Effectiveness of Local Cold Application on Pain among Infants Receiving Immunization in a Selected Immunization Center, Rajbiraj, Nepal

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ABSTRACT

Background: Vaccination is the safest and most effective way to prevent serious illness and death. Vaccine injections are the most common reason for iatrogenic pain which lead to long term psychologically detrimental effects. As a result, it is the health care provider’s responsibility to take measures which are most efficient, timely and effective to reduce vaccination pain.

Methods: A quasi-experimental (post-test only control) design with non-probability purposive sampling with sample size 160 was conducted in Immunization Center in Rajbiraj, Nepal. Ice cube wrapped with gauze was applied on the injection site for 30 seconds before the administration of injection followed by administration of vaccines. FLACC scale was used to assess the pain.

Results: The study shows that local cold application is effective on reducing the pain (p<0.005).

Conclusion: The local cold application can be used as an effective technique on to reduce pain during IM injection among infants receiving immunization. It is a simple effective independent nursing intervention to enhance children comfort and safety with minimal or no risk to children.

Keywords: Pain, cold application, Immunization, IM injection

INTRODUCTION

Children of today are the citizen of tomorrow. World population continues to grow, but the number of children in the world has now reached its peak. According to the United Nation’s population division estimate for the mid 2010, there were 642 million children aged 0-4 years.¹

Pain is unpleasant sensation and subjective experience. Pain is a complex phenomenon whose nature is at least elusive in neonate and it is an integral management to adults but inadequately provided to neonate.² The International Association for the study of pain’s widely used definition states: “Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” The relief of pain or distress during health-related procedures is a basic human right.³ An individual’s reaction to painful stimuli is influenced by their perception of pain and demographic variables such as age, gender, weight of infants and presence of mother.

Non-pharmacological measures was chosen as the primary intervention because it provides a simple approach in reducing pain that has been shown to be effective in a number of settings, it requires little training, and has a number of theoretical sound reasons for why it should work.⁴

NEED OF THE STUDY

Children are building block of nation. This means they can do something in future. It is significant to be healthy from the beginning of life. To prevent from certain communicable diseases, it is necessary to administer vaccine. During
vaccine period, children feel pain and can’t express verbally. Pain is common in children. Pain is the most important single cause leading to temper tantrums and untoward behavioral changes in children. Everyone has right to get relief from pain. It is only possible either from pharmacological or non-pharmacological measures. Though there are various literature supporting the relief of pain by cold application, but it is not practiced in the clinical and community setting among children receiving immunization. As a health personal care provider (nurses), we can apply local ice application prior to injection to infants.

Cold application aims to reduce inflammation, decrease spasm and pain and stimulate blood vessel constriction (vasoconstriction), so it can increase the survival of cells. It is currently debated whether applying ice at the injection site is effective in decreasing pain intensity and hematoma. Cold prevents the intensity of pain through its effect on sensory nociceptors by decreasing the conduction time and the synaptic activity in peripheral nerves. When heat in the nerves is reduced, a decrease in the sensory and motor conduction velocities is observed; thus, the intensity of pain is prevented.

To determine whether the pain is reduce or not, special measuring scale called modified FLACC Pain Scale can be used.

After an extensive review, the investigator found the pain was one of the most intense and under treated problem in infants receiving immunization. The investigator during her personal experience found that there was not standard routine to assess the pain and no intervention to manage to this problem among infants receiving immunization. So, researcher decided to conduct study on cold application to reduce pain.

**METHODOLOGY**

**Objective of the study:**
- To compare the pain during IM injection between study and control group.
- To find the association between level of pain with the selected demographic variables among infants in study and control group.

