

**EFFECT OF COLD VIBRATOR DEVICE ON PAIN PERCEPTION OF
CHILDREN AGED 6-12 YEARS OLD UNDERGOING MANTOUX TEST AT
PHILIPPINE CHILDREN'S MEDICAL CENTER OUT-PATIENT DEPARTMENT**

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ABSTRACT

BACKGROUND: Painful procedures intensify hospital-related stress and anxiety leading to unpleasant experience that can adversely affect procedure outcomes and health seeking behaviors.

OBJECTIVE: To determine the effect of a cold vibrator device on pain perception of children aged 6-12 years old during Mantoux Test at the Out-Patient Department of the Philippine Children's Medical Center.

METHODOLOGY: This is a single blinded, randomized control trial where one-hundred four (104) subjects were randomly assigned to experimental (54 subjects) and control group (50 subjects) through fishbowl method. The experimental group received the cold vibrator prior to Mantoux test while the control group received the Mantoux test alone. Pre and post procedural heart rate, respiratory rate and oxygen saturation were obtained. The responses were evaluated using the Wong-Baker Faces Pain Scale.

RESULTS: Pain score was higher in the control group. Wilcoxon Rank-Sum Test showed mean rank of 67.5 with aggregated pain rank of 3645.00 compared to experimental group (with cold vibrator) of 36.3 with aggregated pain rank of 1815.00 with a p value 0.0000000046. There was no significant difference between the physiologic parameters (heart rate, respiratory rate, and oxygen saturation) before and after procedure between the two groups.

CONCLUSION AND RECOMMENDATION: The use of the cold vibrator was effective in reducing pain perception. It can be used as an adjunct to mitigate pain for needle-related procedures. Demographic data could also be correlated to the pain scores of the subjects.

KEYWORDS: Cold vibrator device, Mantoux Test

INTRODUCTION

Pain is one of the untoward manifestations of clinical events such as trauma, surgery, illness, or an adverse reaction following needle-related procedures

like an immunization. Because of their young age, infants and children have their immature responses yet to pain, hence they experience it as despicable and should be avoided. This in turn upsets parents, relatives, and health care providers as well.

Pediatric procedural pain is often under evaluated or not assessed at all, leading to inadequate pain management. Stevens *et al.* reported that in only 28% of pediatric pain cases was pain documented and children receiving pain management associated with a painful procedure.⁽¹⁾

Through time, there are several non-invasive techniques utilizing different sensation to decrease or even alleviate pain such as cold and vibration sense. A device combining cold and vibration called Buzzy® was created by MMJ Labs Atlanta (2009) to alleviate or decrease procedural pain. It is in this light that this study is being carried out, to document the decrease in pain perception following Mantoux test, with the use of Buzzy®, a device combining both cold and vibratory senses.

Pain management is extremely important for pediatric age group. A child's pain is quite different from that which is experienced by adults. Insufficient pain relief may cause long-term changes in pain understanding and perception and determines specific pain-related behavioral expressions. Procedural-pain-associated stress and discomfort have long-term negative effects on patients and their parents or caregivers. It may contribute to eating and sleeping disorders, provoke post-traumatic stress disorder, diminish social skills, or increase fears⁽³⁾

According to Lodhey, the gate control 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 pain receptive nerves namely A-delta fibers responsible for acute pain and the C fibers for chronic pain are blocked by fast non-noxious motion nerves carried by A-beta. Prolonged cold stimulates the C fibers and, if preceding the pain, may further block the A-delta pain signal. Another mechanism by which the cold sensation is effective is triggering descending noxious inhibitory controls activating a supraspinal modulation raising the body's overall pain threshold⁽⁴⁾

On the other hand, vibration therapy is another intervention done to relieve mild to moderate pain where non-noxious stimuli such as touch, vibration, cold, activate nerve fibers inhibit the transmission of pain as stated in the gate control theory. In a study done by Berberich et al, as cited by Bahorski et al., vibration was used on the opposite arm from where an immunization was given in children 4-6years old. Observational pain score for children who received this vibration technique were significantly lower than those who did not⁽⁵⁾

Cold sensation is effective in triggering descending noxious inhibitory controls activating a supraspinal modulation raising the body's overall pain threshold. A local study done by Ausan MP, at Iloilo Doctors' Medical Center where ice was used as topical anesthetic for Purified Protein Derivative (PPD) Skin Test in children ages 8-12y/o. The study showed significantly lower scores among patients where ice was applied prior to PPD.⁽⁶⁾

