet production. The invasion of the bone marrow with leukemic cells gradually causes weakening of the bone and tendency toward fractures. While, invasion of the periosteum leads to increased pressure and severe pain[(2,3)]. The spleen, liver, and lymph glands demonstrate marked infiltration, enlargement and eventually fibrosis. Involvement of the central nervous system also occurs secondary to leukemic infiltration, which may cause increased intracranial pressure[(3)].

According to the American Cancer Society (2016)[(4)], leukemia accounts for one out of three cases of childhood cancer. The two major subtypes of children`s leukemia are acute lymphoblastic leukemia and acute myeloid leukemia, which account for 80% and 17% of all diagnosed leukemias respectively [(4)]. Leukemia is one of the most common ten malignancies in Egypt and the total mortality rate was 5.5 per 100, 000 populations according to the World Health Organization (2014)[(5)].

The diagnosis and treatment of leukemia present numerous challenges and sources of stress and pain for children[6].Children with leukemia often suffer from unpredictable and uncontrollable pain. They undergo potentially painful procedures throughout their treatment and during the follow-up period[6,7].A wide variety of diagnostic methods and treatments provoke variety of reactions among children with leukemia which range from avoidance reactions to a loud cry due to pain. The first experience of pain may create a vicious cycle for subsequent painful experiences[7].

Pain is defined as, "an unpleasant sensory and emotional experience associated with actual or potential tissue damage". Perception of pain in children is complex, and entails physiological, psychological, behavioral, and developmental factors. However, in spite of its frequency, pain in children is difficult to assess. It is often underestimated and under-treated[8]. Proper pain management requires competent pain assessment tool. The Faces, Legs, Activity, Cry and Consolability scale (FLACC) provides a simple framework for quantifying pain behaviors especially in pre-verbal children from 2 months to 7 years [8, 19].

Pain has been reported as a significant problem for children with leukemia as they regularly experience pain as a result of the disease, side effects of treatment and painful procedures associated with medical management in addition to the generalized psychological distress[9].It is usual for children with leukemia to perceive invasive medical procedures as worse than the disease itself for which they are being treated. Pain associated with needle procedures does not always resolve with time or age, and may result in delays in care or avoidance of treatment in pediatric patients[9, 10]. So, management of procedure-related pain in children with cancer is included as a major recommendation by the American Pain Society in the Guidelines for Management of Cancer Pain in Adults and Children[10].

Myriad of techniques have been studied with the goal of reducing children's pain during venipuncture including pharmacological intervention as application of topical local anesthetics and non-pharmacological such as behavioral distractions and tactile interventions[11-13]. Thermo-mechanical stimulation is a non-pharmacological technique that reduces venipuncture pain by combining vibration, cold therapy and distraction [14]. Vibration is effective in pain management on its own. However, a combination of vibration and cooling provides the most potent analgesic effect and at times completely inhibits moderate pain. Thermo-mechanical stimulation provides pain relief via gate control theory, which suggests that pain is transmitted from the peripheral nervous system to the central nervous system via modulation through a gating system in the dorsal horn of the spinal cord [15]. The vibration will stimulate the A-beta fibers (fast non noxious motion nerves), which subsequently block the A-delta C–fibers (afferent pain receptive nerves)[11, 15]. Moreover, the cold component will stimulate the C fibers and if applied prior to the pain stimulus will block the A-delta pain signal as well. An alternative postulated mechanism in which the cold stimulus provides pain relief is by triggering the descending noxious inhibitory controls, activating a supra-spinal modulation and raising the body's overall pain threshold [11, 14]. Though impressive pain reduction is observed when utilizing thermo-mechanical stimulation, it has not been used in clinical settings until recently [16].

Unfortunately, pain of children with leukemia is often poorly managed and many painful procedures such as venipuncture are carried out without paying much attention to pain alleviation [17, 18]. Pediatric nurses in different health settings have a unique role in reducing pain as much as possible while maintaining patient safety. They need to be able to detect the symptoms and signs of pain in different age groups and determine whether these symptoms are caused by pain or other factors [8, 19]. Relief of pain and suffering, whenever possible, is an important responsibility because unmanaged pain can result in a variety of negative long term consequences [8, 20]. So, pediatric nurses should use non-pharmacologic techniques in an effective and safe manner to relieve children's pain. Provision of comfort and prevention of pain are two primary goals of nursing care for these children [17, 18]. Hopefully, the present study would present thermo-mechanical stimulation approach that could decrease venipuncture pain among children with leukemia.

This study aimed to:

Determine the effect of thermo-mechanical stimulation on pain associating venipuncture among children with leukemia.