**Study Method:** Quasi-experimental (post-test only control) study

**Sampling technique:** Non-Probability purposive sampling technique

**Sample Size:** 160

**Study population:** Infants who come in immunization center for IM injection.

**Inclusion Criteria:**
- Infants undergoing IM injection
- Infants those parents and caregivers were participated

**Exclusion criteria**
- Infants who received any other injection
- Preterm
- Infants with neurological and development delay
- Infants who were healthy

**Ethical Permission:** Ethical approval was obtained from Nepal Health Research Council (NHRC). Informed assent was taken from parents’ of infants by explaining the purpose of the study.

**Study tool:** The study tool consists of two sections:

**Section A**

i) Baseline Performa of infants: Socio demographic data: age, gender, weight of child, presence of mother.

**Section B**

FLACC SCALE: The Face, Legs, Activity, Cry, Consolability or FLACC pain scale is a standard measurement used to assess pain for children between the ages of 2 months-7years.

**Pilot testing**

It was conducted to test the feasibility of the standard tool to the local settings.

**Data Processing:** Based on the inclusion and exclusion criteria the subjects were selected. Purpose of the study was explained to the parents’ of infant and informed assent was taken. An ice cube of size 2*3cm was prepared in refrigerator of immunization center. Prior to injection, ice pack was wrapped with double layer gauze, then placed for 30 seconds, rest for 60 seconds.
and again applied for. Within 2-3 second session minutes of removal of cold application, the IM injection was administered by staff nurse and for the subjects in control group, the IM injection was given using standard technique without any intervention. Separate ice packs used for each subjects. The response to pain during IM injection for subjects in both the group was assessed using FLACC Pain Scale. Pain level was observed for 1 minute.

RESULTS

Table 1: Socio-demographic profile of subjects, n=160

<table>
<thead>
<tr>
<th>Socio-demographic variables</th>
<th>Study group f (%)</th>
<th>Control group f (%)</th>
<th>Chi-square (p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (in month)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-4</td>
<td>60(75)</td>
<td>58(72.5)</td>
<td>0.72 (0.42)</td>
</tr>
<tr>
<td>5-7</td>
<td>20(25)</td>
<td>22(27.5)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>35(43.75)</td>
<td>40(50)</td>
<td>0.42 (0.26)</td>
</tr>
<tr>
<td>Female</td>
<td>45(56.25)</td>
<td>40(50)</td>
<td></td>
</tr>
<tr>
<td>Weight of children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4-6</td>
<td>53(66.25)</td>
<td>47(58.75)</td>
<td>0.25 (0.16)</td>
</tr>
<tr>
<td>7-9</td>
<td>27(33.75)</td>
<td>33(41.25)</td>
<td></td>
</tr>
<tr>
<td>Presence of mother</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>80(100)</td>
<td>80(100)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 1 depicts that 75% of subjects of study group and 72.5 % of subjects of control group are of age 2-4 months. 56.6% of subjects of study group and 50% of control group are female. 66.25% of study group and 58.75% of infant of control group are among 4-6kg. All the subjects (100%) in both the group are accompanied by mother. The homogeneity in the study and control group is statistically tested and it is found that both groups are comparable.

Table 2: Comparison of pain score among study and control groups, n=160

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pain score</th>
<th>z-test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study group</td>
<td>Range: 3-10 Mean (SD): 5.6(0.52)</td>
<td>1.959</td>
<td>0.05</td>
</tr>
<tr>
<td>Control group</td>
<td>Range: 3-10 Mean (SD): 7.6(0.52)</td>
<td>-1.96</td>
<td>0.05</td>
</tr>
</tbody>
</table>

Table 2 shows the mean pain score of study group is 5.587 whereas for control group is 7.625. The obtained z test value is 1.959, which is statistically significant at p<0.005. Local cold application is effective on reducing the pain.

The table 3 shows that there is no significant association between pain level and selected baseline variables.

DISCUSSION

In the present study, 160 children were studied those who were immunized. The study was conducted in Shahari Swasthya Kendra of Rajbiraj, Nepal, where 16 wards children come here for immunization. The investigator studied the baseline variables of the subjects on the presumption that may have a bearing pain. The present study comprises age, gender, weight of child and presence of mother as a demographic variable.

