A RANDOMIZED CONTROL TRIAL ON THE EFFECT OF VIRTUAL REALITY VERSUS COLD VIBRATION ON PAIN AND PHYSIOLOGICAL PARAMETERS DURING PHLEBOTOMY AMONG CHILDREN

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Abstract:

Purpose: This study aimed to evaluate the effect of virtual reality and cold vibration application through the buzzy device on phlebotomy associated pain and physiological parameters (pulse rate and Spo2) among 5-10 years of children.

Design Randomized: control trial

Methods: Total 108 children were randomly assigned to three arms (Cold Vibration, Virtual reality and control) using blocked randomization method. Allocation concealment was ensured using Sequential Numbering Opaque Sealed Envelope. Pain scores were collected after phlebotomy from the children, researcher and the nurse using WBFS scale whereas pulse rate and Spo2 were recorded by a fingertip pulse oximeter.

Result: During phlebotomy, the pain score and pulse rate were found to be lesser in virtual reality and cold vibration group as compared to the control group. There was a statistical difference in pain score between experimental and control group as perceived among the children (p < 0.000), Nurse (p < 0.000), and by the researcher (p < 0.000) during phlebotomy (Table 2). For pulse rate, a statically significant difference between experimental and control group was found (p < 0.05), whereas no statistically significant difference was found for Spo2 (p > 0.05).
Conclusion: The current study proposed both virtual reality and cold vibration application were equally effective in alleviating the phlebotomy related pain and pulse rate of 5-10 years aged children. Hence the author advocates the use of these distraction methods in the clinical practice for pain management.

Keywords: Virtual Reality, Cold Vibration, Pain and Physiological Parameters, Phlebotomy

Introduction:

Pain is a distressing and subjective phenomenon experienced in response to the injury. Exposure to the painful event during early childhood can be remembered for a longer period in life as children have a lack of coping mechanism, unlike adults. But unfortunately the hospitalized children undergo several painful procedures which are routinely performed for diagnosis and treatment. Heel prick, immunization, phlebotomy, bone marrow aspiration, lumbar puncture is the commonest needle-related medical procedures which contribute to the majority of the pain experience. These painful acute medical procedures not only affect the coping mechanism but also become the deciding factor for future response towards painful events. The evidence suggests that persistent untreated procedural pain in the children stimulate the hypothalamus and sympathetic nervous system causing physiological changes like elevated blood pressure and tachycardia, this phenomenon is commonly called as general awareness syndrome. Several scientific studies have demonstrated that the biochemical effect of unmanaged pain can suppress the immune system which can have detrimental consequences on the human body. Suboptimal pain management in the early childhood found to have a strong association with altered cognition, anxiety, reduced pain threshold, behavioural problem, needle phobia and negative effect on memory in the later life. Therefore children with a history of needle-related procedure develop a phobia and subsequently avoid medical care.

Despite deep knowledge and evidence about short term and long-term negative consequences of the untreated needle prick related pain, children are still undermanaged and the fact is called oligo analgesia. Although it has been reported by several studies that the nurses play a critical role in the management of pain during needle-related procedures, still there are numerous barriers like lack of time, excess workload, shortage of staff, inadequate knowledge and limited space make it difficult to practice in the clinical settings. Despite all these hurdles, adherence to pain management is always a paramount concern as this is a matter of human rights.

Both pharmacological and nonpharmacological interventions can be used for effective management of the needle-related pain. But several studies prioritize the nonpharmacological interventions over pharmacological interventions because of cost-effectiveness, lesser side effects, and quick action. Although many nonpharmacological interventions like Virtual reality, cold vibration, blowing soap bubbles, kaleidoscope etc. have been claimed by previous studies as effective methods in diminishing procedural pain, but choosing an ideal method which can be used in the clinical practice to require further investigation to strengthen evidence-based practice. The current study aimed to compare the effectiveness of virtual reality and cold vibration interventions on phlebotomy related pain among children.
Methods:

Design and setting:

This was a prospective randomized control study conducted at phlebotomy units of paediatric medicine and surgery wards of IMS and SUM hospital (a tertiary care hospital), Odisha between 10th March to 31st July to compare the effect between two interventions on pain perception after phlebotomy those are cold vibration and virtual reality.