Hypothesis of this research is:

- Children with leukemia who receive thermo-mechanical stimulation exhibit lower pain score than those who do not.

Operational Definition:

Thermo-mechanical stimulation: It is a non-pharmacological pain management method in which buzzy device is used to eliminate venipuncture pain. Buzzy device is a battery operatedhandheld plastic 'bee' with a vibrating motor and a mechanism to attach an ice pack underneath (blue gel ice wings) (**Figure 1**). It can

be pressed in place or secured to a limb via strap or tourniquet just above the venipuncture site before insertion of needle. It combines vibration and cold therapy to provide distraction and block pain sensation [11, 14].

Figure 1: Buzzy Device [11, 14]

II. Materials and Method

Materials

Research Design:

A quasi-experimental research design was used.

Setting:

The study was conducted at the Outpatient Hematology/Oncology Unit of Alexandria University Children's Hospital at Smouha. The unit consists of one room with a capacity of 6 beds. It provides services for children with leukemia such as taking blood samples or administering chemotherapy.

Subjects:

A convenience sampling of 80 preschool children with leukemia who were visiting the previously mentioned setting for blood sampling or receiving chemotherapy. The study subjects fulfilled the following criteria:

- Age ranged from 3 to 6 years.
- Free from sickle cell disorder.
- Children did not receive any analgesics before venipuncture.

The sample size was estimated according to Epi-Info program using the following parameters:

- Confidence coefficient 95%.
- Ratio of control to cases 1.
- Percent of controls exposed 10%.
- Odd ratio 9.
- Percent of cases with exposure 50%.
- Minimum sample size = 30 for each group
- The research sample will be 80 children with leukemia for better results and statistical analysis

The subjects of the study were divided randomly into two equal groups (40 children in each) as follows:

- The study group received thermo-mechanical stimulation in addition to the routine hospital care before venipuncture.
- The control group received the routine hospital care only before venipuncture.

Tools:

Three tools were used to collect the data.

Tool I: Children's Characteristics and Medical History Tool:

This tool was developed by the researchers after review of related literature to assess children's characteristics and medical history. It included 2 parts:

- Part 1: Characteristics of children which included age and sex.
- Part 2: Medical history including duration of the disease and treatment and frequency of follow up visits.

Tool II: Children's Physiological Parameters Record:-

This tool was developed by the researchers to assess children's physiological parameters. It included heart rate and respiratory rate.

Tool III: FLACC (Face, Leg, Activity, Cry and Consolability) Pain Assessment Tool:

This tool was developed by Merkel et al. (1997) [21]to assess children's behavioral responses during painful procedures. It comprised five categories of behavior: facial expression (F), leg movement (L), activity (A), cry

(C), and consolability (C). It measures pain by quantifying pain behaviors with scores ranging from 0 (no pain behaviors) to 10 (most possible pain behaviors) as follows:

- 0 = Relaxed and comfortable.
- 1-3 = Mild pain.
- 4-6 = Moderate pain.
- 7-10 = Severe pain

II- Method

1. An official letter was directed from the faculty of nursing in Alexandria University to responsible administrative personnel in the previously mentioned setting to collect the necessary data, after explaining the aim and nature of the study.
2. Tool I and II were developed by the researchers after review of literature and were tested for their content validity by five experts in the field of pediatric nursing and necessary modifications were done. The validity was 96% for both.
3. A pilot study was carried out on 8 children to test the feasibility, applicability and clarity of the tools. Those children were excluded from the study subjects.
4. At initial contact before venipuncture, characteristicsand medical history of childrenwere assessed and recorded by the researchers for both groups using tools I.
5. Before venipuncture, physiological parameters were assessed and recorded by the researchers for both groups using tool II. The heart rate was taken radially in one full minute and the respiratory rate was counted by observing the children`s chest movement in one full minute also[(3)].
6. Behavioral responses were observed and recorded by the researchers as baseline data for children in the two groups for 15-20 seconds using tool III before the venipuncture procedure.
7. **For the study group:**

- Initially, the buzzy device was shown to parents and their children prior to enrollmentand children were allowed to touch and turn on the device if they chose.
- Inspection of the limb by the researcher was done to identify suitable veins for cannulation or blood sampling.
- Buzzy device was put by the researcher about 5 cm above the needle insertion site and switched on for at least 15 to 30 seconds before venipuncture.
- Once a suitable vein had been identified by the researchers, a tourniquet was applied on the arm and placed proximal between the device and the insertion site (Figure 2) [13].

(Figure 2) [13]

- The area overlying the vein to be cannulated was cleaned by the researchers with an alcohol swab according to the standard practice and allowed to dry.
- The vibration was continued until the end of the procedure.
- After completion of procedure, buzzy device was removed and the blue gel wing was cleaned by alcohol and put in aplastic bag and then in the fridge's freezer of the unit.

