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"A RANDOMIZED CONTROL TRIAL TO ASSESS THE EFFECTIVENESS OF BUZZY DEVICE ON THE LEVEL OF PAIN DURING VENIPUNCTURE IN CHILDREN ADMITTED AT PAEDIATRIC UNIT OF SELECTED HOSPITAL FROM A METROPOLITAN CITY."

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Abstract:
Background: Venipuncture (VEN-uh-punk-shur) is the process of putting a needle in a vein. This is done to take a blood sample or put in an intravenous cannula to give medicine, fluids, or blood products. Venipuncture is usually done by a nurse, but a physician assistant, diagnostic imaging technologist, or doctor can also do it. During the routine care of children, painful invasive procedures such as venipuncture for the withdrawal of blood for hematological testing or securing intravenous cannula for administration of medicine usually are inevitable in healthy and sick subjects. The importance of pain assessment and pain management is widely acknowledged and alleviation of pain caused by minor invasive procedures in children is an important issue for humane reasons and in terms of their reactions to future painful events and acceptance of subsequent health care interventions. Aim and objective: A study was planned to assess the effectiveness of buzzy device on the level of pain during venipuncture in children admitted at paediatric unit and to find out the satisfaction of the caregivers in relation to the use of Buzzy device for pain management during Venipuncture. Material and method: A experimental approach is used for the study. The study was conducted on the 136 childrens between age group of 6 to 12 years of age undergoing venipuncture procedure from paediatric unit. The samples were divided in experimental and control group using computer generated randomization list. Results: The analysis and interpretation revealed that it was observed that buzzy device is effective in terms to reduce venipuncture associated pain children undergoing venipuncture procedure. Conclusion: The finding of the study shows that, it can be applied in various setting commencing first of all with small preventive procedures like Venipuncture, vaccinations, collecting blood samples, child with juvenile diabetes mellitus who is on insulin etc. to reduce needle associated pain in children**.**

Index Terms **–Assess, Effectiveness, Buzzy device, Pain, Venipuncture, Children, Paediatric unit**.

I. **Introduction**

Hospitalized children are usually segregated by care requirements or by age or by both. Children`s need can be classified under three main headings: Adequate provision of care; protection from physical danger and a psychologically threatening environment. Hospitalization is considered as a stressful event for the children; the environment which surrounds the children in a hospital, physical conditions such as pain, anxiety, underlying disease, hospital procedures or even a medical examination in the hospital could be stressors for children. During the early years, crises of illness and hospitalization have adverse impact on routine activities and rituals of children. Venous cannulation or venipuncture is performed without any analgesia; even though the pain associated with this procedure is at times very distressing. The "Buzzy Device", used in this study, associates three different components and modulations of pain which is a rare phenomenon as most of distraction strategies would focus on single component. Modulations involved in Buzzy device include **Distraction** – cognitive method: distracting the child from painful stimuli, **Vibration:** a mechanical effect created by applying a bee-shaped gadget a few centimeters from the needle entry point, **Cryotherapy effect:** by a removable cold liquid gel pad that the bee-shaped gadget has at its base, hence making the child average beneficiaries of the atraumatic care. It believes that it is important to assess and manage the perception of venipuncture related pain in children. The goal that the investigator draws for this study is to evaluate the effect of applying Buzzy device, to relieve pain, in children undergoing venipuncture.

II. Background of study

Venipuncture (VEN-uh-punk-shur) is the process of putting a needle in a vein. This is done to take a blood sample or put in an intravenous cannula to give medicine, fluids, or blood products. Venipuncture is usually done by a nurse, but a physician assistant, diagnostic imaging technologist, or doctor can also do it. During the routine care of children, painful invasive procedures such as venipuncture for the withdrawal of blood for hematological testing or securing intravenous cannula for administration of medicine usually are inevitable in healthy and sick subjects. The importance of pain assessment and pain management is widely acknowledged and alleviation of pain caused by minor invasive procedures in children is an important issue for humane reasons and in terms of their reactions to future painful events and acceptance of subsequent health care interventions. Moreover, unrecognized pain can become severe and difficult to control and lead to fear and stress. Pain assessment is an on-going and integral part of total pain management particularly in children, and includes such approaches as distraction, evaluation, reassessment and medical intervention. Children and adolescents often describe invasive procedures and their associated anticipatory anxiety as the most distressing aspect of illness or hospitalization.

Statement of Problem:

A Randomized Control Trial to assess the effectiveness of Buzzy Device on the level of pain during Venipuncture in children admitted at Paediatric Unit of selected hospital from a Metropolitan city.