Sample size:

Based on the previous study result (38) sample size was calculated for the current study assuming the medium effect size 0.32, power 0.80 and 0.05 level of significance using G power version 3.1 software. The calculated total sample size required for three groups (virtual reality group, cold vibration group and control group) was 99 (33 participants in each group). Additional 30% of the sample were taken anticipating dropout from the study. In the end, data were collected from 108 children for statistical analysis.

Randomization:

The children admitted to medicine and surgery wards of IMS and SUM Hospital between the ages of 5-10 years were screened for eligibility. The eligible children and the respective parent were then approached and explained thoroughly about the study. The children those did not meet the study criteria were excluded. The remaining students were randomized using blocked randomization method. The block identity, sequence within block and intervention groups were randomly generated using www.sealedenvelope.com website and the children were grouped as per the age into six blocks and within each block, children were randomly assigned to two experimental (Virtual reality group and cold vibration group) and one control group. Allocation concealment was guaranteed by Sequential Numbering Opaque Sealed Envelope (SNOSE). Randomization, coding and envelop preparation was carried out by a statistician to ensure blinding towards the assignment of the children to the study groups. No one was blinded to the intervention.

Ethical consideration:

Ethical approval was obtained from the Institutional ethical committee, IMS and SUM Hospital (Ref. No./DMR/IMS.SH/180149). The study was also prospectively registered to Clinical Trial Registry of India (Registration no CTRI/2019/03/017984). The parents and children were explained about the purpose and methods of the study. Approval from the parents was collected in the written informed consent from and verbal consent form the children if agreed to participate in the study. The parents and children were assured that they can withdraw from the study at any time without the need for any explanation.

Participant selection:

The participants were included in the study based on the criteria: children between 5-10 years of age, admitted to paediatric medicine and surgery wards of IMS and SUM Hospital, planned for phlebotomy and children those accepted to wear virtual reality device and a cold vibration device. The children were excluded those had a pre-existing IV line, any visual problem, features of developmental delay or neurocognitive impairment or damaged skin or sensory-neural dysfunction at the site where cold vibration device has to be placed and diagnosed with chronic medical conditions like Reynaud’s syndrome, sickle cell disease, diabetic Mellitus, asthma, cystic fibrosis.
Devices:

Virtual reality device:

The immersive 3d experience was provided to the children in Virtual Reality group using Ocular Grand Virtual Reality device equipped with elastic head strap, inbuilt 3.5 mm jack headphones, 42 mm PMMA HD optical resin lens, volume controller and knobs to adjust focal and interpupillary distance manually. A Xiaomi note5 Pro smartphone was placed in the Virtual reality device to show the animation to the children 5 mins before the phlebotomy and also during the procedure. The animation used was selected after taking reviews of 10 children.

![Virtual Reality device]

Figure. 1 Virtual Reality device

Cold vibration device (Buzzy device)

The combined cold vibration intervention was delivered using the buzzy device which is a battery-operated, vibrating plastic device resembles like a ladybug with a thin cooled wing which is disposable or reusable (In the current study reusable wings were used). The device can be secured at the desired site using a tourniquet that comes with the product or manually by holding it. The reusable wings were frozen till they solidify before each use. As per the instruction of the manufacturer the buzzy device was placed 3-5 cm proximal to the selected phlebotomy site 30-60 seconds before the procedure.

![Buzzy device]
Figure 2 Buzzy device with reusable cooling wings

Measures/ Instruments:

Sociodemographic proforma:

This proforma composed of items related to children’s characteristics: age, gender, no of phlebotomies in the previous year, the last phlebotomy time. One to one interview was conducted with the parents those who had given consent to take part in the study to collect the required sociodemographic data.

Wong-Baker Faces Pain Rating Scale (WBFPRS)

To assess the level of pain related to phlebotomy Wong-Baker Faces Pain Rating Scale was used after getting approval from the Wong-Baker FACES Foundation. This scale contains scores from 0-10 and six different visuals on a facial expression that denotes the varying degree of pain ranging from no hurt to hurts worst.