8. **For the control group:**

- The venipuncture done by the researchers for those childrenwithout any interventions except the routine hospital care.

9. The researchers observed and recorded the behavioral responses for the two groups using FLACC pain scale during and after the venipuncture procedure.
10. Physiologic parameters as heart rate and respiratory rate for the two groups were measured by the researchers and recorded using tool II immediately after venipuncture.
11. A comparison was done between the two groups to evaluate effect of thermo-mechanical stimulation on physiological and behavioral pain responses associated with venipuncture among children with leukemia.
12. Data were collected over 3 months during the period from July to September 2018.

Ethical Considerations:

- Written informed consents were obtained from parents of children with leukemia after explaining the aim and nature of the study.
- The researchers ensured confidentiality of the information given. Data collected was only used for the intended research purpose.
- Privacy was considered.
- Parents had the right to withdraw their children from the study at any time.

Statistical Analysis:

The raw data were coded and entered into SPSS system files (SPSS package version 20, Chicago, USA). Analysis and interpretation of data were conducted.

The following statistical measures were used:

- Descriptive statistics including frequency, distribution, mean and standard deviation were used to describe different characteristics.
- Kolmogorov – Smirnov test was used to examine the normality of data distribution.
- Univariate analyses including: t-test was used to test the significance of results of quantitative variables. Chi-Square test and Monte Carlo test were used to test the significance of results of qualitative variables.
- The significance of the results was at the 5% level of significance.

III. Results

Table (1) illustrates Demographic characteristics and medical history of children with leukemia. It is revealed from the table that, slightly more than half of children in the study group (55%) were in the age group from 5 to 6 years compared to 45% of children in the control group. The mean age of children in the study and control groups were 4.8±1.2 and 4.4±1.2 years respectively. Nearly three-quarter of children in the study group (72.5%) were males compared with 65% of children in the control group.

The same table also shows that 65% of children in the study group had leukemia since one to less than two years compared to 37.5% of children in the control group. Regarding duration of treatment, 62.5% of children of the study group had initiated their chemotherapy since one to less than two years compared to 37.5% of children in the control group. Concerning frequency of outpatient visits, more than half of children's mothers in the study group (52.5%) reported that their children visited outpatient clinic four times per month compared to 35% of children's mothers in the control group

Table (2) presents comparison between the study and control groups regarding their physiological parameters before and after venipuncture. The table revealed that the mean heart rate among children of the study group was 111.8±11.2 beats /minute before venipuncture and declined to 106.3±11.4 beats /minute after venipuncture. While, the mean heart rate among children of the control group was 109.8±10.9 beats /minute before venipuncture and increased to 112.9±9.3 beats /minute after venipuncture. There was a statistical significant difference between the two groups regarding children`s heart rate after venipuncture where p= 0.006.

It is clear from the same table that the mean respiratory rate among children of the study group was 32.1±2.9 breaths/minute before venipuncture and decreased to 28.2±2.2 breaths/minute after venipuncture. Whereas, the mean respiratory rate among children of the control group was 27.9±4.4 breaths/minute before venipuncture and increased to 30.2±3.6 breaths/minute after venipuncture. There was a statistical significant difference between the two groups regarding children`s respiratory rate before and after venipuncture where p= 0.000 and 0.005 respectively.

Table (3) portrays comparison between the study and control groups regarding facial expression before, during and after venipuncture. It is noticed from the table that 85% of children in the study group had no particular facial expression compared to none of children in the control group during venipuncture. On the other hand, 52.5% of children in the control group had occasional grimace or frowned and were withdrawn and disinterested during venipuncture compared to only 15% of children in the study group. After venipuncture, all children of the study group (100%) had no particular facial expression compared to only 12.5% of children in the control group. There were high statistical significant differences between the two groups regarding children`s facial expression during and after venipuncture where p= 0.000.

Table (4) clarifies comparison between the study and control groups regarding legs movement before, during and after venipuncture. It is clear from the table that 97.5% of children in the study group had their legs in normal position and relaxed during venipuncture compared to none of children in the control group. On the other hand, 55% of children in the control group kicked or drew up their legs during venipuncture compared to none of children in the study group. Moreover, all children of the study group (100%) were in normal position and had relaxed legs after venipuncture compared to 35% of children in the control group. High statistical

significant differences were found between the study and control groups during and after venipuncture where p= 0.000 for each.