Objectives of study:

1. To compare level of venipuncture associated pain in children using Buzzydevice versus standard of care admitted in paediatric unit of selected hospital.
2. To assess the satisfaction of the caregivers in relation to the use of Buzzy device for pain management during Venipuncture.

Assumptions:

1. During childhood pain is more psychological than physiological although Physiological parameters are altered during Venipuncture.
2. The perception of pain among children will alter their experience in the years to come.
3. It is assumed that three effects of the Buzzy System (Distraction, Vibrations, and Cryotherapy etc.) more efficient in pain control during Venipuncture in children.
4. It is assumed that with the help of Buzzy Device we were not able to verify the effect of Buzzy System in reducing pain in children with an altered emotional state and in Early Childhood.

Delimitations:

1. The researcher delimits the research to the children with normal emotional status.
2. The researcher does not cover the pharmacological method used for pain relief in children.

III. Research Methodology:

In this present study, experimental approach is used. **Randomized Control Trial** in which subjects are allocated at random to receive application of Buzzy device to manage venipuncture associated pain in children. The researcher has adopted this approach to assess the effectiveness of indigenously prepared Buzzy Device on the physiological and behavioral response to pain of children of age group 6 to 12years undergoing venipuncture. Therefore, two groups were made; where one group is provided with an intervention (Buzzy device) and the other is only with standard of care.

3.1 Population and Sample:

The study was conducted among children between age group of 6 to 12 years of age undergoing venipuncture procedure from paediatric unit from selected hospital of metropolitan city.

Data was collected by using interviewing method is used to obtain demographic data. Modified Children Pain Scale (MCPS) was used to observe the selected behavioral patterns suggesting the response towards pain during venipuncture.

3.3 Theoretical framework

A framework is an abstract logical structure of meaning that guides the development of the study and enables the researcher to link the findings to nursing body of knowledge. Not every study is based on theory or conceptual model, but every study has framework. Theories and conceptual models are primary means of providing a conceptual context for a study. The aim of the present study is to assess the effectiveness of Buzzy Device on the level of pain during Venipuncture in children admitted at Paediatric Unit of selected hospital of Metropolitan city. The conceptual framework of this study is BASED ON "**Widenbach's helping Art of Clinical nursing Theory.''** Ernestine Widenbach's was born in August 18, 1900, in Hamburg Germany. She proposed this helping art of clinical nursing theory, as a perspective theory proposed direct action towards an explicit goal. Based on perception Practice are those observable nursing actions that are affected by beliefs and feelings about meeting the patient's need for help through observation of presenting symptoms. The Art of nursing includes understanding patients' needs and concerns, developing goals and actions intended to enhance patient's ability and directing the activities related to the medical plan to improve the patient' condition. Nursing primarily consists of identifying a patient's need for help. It is based on three factors; namely, Central purpose, prescription and realities.

IV. Results and Discussion

TABLE 4.1 – DISTRIBUTION OF SUBJECTS IN RELATION TO AGE AND GENDER

N=100

SN	Demographic data	Experimental		Control	
		Frequency	Percentage	Frequency	Percentage
AGE					
1	6 – 8 years	24	48%	27	54%
2	>8 – 10 years	15	30%	8	16%
3	> 10 – 12 years	11	22%	15	30%
GENDER					
1	Female	21	42%	20	40%
2	Male	29	58%	30	60%