Another local study done at University of Sto.Tomas Hospital on the

effectiveness of ice cube as topical anesthetic in reducing the pain of intramuscular injection among 4 to 6 years old children using the Wong Baker Faces pain scale for pain assessment. The subjects who were given ice compress prior to intramuscular injection experienced less pain with an average pain level of 5.14 compared to the control group where the average pain level was significantly higher at 7.18⁽⁷⁾

In a study done by Baxter *et al*, the cold vibrator was compared to vapocoolant spray in 81 subjects, presenting at the Emergency Department for venipuncture. Before the procedure, the gadget was applied for 15-30 seconds where there was more pain relief ($p=0.035$) as well as increased venipuncture success rate in the Buzzy group⁽⁹⁾

In a study utilizing the vibratory device on foot and ankle injection, the gadget was applied 5-10cm proximal to the injection site over the anatomical location of the appropriate sensory nerve(s). The vibratory device was turned on for approximately 1 minute prior to and maintained during the injection⁽¹¹⁾.

Another study by Nemet *et al*, showed the use of “Buzzy” in a RCT during IV insertion in 48 children aged 4-12 at American University Medical Center. “Buzzy” was applied 5 to 10cm proximal to the dorsum of the hand site 15 to 60 seconds before and during the procedure while the other group underwent the usual procedure without any gadget or intervention applied. Pain scale was rated using the Wong Baker

FACES Pain Rating Scale. The study showed lower pain score in the Buzzy group for the children and nurses. However, in this same study, gender, age, previous hospitalization, analgesics were all factors associated with children’s pain score. On regression analysis they found out that Buzzy remained significant predictor of (lower) pain scores in children in this study.⁽¹³⁾

Across the globe there are different pain scales used in the pediatric age group such as the faces scales, numerical rating scales and visual analogue scales. In a review done by Baeyer, CL (2010), generally, children prefer faces scales with minimum age of 4⁽¹¹⁾. One of the widely used face scale, Wong-Baker Faces Pain Rating Scale (WBFPRS) has been preferred by children (any age), parents, and practitioners. In a study done by Tomlinson *et al*, concerning validity, WBFPRS has a high correlation with other self-reported pain scale used at the same time and shows differences ($p < 0.05$) in score between two comparable but different groups. Reliability has been proved using “test and retest” ($r > 0.5$) and by the concordance with simultaneous observational score ($r > 0.4$). WBFS has a significant ($p < 0.05$) responsiveness to pain-increasing (painful procedures) and pain-decreasing (analgesia) events⁽¹⁴⁾

Buzzy® is a device created by MMJ Labs, Atlanta, GA which combined cold and vibration in a bee shaped device measuring 7.2cm x 4.8cm x 2.2cm, AAA+ battery-operated with removable ice gel wings, measuring 4.2 x 1.1 x 3.2 inches weighing

2.2 ounces. The device is pressed manually or secured by a rubber strap. Batteries will last at least at full strength for 20 hours as instructed in the manual. ⁽¹⁶⁾ Only vibratory, cold sensation, transient erythema and numbness were felt by the participants. There was no report of electrocuted subject using this gadget.

OBJECTIVES OF THE STUDY

General Objective:

To determine the effect of a cold vibrator device on pain perception of children aged 6-12 years old during Mantoux Test at the Out-Patient Department of the Philippine Children's Medical Center.

Specific Objectives:

To describe the demographic profile of children involved in the study as to age, gender, and school level.

Compare the following physiologic parameters before and after the procedure between the 2 groups, a) heart rate, b) oxygen saturation, b) respiratory rate

Determine the perceived pain among the 2 groups using the Wong Baker Faces Rating Scale for Pain

METHODOLOGY

This was a single blind randomized controlled study. The target population were children aged 6-12 years old, who were for Mantoux Test at Philippine Children's Medical Center Outpatient Department.

Excluded in the study were those with chronic and persistent pain disorder, with vision and hearing impairment, those with intellectual disability, patients with maintenance medication given as injection and patients with neurologic condition because of the possibility of altered sensation capacity. Those who could not recite back the instructions on how to answer or use the Wong Baker Face Scale after instruction was repeated three (3) times by the investigator or co-investigator were also excluded.