Table (5) shows comparison between the study and control groups regarding activity before, during and after venipuncture. It is clear from the table that most of children in the study group (97.5%) were in normal position, lied quietly and moved easily during venipuncture compared to none of children in the control group. Meanwhile, Squirming, shifting back and forth and being tense were observed after venipuncture among 67.5% of children in the control group compared to none of children in the study group. High statistical significant differences were found between the study and control groups during and after venipuncture as p= 0.000 for each

Table (6) displays comparison between the study and control groups regarding crying before, during and after venipuncture. It is noticed from the table that 90% of children in the study group did not cry during venipuncture compared to none of children in the control group. On the other hand, fifty percent of children in the control group cried steadily, screamed and complained frequently during venipuncture compared to none of children in the study group. Moreover, all children of the study group (100%) did not cry after venipuncture compared to only 7.5% of children in the control group. While, 87.5% of children in the control group moaned, whimpered and occasionally complained after venipuncture compared to none of children in the study group. High statistical significant differences were found between the study and control groups during and after venipuncture where p= 0.000 for each.

Comparison between the study and control groups regarding consolability before, during and after venipuncture is presented in **Table (7)**. It was observed from the table that most of children in the study group (95%) were content and relaxed during venipuncture compared to none of children in the control group. While, nearly two-thirds of children in the control group (60%) were reassured by occasional touching, hugging, or talking to during venipuncture compared to only 5% of children in the study group. After venipuncture, all children in the study group (100%) were content and relaxed compared to nearly one-third of children in the control group (30%). High statistical significant differences were found between the study and control groups during and after venipuncture as p= 0.000 for each.

Table (8) represents the total score of pain that was perceived by children with leukemia before, during and after venipuncture among both the study and control groups. It was found that 80% of children in the study group were relaxed and comfortable during venipuncture compared to none of children in the control group. Furthermore, more than half of children in the control group (55%) exhibited severe pain during venipuncture compared to none of children in the study group. On the other hand, all of children in the study group were relaxed and comfortable after venipuncture compared to only 7.5% of children in the control group. Meanwhile, more than two-thirds of children in the control group (67.5%) exhibited moderate pain after venipuncture compared to none of children in the study group. High statistical significant differences were found between the study and control groups regarding the total pain percent score during and after venipuncture where p= 0.000 for each.

IV. Discussion

The painful, stressful, and prolonged processes of diagnosis, hospitalization, and treatment of leukemia can negatively influence on different aspects of children's physical, emotional, and psychosocial abilities [(22)]. Procedures that require needle insertion are among the most common procedures that are sources of pain for pediatric patients in the health care settings [(11)].

Acute pain can exacerbate autonomic neuro-humoral stress responses that triggers the sympathetic nervous system, resulting in significant increase in physiological responses [(23)]. In this regard, the current study illustrated that the mean heart rate and respiratory rate declined after venipuncture among the study group and increased among the control group (Table 2). The finding of the current study could be justified by the fact that thermo mechanical stimulation as a distractive technique acts by focusing the children's concentration away from the noxious stimuli and engages them in a pleasant activity. Consequently, their pain perception was modified by altering nociceptive responses and triggering an internal mechanism of pain inhibition[(24)]. The findings of the present study were similar to a study conducted by McGinnis et al. (2016) who pointed out that the study group had more stable physiological parameters at the time of the heel lance and 2 minutes after the lance compared with the control group, whereas the control group's mean heart rate remained significantly elevated above baseline [(25)].

The use of behavioral indicators is recommended for pain assessment in children. Behavioral responses to pain include facial expressions, body movements and crying[(26)]. The current study findings clarified that more than three quarters of the study group had no particular facial expression during venipuncture whereas more than half of the control group had occasional grimace and were frowned, withdrawn and disinterested (Table 3). Regarding legs movement, the majority of the study group had their legs in normal position and relaxed during venipuncture while more than half of the control group kicked or drew up their legs during venipuncture (Table 4). Concerning children`s activity, the majority of the study group were in normal position, lied quietly and

moved easily during venipuncture. Meanwhile, Squirming, shifting back and forth and being tense were observed after venipuncture among more than two-thirds of the control group (Table 5). The findings of the present study could be justified by the fact that thermo-mechanical stimulation as a distractive technique interrupts the affective and sensory component of pain and exhibits less distress and behavioral responses during and after painful procedures in children[(11)]. Similarly, a study conducted by Attia and Hassan (2017) reported lower incidence of behavioral responses to pain such as crying, grimacing, and muscle tension during and after applying cryotherapy at the puncture site of arteriovenous fistula among children undergoing hemodialysis [(27)].