FIGURE 4.1 DISTRIBUTION OF SUBJECTS ACCORDING TO AGE

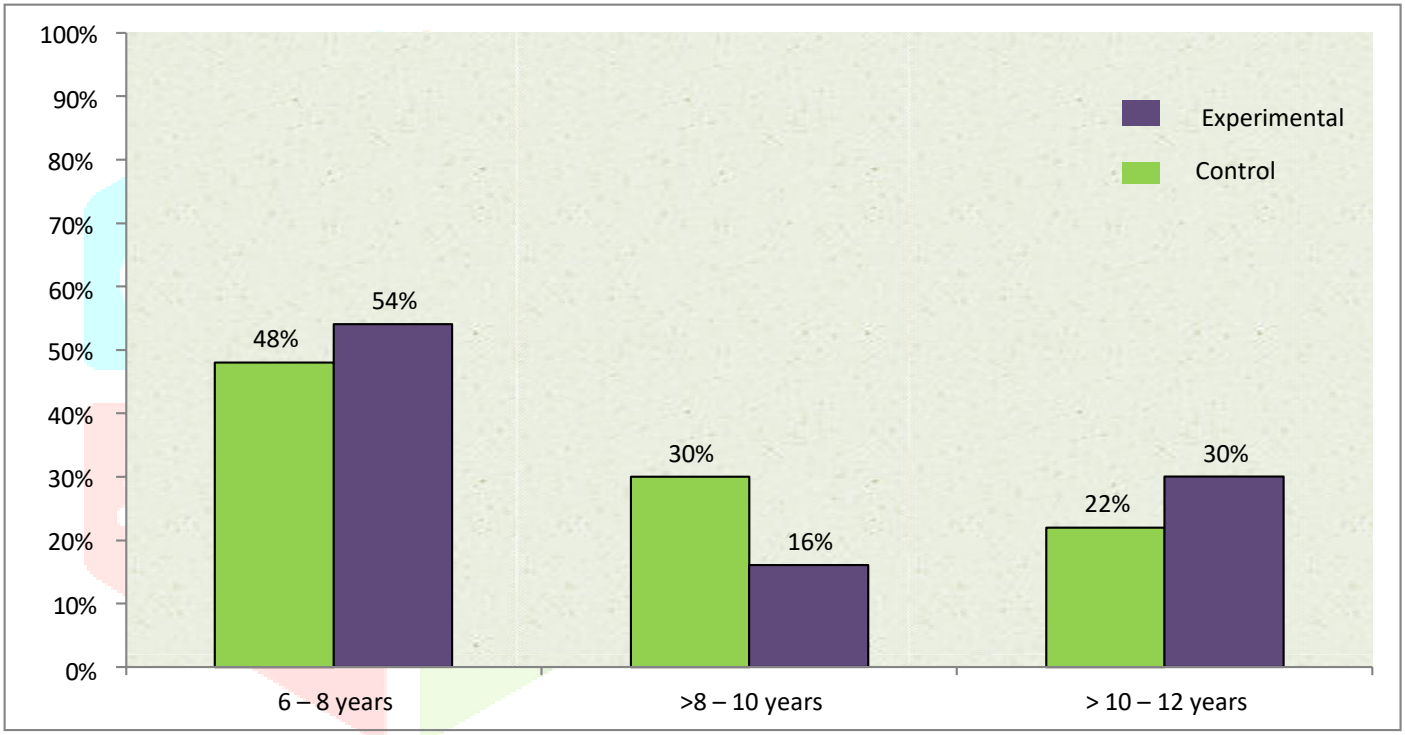

Table 4.1 and Figure 4.1: Depict distribution of the respondents in relation to their age and gender. In the Experimental group among 50 subjects, 24 (48%) were in between 6-8 years of age, 15 (30%) were in >8-10 and only 11 (22%) subjects of them were in > 10-12years. In the control group out of 50 subjects, maximum 27 (54%) subjects were in between 6-8yeras of age, 15 (30%) were in >10-12 years and only 8 (16%) subjects of them were in between > 10-12years.The data regarding gender, in the Experimental group among 50 subjects, maximum 29 (58%) subjects were male and rest 21 (42%) subjects were females. Similarly, in the control group, maximum 30 (60%) subjects were males and rest 20 (40%) subjects were females.

4.2 DISTRIBUTION OF SUBJECTS WITH REGARD TO HISTORY OF PREVIOUS HOSPITALIZATION AND EXPOSURE TO VENIPUNCTURE

N=100

SN	Demographic data	Experimental		Control	
		Frequency	Percentage	Frequency	Percentage
History of Previous Hospitalization					
1	No	27	54%	25	50%
2	Yes	23	46%	25	50%
Child undergone Venipuncture during hospitalization					
1	Not undergone venipuncture	27	54%	25	50%
2	within 6month	17	34%	17	34%
3	6months-1Year	6	12%	8	16%

Table 4.2 History of previous hospitalization of subjects and exposure to venipuncture. In the Experimental group among 50 subjects, 27 (54%) were not had history of previous hospitalization and only 23 (46%) subjects of them had history of previous hospitalization. In the control group out of 50 subjects, equally 25 (50%) subjects had history of previous hospitalization and remaining 25 (50%) of subjects not history previous hospitalization. In relation to subjects undergone venipuncture procedure during hospitalization, In Experimental group among 50 subjects, 27 (54%) subjects not undergone venipuncture, 17 (34%) subjects undergone venipuncture and remaining total subjects 6 (12%) undergone venipuncture in 6months-1year. In control group among 50 subjects, maximum 25 (50%) subjects were not undergone venipuncture procedure, whereas 17 (34%) subjects undergone venipuncture within 6month and minimum 6 (12%) subjects were undergone venipuncture in 6 months -1year during hospitalization.