The participants were divided into control and experimental group. Each patient was randomized by drawing a piece of paper from a fishbowl given by the nurse where their respective group was written. The control subjects received Mantoux Test alone while the experimental group received the cold vibrator application 30 seconds prior and during the procedure.

A total of 104 subjects would achieve 80% power to detect a difference of 2.0 in pain score with a significance level of 0.05 using 2 tailed sided 2 sample t—test. This calculation assumed that the mean score for the controlled group is 7.2 with estimated group standard deviation of 3.6. ⁽⁷⁾
(44)

Patients and their caregivers coming in for Mantoux Test at PCMC OPD were oriented by the investigator or co-investigator regarding the study and invited to participate in the study. For those who joined, an Informed consent was obtained from the parents or guardian and assent for children 6-12y/o (appendix 5). The picture

of the gadget was shown and the Mantoux Test procedure was discussed to the participants and parents during the orientation prior to the procedure for them to have an idea of the procedure. Consenting participants were given a form for demographic data which they filled out. Instructions on how to answer the Wong Baker pain rating scale was discussed by the investigator or co-investigator after they filled out the form. Once the patient understood the process of answering the pain scale as evidenced by being able to recite and demonstrate on how to answer the scale, the following vital signs were obtained, namely: heart rate, respiratory rate, and oxygen saturation, by the investigator or co-investigator 1-2 minutes before the procedure. After obtaining baseline vital signs for 2 minutes, the participant was transferred to the adjacent procedure room. Fishbowl method was used by the subjects to identify their group. For the controlled group, the area was cleaned with cotton and 70% alcohol, after which Mantoux Test was be administered via intradermal injection on the volar aspect of the forearm. While in the experimental group, the cold vibrator was applied 5 to 10 cm proximal to the volar aspect of the forearm where the Mantoux Test would be done, 30 seconds prior and during the procedure. The cold vibrator device was secured using the rubber strap provided. It took 1 minute for drawing paper, 2 minutes to clean and strap the gadget, then 30 seconds in applying the gadget and another 30 seconds in injecting the Mantoux Test. After the procedure, the patient rated the experienced pain using the Wong-Baker Faces rating scale as oriented

prior to the procedure. He was given 2 minutes to answer. After completion, the answer sheet was then folded, sealed, and placed by the participant in a collecting box beside the nurse. After the procedure, the patient returned to the holding room, where the investigator or co-investigator obtained the post-procedural vital signs: heart rate, respiratory rate, and oxygen saturation rate for another 2 minutes. The entire procedure took 10 minutes.

The investigator and co-investigator were blinded on the pain scale result of the patient since it was only the patient and parent who saw the pain score of the participant written on the paper which was then sealed and collected on the box. To ensure that uniformity of instructions given to the participants, a script was utilized by the investigator and co-investigator during the orientation of parents and patient.

The Wong Baker Faces Pain rating scale was used in this study. It is an instrument that measured the pain by an individual to certain stimuli which was recommended for ages 3 years old and above⁽¹⁷⁾. There were 6 faces in this rating scale. The first face represented a pain score of 0 "no hurt". The second face represented a pain score of 2, "hurts a little bit." The third face represented a pain score of 4 "hurts a little more". The fourth face represented a pain score of 6, "hurts even more". The fifth face represented a pain score of 8, "hurts a whole lot" while the sixth face had a pain score of 10, "hurts worst"⁽¹⁸⁾.

The guardian or participant answered the data sheet containing the demographic data: age, birthday, gender, and date. The objective findings such as the heart rate, respiratory rate, and oxygen saturation pre- and post-procedure along with the Wong baker faces pain rating scale were obtained.

The test for the significant difference between the effect of cold vibrator in the pain perception during Mantoux test compared to those who did not receive the treatment was measured using Wilcoxon Rank-Sum Test. The WongBaker Pain Scale score was greater in the control group than in the experimental group, $U = 540$ with a p value < 0.05 (0.0000000046). T test was used for the evaluation of the pre- and post-procedural vital signs between and among groups. There was no significant difference between the physiologic parameters (heart rate, respiratory rate, and oxygen saturation) before and after procedure between the two groups with p value > 0.5 for each vital sign.

This study was submitted and approved by the IRB-EC to ensure non-violation of patient's rights and safety. An Informed consent was obtained from the subjects' parents where simple explanation about the objective of the study was also explained. This study ensured the safety, privacy, and confidentiality for each patient. Each patient was given a chance to ask questions regarding the procedure to be taken. All data from this study was kept confidential.