Crying is the most common children's behavior that reflects pain [(28)]. The findings of the present study highlighted that the majority of the study group did not cry during venipuncture whereas, half of children in the control group cried steadily, screamed and complained frequently. Moreover, more than three- quarters of children in the control group moaned, whimpered and complained occasionally after venipuncture compared to none of children in the study group (Table 6). The finding of the current study could be explained by the possibility that the use of effective suitable pleasant distractive technique such as Buzzy device for young age children helps in attracting their attention from the painful procedure and thus minimizes their feeling of pain. Moreover, cryo-therapy lowers the temperature over the painful area of the skin and reduces the velocity of nerve conduction in C- and A-delta fibers, thereby slowing the transmission of pain signals [(27)].These results are in harmony with the findings of Bagherian et al. (2016) who found that physical distraction with vibration can be more helpful than the routine topical anesthesia procedure in reducing behavioral pain reactions including crying in children during local anesthesia administration [(29)].

The findings of the present study also revealed that the majority of the study group were content and relaxed during venipuncture procedure. While, nearly two-thirds of children in the control group were distractible and reassured by occasional touching, hugging, or talking to during venipuncture (Table 7). The finding of the current study could be explained in the light of fact that prolonged cold stimulates the C fibers and may further block the A-delta pain signal[(15, 30)]. Another mechanism is that cold stimulation can activate the descending supraspinal modulation and raise the body's overall pain threshold. The 15- to 30-second duration of contact between the device and the skin during cleaning and preparation for venipuncture may enhance C fiber summation and descending noxious inhibitory control pain relief [(15, 30)].

The results of the current study revealed that the study group had significantly lower pain levels than the control group as more than three-quarters of the study group were relaxed and comfortable during venipuncture, while more than half of the control group felt severe pain. Moreover, More than two-thirds of children in the control group felt moderate pain after venipuncture compared to none of children in the study group (Table 8). The gate control theory may offer an explanation for the current study finding as thermo-mechanical stimulation combines multiple approaches by supplying cold analgesia, tactile stimulation, and distraction. It provides pain relief by stimulating nerves with cold to "close" the fast pain gate. Simultaneously, stimulating Aβ mechanoreceptors with vibration can also close the fast pain gate via presynaptic inhibition at the dorsal horn. Moreover, the combination of the two would provide optimal pain relief [(11, 30)]. A study carried out by Redfern et al. (2018) and Canbulatet al. (2015) showed similar findings, where they concluded that significant pain reduction was achieved by combining both cold and vibration during vaccines injections among children [(11, 31)]. Furthermore, a study investigating the use of Buzzy device in pediatric populations had also demonstrated superior pain relief in children and confirmed the feasibility of its use in fast-paced care settings[(30)]. On the other hand,the findings of the present study were contradicted with Benjamin et al. (2016) who reported that vibration did not improve pain scores among 100 children undergoing routine vaccinations [(32)].

V. Conclusion And Recommendations

Conclusion:

Based on the finding of the current study, it can be concluded that thermo-mechanical stimulation was effective in reducing physiological and behavioral pain responses during and after venipuncture among children with leukemia.

VI. Recommendations

Based on the findings of the current study, the following recommendations are suggested:

- Nurses should use thermo-mechanical stimulation as non-pharmacological interventions to reduce venipuncture pain among children with leukemia who are exposed to a variety of painful procedures.
- Non-pharmacological pain relief interventions particularly thermo-mechanical stimulation should be incorporated in the pediatric health settings.
- Pediatric Nurses should use reliable and valid pain assessment tool as FLACC scale for assessing pain among preschool children.

Table (1): Demographic Characteristics and Medical History of Children with Leukemia

Demographic characteristics and medical history	Study group (n=40)		Control group (n=40)		Test of Significance
	No.	%	No.	%	
Age (years)					
▪ 3-	13	32.5	14	35.0	
▪ 4-	5	12.5	8	20.0	
▪ 5- 6	22	55.0	18	45.0	
- Min-Max	3.0-6.0		3.0-6.0		t=1.359
- Mean±SD	4.8±1.2		4.4±1.2		P=0.178
Gender					
▪ Male	29	72.5	26	65.0	X^2=0.524
▪ Female	11	27.5	14	35.0	P=0.233
Duration since onset of disease (months)					
▪ 1- <12	10	25.0	5	12.5	
▪ 12-<24	26	65.0	15	37.5	
▪ 24-<36	2	5.0	14	35.0	
▪ 36 and more	2	5.0	6	15.0	
- Min-Max	5-50		2-48		
- Mean±SD	17.9±9.7		22.3±11.5		t=0.1876 P=0.064
Duration since onset of treatment (months)					
▪ Less than 12	11	27.5	6	15.0	
▪ 12-<24	25	62.5	15	37.5	
▪ 24-<36	2	5.0	14	35.0	
▪ 36 and more	2	5.0	5	12.5	
- Min-Max	5-49		2-47.5		
- Mean±SD	17.3±9.7		22.1±11.4		**t=2.043 P=0.044***
Prescribed Chemotherapy					
▪ Oncovin	17	42.5	16	40.0	
▪ Methotrexate	11	27.5	11	27.5	X^2=0.121
▪ Adriamycin	7	17.5	7	17.5	P=0.989
▪ Cytozar	5	12.5	6	15.0	
Frequency of outpatient visits/ month					
▪ Once	0	0.0	10	25.0	
▪ Twice	7	17.5	10	25.0	**X^2=13.929**
▪ Three times	12	30.0	6	15.0	**P=0.003***
▪ Four times	21	52.5	14	35.0	