Pulse oximeter:

The physiological parameters i.e. pulse rate and SPO2 during phlebotomy procedure were recorded using HICKS, N-310 fingertip pulse oximeter. Reliability of the fingertip Pulse Oximeter was ensured by conducting test re-test on 20 children between the ages 5-10 years (r =0.812 for pulse rate and r=0.868 for spo2 at 0.05 level of significance) at paediatric wards of IMS and SUM Hospital.

Procedure:

The study was conducted after taking formal administrative and ethical permissions. Keeping in mind about the shift duty, rotation and leave during the study period eight nurses were selected for the study based on similar clinical experience and qualification. The researcher oriented the nurses about the study protocol and appropriate techniques to use the test devices (virtual reality and cold vibration device) during phlebotomy. Upon admission to the paediatric department, the children were screened for study eligibility. If the child met the study criteria, then the parent and children were asked for their interest to take part in the study on a volunteer basis. Demographic characteristics of the children were then collected using sociodemographic proforma. The child in the Virtual Reality group wore the Ocular Grand Virtual Reality device containing MI note5 pro smartphone 5 mins before the phlebotomy and also during the procedure. The buzzy group wore the buzzy device which was placed 3-5 cm proximally 30-60 sec. before the procedure. No intervention was administered to the control group. During the procedure, pulse oximeter was used to measure the pulse rate and SPo2 level. A research assistant collected the pain scores from the child in the phlebotomy room and the researcher and the phlebotomy nurse in a separate room one by one immediately after the procedure using Wong-Baker Faces Pain Scale.
Note. CV group=Cold Vibration Group, VR Group: Virtual Reality Group

Figure 3 Diagram showing the flow of participants

Data Analysis:

SPSS version 20 was used for statistical analysis. Socio-demographic characteristics were analysed by using descriptive statistics. Normal distribution of the parameters was analysed through the Shapiro-Wilk test. (data not normally distributed) The intergroup comparison of
pain scores and physiological parameters were statistically compared using the Kruskal Wallis test at 0.05 level of significance.

**Result:**

**Demographic Data:**

Total 214 children were screened for eligibility, out of which 12 were excluded because of already existing IV line, 43 were denied to participate and 11 had a chronic disease. In the end, only 108 children completed the study. Several participants in each group were equal according to their age. There were 51.9% of the female and 48.1% of male participants in the study (Table 1).

**Pain and Physiological Parameters:**

Comparison of phlebotomy related pain between experimental and control group using Kruskal Wallis test revealed a statistically significant difference as perceived among the children (p < 0.000), Nurse (p < 0.000), and by the researcher (p < 0.000) (Table 2). Comparison of pulse rate revealed a statistically significant difference between experimental and control group as p was <0.05. But no statistically significant difference was found among the groups for SPO2 as p was >0.05.

**Pairwise comparison of phlebotomy related pain scores and physiological parameters:**

Table 4 shows a statistically significant difference between CV-CO group (Cold vibration and Control group) and VR-CO group (Virtual Reality and Control group) based on WBFPRS pain scores reported by the child, nurse and the researcher as p was <0.05. But the pairwise comparison of CV-VR group (Cold vibration and Virtual Reality group) revealed no difference in these scores. Whenthe physiological parameters were compared between the groups for pulse rate, it revealed a statistically significant difference (p < 0.05), whereas in SPO2 there was no difference (p >0.05) (Table 5). Hence both cold vibration and Virtual reality therapy were effective when compared with the control group.

**Table 1: Socio-demographic characteristics of the children**

<table>
<thead>
<tr>
<th>Socio-demographic characteristics</th>
<th>Control group (n1=36)</th>
<th>CV group (n2=36)</th>
<th>VR group (n3=36)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age Mean± SD</td>
<td>7.5± 1.732</td>
<td>7.5± 1.732</td>
<td>7.5± 1.732</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>15 41.7</td>
<td>16 44.4</td>
<td>21 58.3</td>
<td>52(48.1%)</td>
</tr>
<tr>
<td>Female</td>
<td>21 58.3</td>
<td>20 55.6</td>
<td>15 41.7</td>
<td>56(51.9%)</td>
</tr>
<tr>
<td>No of phlebotomy in the previous year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>15 41.7</td>
<td>9 25</td>
<td>12 33.3</td>
<td></td>
</tr>
<tr>
<td>1 Time</td>
<td>9 25</td>
<td>17 47.2</td>
<td>13 36.1</td>
<td></td>
</tr>
<tr>
<td>≥ 2</td>
<td>12 33.3</td>
<td>10 27.8</td>
<td>11 30.6</td>
<td></td>
</tr>
</tbody>
</table>
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Table 2: Comparison of pain scores among the control group and experimental groups