RESULTS

There were 104 subjects aged 6-12 who participated in this study. Subjects were randomly assigned using the fishbowl method where in fifty (50) children belonged to the controlled group while fifty-four (54) on the experimental (with cold vibrator) group. All of which received Mantoux Test at the Out-Patient Department of the Philippine Children's Medical Center from October 1 to 18, 2019.

Table 1. Demographic profile of children as to age, gender, and school level.

Age in Years	N = 104	
Mean	9.01 ± 1.95	
Median	9.0	
Minimum	6	
Maximum	12	
	Frequency	Percent
Sex		
Female	50	48.1
Male	54	51.9
Educational Level		
GR 1	10	9.6
GR 2	12	11.5
GR 3	14	13.5
GR 4	23	22.1
GR 5	16	15.4
GR 6	13	12.5
GR 7	6	5.8
KINDER	10	9.6

Table 1 shows the demographic profile of children as to age, gender, and school level. The median age of the participants was 9 years old, the ages ranged from 6 years to 12 years old. As to gender, there were more

males than females wherein 54 (51.9%) were males and 50 were females (48.1%). All participants were also enrolled in school with the following grade level; grade 1, 10 participants (9.6%), grade 2, 12 participants (11.5%), grade 3, 14 (13.5%), grade 4, 23 (22.1%), grade 5, 16 (15.4%), grade 6, 13 (12.5%), grade 7, 6 (5.8%) and kinder with 10 students (9.6%).

Table 2. Comparison of Physiologic Parameters between the Experimental and Control Groups

Physiologic Parameters	Experimental Mean	Control Mean	p value
Pre procedure Heart Rate	101.92	102.87	0.732
Post procedure Heart Rate	98.48	99.02	0.848
Pre procedure Respiratory Rate	24.58	24.41	0.729
Post procedure Respiratory Rate	23.86	23.63	0.679
Pre procedure O2 Saturation	98.82	98.69	0.519
Post procedure O2 Saturation	98.84	99.0	0.613

Table 2 shows the comparison of the physiologic parameters between the experimental and control group. There was noted higher mean scores for the heart rate and respiratory rate for the pre procedural physiologic parameters for both the control and experimental group.

Table 3. Physiologic Parameters in the Control Group

Physiologic Parameter	Pre-Procedure Mean	Post Procedure Mean	p value
Heart Rate	103.17	99.21	0.008
Respiratory Rate	24.50	23.77	0.010
O2 Saturation	98.65	99.04	0.134

Table 3 shows the pre- and post-procedural physiologic parameters of the control group which showed higher heart rate and respiratory rate for the pre procedural heart rate and respiratory rate. The mean score of 102.87, 24.41, 98.69% compared to its post procedural physiologic parameters 99.02, 23.6, 99% for heart rate, respiratory rate, and oxygen saturation, respectively.

Table 4. Physiologic Parameters in the Experimental Group

Physiologic Parameter	Pre-Procedure Mean	Post Procedure Mean	p value
Heart Rate	101.85	98.15	0.008
Respiratory Rate	24.60	23.79	0.010
O2 Saturation	98.87	98.87	0.134

Table 4 shows the pre- and post-physiologic parameters for the experimental group. Like in the control group, the experimental group showed higher pre procedural mean score for heart rate and respiratory rate. There were 101.92, 24.5, 98.82 compared to its post procedural physiologic parameters of

98.48, 23.86, 98.84% heart rate, respiratory rate, and oxygen saturation respectively.

Table 5. Perceived pain among the 2 groups using the Wong Baker Faces Rating Scale for Pain using Mann-Whitney Test/Wilcoxon Rank-Sum Test

Group	N	Mean Rank	Sum of Ranks
1 – experimental	50	36.3	1815.00
2 - control	54	67.50	3645.00
Total	104		

Table 5 shows the perceived pain using Wong Baker Faces Rating Scale for Pain between the two groups. There was higher mean for the control group with mean rank of 67.5 with aggregated pain rank of 3645.00 compared to experimental group (with cold vibrator) of 36.3 with aggregated pain rank of 1815.00 with a p value < 0.05 (0.0000000046) using Wilcoxon Rank-Sum Test.