t: Student t-test **X^2: Chi-Square test** ***significant at P≤0.05**

Table (2): Comparison between the Study and Control Groups regarding Physiological Parameters before and after Venipuncture

Physiologic parameters	Before venipuncture		After venipuncture	
	Study group (n=40)	Control group (n=40)	Study group (n=40)	Control group (n=40)
Heart rate				
– **Min-Max**	85-125	85-123	80-120	90-125
– **Mean±SD**	111.8±11.2	109.8±10.9	106.3±11.4	112.9±9.3
Significance	t=0.808 P=0.421		**t=2.811 P=0.006***	
Respiratory rate				
– **Min-Max**	25-37	20-35	25-30	22-35
– **Mean±SD**	32.1±2.9	27.9±4.4	28.2±2.2	30.2±3.6
Test of Significance	**t=4.905 P<0.000***		**t=2.918 P=0.005***	

t: Student t-test ***significant at P≤0.05**

Table (3): Comparison between the Study and Control Groups regarding Facial Expression before, during and after Venipuncture

FLACC pain scale "Face"	Before venipuncture				During venipuncture				After venipuncture			
	Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
– No particular expression or smile	25	62.5	28	70.0	34	85.0	0	0.0	40	100.0	5	12.5
– Occasional grimace or frown, withdrawn and disinterested	15	37.5	12	30.0	6	15.0	21	52.5	0	0.0	33	82.5
– Frequent to constant frown, clenched jaw or quivering chin	0	0.0	0	0.0	0	0.0	19	47.5	0	0.0	2	5.0
Test of Significance	X^2=0.503 P=0.478				**X^2=61.333 P<0.000***				**X^2=62.222 ^{MC}P<0.000***			

X^2: Chi-Square test **^{MC}P: Monte Carlo corrected P-value** ***significant at P≤0.05**

Table (4): Comparison between the Study and Control Groups regarding Legs Movement before, during and after Venipuncture

FLACC pain scale "Legs"	Before venipuncture				During venipuncture				After venipuncture			
	Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
– Normal position or relaxed	29	72.5	34	85.0	39	97.5	0	0.0	40	100.0	14	35.0
– Uneasy, restless or tense	11	27.5	6	15.0	1	2.5	18	45.0	0	0.0	24	60.0
– Kicking or legs drawn up	0	0.0	0	0.0	0	0.0	22	55.0	0	0.0	2	5.0
Test of Significance	X^2=1.867 P=0.172				**X^2=76.211 P<0.000***				**X^2=38.519 ^{MC}P<0.000***			

X2: Chi-Square test **MCP: Monte Carlo corrected P-value** ***significant at P≤0.05**

Table (5): Comparison between the Study and Control Groups regarding Activity before, during and after Venipuncture

FLACC pain score "Activity"	Before venipuncture				During venipuncture				After venipuncture			
	Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
– Lying quietly, normal position, moves easily	33	82.5	28	70.0	39	97.5	0	0.0	40	100.0	11	27.5
– Squirming, shifting back and forth or tense	7	17.5	12	30.0	1	2.5	22	55.0	0	0.0	27	67.5
– Arched, rigid, or jerking	0	0.0	0	0.0	0	0.0	18	45.0	0	0.0	2	5.0
Test of Significance	X^2=1.726 P=0.189				**X^2=76.174 P<0.000***				**X^2=45.490 ^{MC}P<0.000***			

X^2: Chi-Square test **^{MC}P: Monte Carlo corrected P-value** ***significant at P≤0.05**

Table (6): Comparison between the Study and Control Groups regarding Crying before, during and after Venipuncture

FLACC pain score "Cry"	Before venipuncture				During venipuncture				After venipuncture			
	Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
– No cry (awake or asleep)	31	77.5	28	70.0	36	90.0	0	0.0	40	100.0	3	7.5
– Moans or whimpers, occasional complaint	9	22.5	12	30.0	4	10.0	20	50.0	0	0.0	35	87.5
– Crying steadily, screams or sobs and frequent complaints	0	0.0	0	0.0	0	0.0	20	50.0	0	0.0	2	5.0
Test of Significance	X^2=0.581 P=0.446				**X^2=66.667 P<0.000***				**X^2=68.837 ^{MC}P<0.000***			