TABLE 4.3 COMPARISON OF HEART RATE IN EXPERIMENTAL AND CONTROL GROUP

N=100

SN	HEART RATE	EXPERIMENTAL n1= 50		CONTROL n2= 50	
		Mean	S.D.	Mean	S.D.
1	Baseline H. R	99.51	±7.44	103.07	±10.41
2	H.R. during insertion of cannula	101.79	±10.62	115.63	±11.67
3	H. R. after securing cannula	102.48	±11.14	115.47	±11.63

Table 4.3 In experimental group mean value heart rate during insertion of cannula was 101.79 ±10.62 whereas mean value of Heart rate in control group increases by 115.63±11.67 which shows there is increase in mean value of heart rate during insertion of cannula in control group is high as compare to experimental group. In control group mean value of heart rate after securing of intravenous cannula is 115.47 +11.63 which is high as compare to that of mean value of Heart rate of experimental group that is 102.48 ±11.14. That means mean heart rate after securing of intravenous cannula is more in control group as compare to experimental group.

Table 4.4 COMPARISON OF MEAN OXYGEN SATURATION IN EXPERIMENTAL AND CONTROL GROUP.

N=100

SN	Assessment of oxygen rate	Experimental n_1= 50		Control n_2 = 50	
		Mean	SD	Mean	SD
1	Baseline Oxygen Rate	97.71	±1.5189	97.75	±1.5194
2	Oxygen saturation during insertion of cannula	95.37	±4.6586	91.70	±5.6288
3	Oxygen saturation after securing of cannula	95.92	±4.5292	92.49	±5.5535

Table 4.4 Illustrates the comparison of mean oxygen saturation in experimental and control group. In both Experimental (97.71±1.5189) and control group (97.75±1.5194) mean oxygen saturation rate is almost same values. The mean value of oxygen saturation during insertion of cannula in experimental group is 95.3 ±4.6586 whereas low mean value oxygen saturation in control group 91.70±5.6288 as compare experimental group. The mean value of Oxygen saturation after securing of cannula in Experimental group is higher 95.92±4.5292 and Control group 92.49±5.5535, higher the value high oxygen saturation.

TABLE 4.5: ASSESSMENT OF MODIFIED CHILDREN PAIN (MCPS) SCALE BETWEEN EXPERIMENTAL AND CONTROL GROUP

N=100

Venipuncture associated level of pain	Score Range	Experimental n_1= 50		Control n=$_2$50	
		Frequency	Percentage	Frequency	Percentage
Mild pain	1 – 3	26	52%	2	4%
Moderate pain	4 – 6	24	48%	19	38%
Severe pain	7 – 10	0	0%	29	58%

Table 4.5: Assessment of modified children pain (mcps) scales between experimental and control group. Among the experimental group, 26 (52%) subjects of them had Mild pain, 24 (48%) subjects had Moderate pain, whereas nobody reported severe pain in experimental group. Among 50 subjects in control group, only 2 (4%) subjects had mild pain, 19 (38%) subjects had moderate pain and 29 (58%) had severe pain.

Table 4.6 DISTRIBUTIONS OF DATA RELATED TO EFFECTIVENESS OF BUZZY DEVICE

SN	Particulars	Strongly Agree/ Agree		Uncertain	
		F	%	F	%
1	Parent presence was not needed	38	76%	12	24%
2	No Efforts and counseling required to restrain child	40	80%	10	20%
3	Child was calm during Venipuncture	36	72%	14	28%
4	Buzzy device can be recommended for children of other age groups.	28	56%	22	44%
5	Buzzy Device application recommended for other painful procedures.	34	68%	16	32%
6	Buzzy Device helped to distract child from painful stimuli.	33	66%	17	34%

Table. 4.6 The table elicits 80% parents/caregivers agree to that No Efforts and counselling require to restrain child. Majority of the caregivers (76%) agree to parents / caregiver presences were not needed during procedure. Majority (44%) parents/ caregivers were uncertain about the Buzzy device can be recommended for children of other age group. About (42%) of parents / caregivers were uncertain with Buzzy device should be used frequently while any invasive related procedure.

V. Acknowledgment

With sincere gratitude, the investigator wishes to acknowledge all those who have put their efforts in the making of this study. It was the contribution of many people, which helped in the successful completion of the study. I owe my heartfelt gratitude to those who have participated in this study and provide me all the information required for the completion of the project and without whom this project would have been incomplete.

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