DISCUSSION

Vaccinations are one of the earliest and most commonly experienced painful procedure in healthy children, being reported as one of the most feared and painful medical experiences.⁽¹⁹⁾ The pain of needle related procedure as well as adverse events, such as swelling and redness at the injection site, are key barriers to vaccination,⁽²⁰⁾ hindering coverage rates and, therefore, herd immunity. Furthermore, the distress felt by the child, and the parent during the procedure has been shown to influence hesitancy to vaccinate⁽²¹⁾ which ultimately increases the likelihood for the vaccine preventable diseases. For this

reason, the WHO continues to emphasize pain management as a fundamental right regardless of age, culture, race, ethnicity, and socio-economic status.^{(22) (23)}

In our study, there was greater pain score experienced by the control group compared to the experimental or Buzzy group with a p value < 0.05 (0.0000000046) which makes the difference significant. In a similar study done by Susam V. *et al*⁽²⁴⁾ where cold vibrator was utilized during venipuncture stated that the mechanisms which could explain the impact of vibration and cryotherapy could be found through the gate-control theory⁽²⁵⁾ Based on gate control theory, mechanisms of pain relief induced by vibration can be reduced by simultaneous activation of nerve fibers that conduct no noxious stimuli.^{(26) (27)} In another study, where vibration was applied as a counter stimulation to an anesthetic injection, it reached the brain before the pain sensation does. The brain can perceive only one sensation at a time. Therefore, the sensation that arrived at the brain first was the one that was felt. Hence as counter stimulation vibration reduces pain perception.^{(28) (29)}

On the other hand, pain is subjective, complex and multidimensional construct that involves sensory, emotional, and cognitive processes⁽³⁰⁾ The primary outcome assessment was evaluated by self-report, which was considered as a primary source of evidence for pediatric pain intensity.⁽³¹⁾ This could increase the magnitude of the detection bias as pain is a subjective measure.⁽³²⁾ However, some have argued that self-report assessment could be considered as equivalent to blinding of

outcome assessors considering that it is not associated with an overestimated intervention effects, as is the case in psychotherapy meta-analyses.^{(33) (34)}

Previously published studies had reported that pain rating was influenced by demographic variables such as age, gender, and educational level of parents ⁽³⁵⁾. In a local study done by Acero AJ, analysis of the perceived injection pain among male and female groups showed no significant difference ⁽³⁶⁾. In a study conducted by Matthew T. Feldner and Hamid Hekmat (2001), it was investigated as to the extent of perceived control over anxiety-related events contributes to the experience of pain. It was discovered that pain tolerance and endurance, but not pain intensity or threshold, were predicted by perceived control over anxiety-related events ⁽³⁷⁾. In our study, correlation of demographics with regards to pain perception were beyond our scope and could be an avenue for future study.

In our study, there was no significant change between the vital signs (heart rate, respiratory rate, oxygen saturation) before and after the procedure between the two groups. Like in the study of Mohamed RA, on the effect of play intervention on anxiety and vital sign in children during preoperative period, vital signs had no statistically significant difference between the study and control group regarding vital signs one hour before transferring to operating room⁽³⁸⁾ However in our study, there was noted higher heart rate and respiratory rate among each group. This might be attributed to anxiety or fear felt by

the subjects with the procedure. Fear can increase the secretion of cortisol and norepinephrine, which in turn affect the vital signs. This result was supported by a study done by Aranha, et al., (2017) about impact of multimodal preoperative preparation program on children undergoing surgery who found that multimodal preoperative preparation program is effective in stabilizing pulse, respiration, and blood pressure of children ⁽³⁹⁾

In the study of Hatfield and colleagues in 2008, it was explained that the long-term effects of unmanaged pain in human infants have been shown to include permanent impairment of elements of cognitive development, including learning, memory, and behavior and increased somatization in childhood ⁽³⁶⁾. The plasticity of the developing brain and the changes that occur in response to painful stimuli also contribute to altered perceptions of pain later in life ⁽⁴⁰⁾

CONCLUSION AND RECOMMENDATION/S

In this study, the use of the cold vibrator was shown to be efficacious in reducing pain perception felt by the children during Mantoux test. This gadget could also be applied to other needle related procedure as indicated on above mentioned studies. An inter-observer rating score could be utilized to assess and verify the pain experienced by the participants were congruent. Due to its vibratory mode potential use of this gadget as chest precursor to infants could also be explored.

Lastly, the demographic data could also be correlated to the pain scores of the subjects. While it may have a positive and significant effect, its measure and evidence were beyond the scope of this study but may be another avenue for a similar research along this topic.

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