X^2: Chi-Square test **^{MC}P: Monte Carlo corrected P-value** ***significant at P≤0.05**

Table (7): Comparison between the Study and Control Groups regarding Consolabilitybefore, during and after Venipuncture

FLACC pain score "Consolability"	Before venipuncture				During venipuncture				After venipuncture			
	Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
– Content and relaxed	25	62.5	34	85.0	38	95.0	0	0.0	40	100.0	12	30.0
– Reassured by occasional touching, hugging, or talking to and distractible	15	37.5	6	15.0	2	5.0	24	60.0	0	0.0	26	65.0
– Difficult to console or comfort	0	0.0	0	0.0	0	0.0	16	40.0	0	0.0	2	5.0
Test of Significance	X^2=5.230 P=0.022*				X^2=72.615 P<0.000*				X^2=43.077 ^{MC}P<0.000*			

X^2: Chi-Square test ^{MC}P: Monte Carlo corrected P-value *significant at P≤0.05

Table (8): The Total Score of Pain that was Perceived by Children with Leukemia before, during and after Venipuncture among both the Study and Control Groups

Total Score of FLACC Pain Scale	Before venipuncture				During venipuncture				After venipuncture			
	Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)		Study group (n=40)		Control group (n=40)	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
– Relaxed and comfortable (zero)	23	57.5	24	60.0	32	80.0	0	0.0	40	100.0	3	7.5
– Mild pain (1-3)	9	22.5	10	25.0	8	20.0	0	0.0	0	0.0	8	20.0
– Moderate pain (4-6)	8	20.0	6	15.0	0	0.0	18	45.0	0	0.0	27	67.5
– Severe pain (7-10)	0	0.0	0	0.0	0	0.0	22	55.0	0	0.0	2	5.0
Test of Significance	X^2=0.360 P=0.835				X^2=80.0 ^{MC}P<0.000*				X^2=68.840 ^{MC}P<0.000*			

t: Student t-test X^2: Chi-Square test ^{MC}P: Monte Carlo corrected P-value *significant at P≤0.05

References

[1]. Kaatsch P, Mergenthaler A. Incidence, time trends and regional variation of childhood leukaemia in Germany and Europe. Radiat Prot Dosimetry J. 2008; 132(2): 107-13.

[2]. Nève J, Pim V. Childhood leukemia and environmental factors. Health Council of the Netherlands J. 2012; 90(5):926-9.Available from: http://www.HealthCouncil.nl. Retrieved on: 4 July2018.

[3]. Hockenberry M, Wilson D. Wong's Essentials of Pediatric Nursing. 9th ed. St. Louis: Elsevier; 2013. p. 888-92.

[4]. American Cancer Society. What Are the Key Statistics for Childhood Leukemia? 2016. Available from: https://www.cancer.org/cancer/leukemia-in-children/about/key-statistics.html. Retrieved on: 5 July 2018.

[5]. World Health Organization. Health Profile Egypt. World Health Rankings; 2014. Available from: http://www.worldlifeexpectancy.com/country-health-profile/Egypt. Retrieved on: 5 August 2016.

[6]. Rodriguez E, Dunn M, Zuckerman T, Vannatta K, Gerhardt C, Compas B. Cancer-related sources of stress for children with cancer and their parents. J Pediatr Psychol. 2012; 37(2):185-97.

[7]. Firoozi M, Rostami R. Sensitivity to Pain in Children With Acute Lymphoblastic Leukemia (ALL). Iranian Journal of Cancer Prevention. 2012;5(2):74-80.

[8]. Gupta H, Gupta V, Kaur A, Singla R, Chitkara N, Bajaj K. Comparison between the analgesic effect of two techniques on the level of pain perception during venipuncture in children up to 7 years of age: a quasi-experimental study. J Clin Diagn Res. 2014; 8(8):PC01-4.

[9]. Twycross A, Parker R, Williams A, Gibson F. Cancer-related pain and pain management: sources, prevalence, and the experiences of children and parents. J Pediatr Oncol Nurs. 2015; 32(6): 369-84.

[10]. American Pain Society. Guidelines for Management of Cancer Pain in Adults and Children. 2004. Available from: http://apps.americanpainsociety.org/store/product-details?ProductId=472. Retrieved on: 5 August 2018.