<table>
<thead>
<tr>
<th>Procedural pain scores by WBFPRS</th>
<th>CO Group (n1=36)</th>
<th>CV Group (n2=36)</th>
<th>VR Group (n3=36)</th>
<th>kw value p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBFPRS by Child</td>
<td>8.0±.434</td>
<td>1.39±1.337</td>
<td>2.50±1.748</td>
<td>kw=76.487*</td>
</tr>
<tr>
<td>Min:6</td>
<td>Max:10</td>
<td>Min:0</td>
<td>Max:6</td>
<td></td>
</tr>
<tr>
<td>7.94±1.308</td>
<td>1.11±1.116</td>
<td>2.39±1.777</td>
<td></td>
<td>kw=78.287*</td>
</tr>
<tr>
<td>Min:6</td>
<td>Max:10</td>
<td>Min:0</td>
<td>Max:6</td>
<td></td>
</tr>
<tr>
<td>8.0±1.352</td>
<td>1.17±1.207</td>
<td>2.50±1.748</td>
<td></td>
<td>kw=78.386*</td>
</tr>
<tr>
<td>Min:6</td>
<td>Max:10</td>
<td>Min:0</td>
<td>Max:6</td>
<td></td>
</tr>
<tr>
<td>Pulse Rate</td>
<td>109.92±9.440</td>
<td>91.11±4.857</td>
<td>91.97±5.897</td>
<td>kw=60.674*</td>
</tr>
<tr>
<td>Min:94</td>
<td>Max:126</td>
<td>Min:83</td>
<td>Max:102</td>
<td></td>
</tr>
<tr>
<td>97.28±1.003</td>
<td>97.39±.766</td>
<td>97.31±.749</td>
<td></td>
<td>kw=.295</td>
</tr>
<tr>
<td>Min:95</td>
<td>Max:99</td>
<td>Min:96</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPO2</td>
<td>97.28±1.003</td>
<td>97.39±.766</td>
<td>97.31±.749</td>
<td></td>
</tr>
<tr>
<td>Min:95</td>
<td>Max:99</td>
<td>Min:96</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n=108  
kw = Kruskal-Wallis  *=statistically significant at 0.05 level of significance  
Note. CO = Control, CV = Cold Vibration, VR=Virtual Reality

Table 3: Comparison of physiological parameters between control group and experimental groups

<table>
<thead>
<tr>
<th>Physiological parameters</th>
<th>CO Group (n1=36)</th>
<th>CV Group (n2=36)</th>
<th>VR Group (n3=36)</th>
<th>kw Value p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse Rate</td>
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<td>kw=60.674*</td>
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<td></td>
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</tr>
<tr>
<td>Min:95</td>
<td>Max:99</td>
<td>Min:96</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*=statistically significant at 0.05 level of significance

Note.kw=Kruskal-Wallis, CO = Control, CV = Cold Vibration, VR=Virtual Reality

Table 4 Pairwise comparison of phlebotomy related pain scores between the groups
Phlebotomy related pain scores by WBFP by Child

<table>
<thead>
<tr>
<th>Physiological parameters</th>
<th>CV-VR Group</th>
<th>CV-CO Group</th>
<th>VR-CO Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>p</td>
<td>.210</td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>p</td>
<td>.111</td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>p</td>
<td>1.00</td>
<td>.000</td>
<td>.000</td>
</tr>
</tbody>
</table>

Table 5: Pairwise comparison of physiological parameters

<table>
<thead>
<tr>
<th>Physiological parameters</th>
<th>CV-VR Group</th>
<th>CV-CO Group</th>
<th>VR-CO Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>p</td>
<td>1.00</td>
<td>.000</td>
<td>.000</td>
</tr>
<tr>
<td>p</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

DISCUSSION:

Although many non-pharmacological interventions are available, several studies advocated that cold vibration application is quick-acting, simple to use and significantly reduces the pain among the children undergoing common painful medical procedures which is similar to the findings of the current study. Combined cold and vibration is provided using a commercially available Buzzy device to alleviate pain during routine needle-related medical procedures. Cold vibration therapy works based on gate control and diffuse noxious inhibitory control theory (DNIC). According to gate control theory, the nociceptive afferent fibres (A-delta and C fibre) carry the pain signal from the site of injury to the brain through transmission cells located in substantia gelatinosa of the spinal cord. A non-nociceptive A-beta fibre creates a hypothetical gate that can impede the transmission of pain signal carried by A-delta and C fibre. During venepuncture, the nociceptive fibre carries the pain signal but the application of cold and vibration activates the A-beta fibre to close the gate and minimize the pain experience. As per DNIC cold (noxious stimuli) application increases the pain threshold of the body in the brain, hence effective in easing the phlebotomy pain.

Our study proposed that Cold vibration application is significantly effective in ameliorating the phlebotomy associated pain and this result was found to be congruent with a study of NejlaCanbulatet. al. who investigated one effect of external cold vibration in reducing pain related to phlebotomy among children. Similarly, cold vibration intervention significantly minimizes the pain associated with IV insertion was demonstrated in another randomized control trial study conducted by NematMoadad et. al on 4-12 years aged children. An equivalent result also was demonstrated by Volkan Susam et.al. in a study comparing combined intervention of distraction card, cold and vibration (experimental group) with magic glove technique (Control group) among children of 3-10 years of age in mitigating venepuncture pain. Although virtual reality is frequently used as a
nonpharmacological distraction intervention to diminish various needle-related routine medical procedures in several countries, it’s an application in Indian setting is rare.\textsuperscript{51-57} Our study in an Indian tertiary care hospital revealed that virtual reality application was effective in reducing phlebotomy-related pain when compared with the control group. Evelyn Chan demonstrated parallel result related to the effectiveness of virtual reality therapy in reducing pain experienced during phlebotomy in two randomized clinical trial study conducted at two different settings taking 250 children between the ages of 4-11 years old.\textsuperscript{58} Various authors reported similar findings in their scientific studies and recommended the use of a virtual reality device to alleviate the procedural pain in health care settings.\textsuperscript{31, 59-62} Kevin M Malloy reported an analogous result in a systematic review that virtual reality application is effective in minimizing pain related to burn injury, IV cannulation, chronic pruritus and experimental pain.\textsuperscript{63} The current study confirmed that both cold vibration and virtual reality application were equally effective in minimizing the pain associated with phlebotomy procedure. These interventions are cost-effective, safe and devoid of much side effect as compared to pharmacological interventions of procedural pain management, therefore can be adopted for clinical practice.\textsuperscript{64} Similar finding was presented by Gulcin O Gerceker et al. in a study on 7-12 year aged children regarding the effectiveness of virtual reality and cold vibration intervention in alleviating the phlebotomy related pain.\textsuperscript{65}

Inclusion of physiological parameters added to the pain scores in this study is a significant input variable in contrast to the previous studies. Though SPO2 score did not show any difference there was the difference in pulse rate between the groups. During an intervention, it was observed that few children in the virtual reality group hesitated to wear the head mount VR device as they wanted to see the phlebotomy procedure (although previously agreed to wear the device) therefore were excluded from the analysis. It was not possible to blind the children, nurses or the researcher to the allocated intervention, but the researcher was masked for allocation of the children to the groups and statistical analysis. The flaws of the current study are that participants were selected from a single setting and the record was not kept for those who refused to participate.

**Conclusion:**

The current study demonstrated a considerable advantage of virtual reality and cold vibration intervention to strangle the phlebotomy related pain and pulse rate among the children. Moreover, no significant post-intervention complications (inflammation) were reported by the children, parents or by caregivers indicating these applications are safe to implement during routine clinical practice with low resource investment. Hence, we advocate that health care providers might consider the use of cold vibration and virtual reality device during phlebotomy of children.

**Acknowledgement:**

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**Conflict of Interest:**

The author declares no conflict of interest

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References:


33. Das DA, Grimmer KA, Sparnon AL, McRae SE, Thomas BH. The efficacy of playing