[11]. Redfern R, Chen J, Sibrel S. Effects of thermomechanical stimulation during vaccination on anxiety, pain, and satisfaction in pediatric patients: a randomizedcontrolled trial. Journal of Pediatric Nursing.2018; 38(1): 1-7.

[12]. Curry S, Finkel J. Use of the Synera patch for local anesthesiabefore vascular access procedures: a randomized, double-blind,placebo-controlled study. Pain Med. 2007; 8(6):497-502.

[13]. Farion K, Splinter K, Newhook K, Gaboury I, Splinter W. The effect of vapocoolantspray on pain due to intravenous cannulation in children: a randomizedcontrolled trial. CMAJ. 2008;179(1):31-6.

[14]. Abidin N, Yahya N, Izaham A, Wan-Mat W, Zain J, Zainuddin M. Assessing the effectiveness of a thermomechanical device (Buzzy®) in reducing venous cannulation pain in adult patients. Middle East Journal of Anesthesiology. 2018 25(1):61-7.

[15]. Melzack R, Wall P. Pain mechanisms: a new theory. Science. 1965; 150(3699):971-9.

[16]. Secil A, Fatih C, Gokhan A, Alpaslan G, Gonul S. Efficacy of vibration on venipuncture pain scores in a pediatric emergency department. Pediatr Emerg Care. 2014; 30(10): 686-8.

[17]. American Academy of Pediatrics. Assessment and Management of Acute Pain in Infants. 2011. Available from: http://aappolicy.aappublications.org/cgi/reeprint/pediatrics.pdf. Retrieved on 17 July 2018.

[18]. Sng Q, Taylor B, Liam J, Klainin-Yobas P, Wang W, He H. Postoperative pain management experiences among school-aged children: a qualitative study. J Clin Nurs. 2013; 22(7): 958-68.

[19]. Srouji R, Ratnapalanm S,Schneeweiss S. Pain in children: assessment andnonpharmacological management. Int J Pediatr. 2010;4: 11-12.

[20]. Kennedy R, Luhmann J, Zempsky W. Clinical implicationsof unmanaged needle-insertion pain and distress in children. Paediatrics.2008;122S(3);130-3.
[21]. Merkel S, Voepel-Lewis T, Shayevitz J, Malviya S. The FLACC: a behavioral scale forscoring postoperative pain in young children. Pediatr Nurs. 1997; 23(3):293-7.
[22]. Mohammadi A, Mehraban AH, Damavandi SA. Effect of play-based occupational therapy on symptoms of hospitalized children with cancer: a single-subject study. Asia-Pacific Journal of Oncology Nursing. 2017;4(2):168-72.
[23]. Dunwoody C, Krenzischek D, Pasero C, Rathmell J, Polomano R. Assessment, physiological monitoring, and consequences of inadequately treated acute pain. Pain Manag Nurs. 2008; 23(1 Suppl): S15-27.
[24]. Kaheni S, Sadegh Rezai M, Bagheri-Nesami M, Goudarzian A. The effect of distraction technique on the pain of dressing change among 3-6 year-old children. Int J Pediatr. 2016; 4(4): 1603-10.
[25]. McGinnis K, Murray E, Cherven B, McCracken C, Travers C. Effect of vibration on pain response to heel lance: a pilot randomized controltrial.Adv Neonatal Care. 2016;16(6): 439-48.
[26]. Prkachin K. Assessing pain by facial expression: facial expression as nexus. Pain Res Manag. 2009; 14(1):53-8.
[27]. Attia A, Hassan A. Effect of cryotherapy on pain management at the puncture site of arteriovenous fistula among children undergoing hemodialysis. International Journal of Nursing Sciences. 2017;4(1):46-51.
[28]. Lalloo C, Stinson J. Assessment and treatment of pain in children and adolescents. Best Pract Res Clin Rheumatol. 2014; 28(2): 315-30.
[29]. Bagherian A, Sheikhfathollahi M. Children's behavioral pain reactions during local anesthetic injection using cotton-roll vibration method compared with routine topical anesthesia: a randomized controlled trial. Dental Research Journal. 2016;13(3):272-7.
[30]. Baxter A, Cohen L, McElvery H, Lawson M, Baeyer C. An integration of vibration and cold relieves venipuncture pain in a pediatric emergency department. Pediatr Emerg Care. 2011; 27(12): 1151-6.
[31]. Canbulat N, İnal S, Sevim A. The effect of combined stimulationof external cold and vibration during immunization on pain and anxiety levelsin children. Journal of Perianesthia Nursing. 2015; 30(3): 228-35
[32]. Benjamin A, Hendrix T, Woody J. Effects of vibration therapy in pediatricimmunizations. Pediatr Nurs. 2016;42(3):124-9.

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