The vaccines provided to infants comprised BCG: as soon to birth to 12 months; polio, FIPV, PCV, DPT, Hep B, hib: at 6 weeks; polio, PCV, DPT., Hep B, hib: at 10 weeks; polio, FIPV, DPT, Hep B, hib: at 14 weeks; PCV, Measles- rubella: 9 months; Japanese encephalitis: 12 months.

Demographic details of the present study subjects revealed that 75% and 72% infants were of age 2-4 months and 25% and 27.5% infants were of age 5-7 months in study and control group respectively. This can be explained that the most of the vaccine were given to 2-4 months of infants. 43.75% and 50% of male and 56.25% and 50% of female were in study and control group respectively. 66.25% and...
58.75% of 4-6 kg and 33.75% and 41.25% of 7-9 kg were in study and control group. All the mothers were present during immunization.

The present study depicted that the mean score of children in the control group (7.625) was greater than that of the study group (5.587). The statistically significant difference was tested with ‘z’ test and the table value was -1.96 which was significant at P<0.05 level. The study findings revealed that the effectiveness of local cold application in reducing injection pain among infants. In the present study, local cold application was given as a cutaneous stimulation during immunization among infants.

It was suggested that cutaneous stimulation at the injection site would reduce the pain associated with immunization. This activity is based on the Gate - control theory of pain, which explains that physical interventions such as massage, stroking, rubbing, stimulation of the tissue are theorized to travel through the faster A beta fibers and interfere with the other ascending pain signal, which is transmitted on the slower A-delta fibers, which reduces the intensity of a painful stimulus in the same area.

This finding was supported by similar studies which show relaxation of muscle by stroking the skin close to injection site, application of local cold was effective in reducing the pain during IM injection.

The application of cold at repeated intervals leads to an analgesic effect on the parts of the body treated.

The finding was supported by a similar study conducted in Toronto, Canada revealed that 78% of the subject demonstrated less pain with local cold packs to the skin during intramuscular injection than usual standard technique (p<0.001).11

Another similar study conducted in Mangalore, India revealed that 60% (p<0.05) of the toddler in experimental group had experienced mild pain perception after ice application where as 93.3% experienced severe pain in control group.10

Similar to the present study, conducted in Andhra Pradesh, a study revealed that that 80% (p<0.05) of the children in the experimental group had mild pain after ice application and 93% of subjects in the control group had severe pain.12

It has been demonstrated that nerve conduction decreases constantly with a decrease in temperature until conduction within the nerve fibers ceases completely. The myelinated fibers are the first ones to be affected. This slowing of the conductivity of the peripheral nerve fibers is found when the temperature drops to below 80.6 F.

Other mechanisms are also involved: cold has a specific ‘anti-irritant’ function that protects from pain stimulus.

Cold can also remove the causes of pain by reducing muscle spasm of the traumatized area, thus reducing the effects of ischemia secondary to the trauma.

The similar study conducted in Maharashtra, India revealed that the mean pain score of experimental group was 0.66 after local cold application and control group was 8.93. The unpaired t test value was 24.817 (p<0.01), showing significant difference between mean pain score level among children in control and experimental group as p value < 0.05.13

The present study revealed that there was no statistically significant association between age and pain level but the mean scores of age of 5-7 months infants (6.23) was less as compared to age of 2-4 months (6.73), this concluded as age level increases, pain level decreases. It was clinically found that children with greater age experience less pain as diversational therapies can be used for them like distractors, music therapy, massage, breastfeeding etc.

The similar study was conducted in Mangalore found there was no statistical significant association between level of pain and selected demographic variables (age, gender and care provider) of experimental
and control group at p<0.05 level of significance.10

Likewise similar study was conducted in Maharashtra, India where 60 children aged 6-12 years were selected to assess the effectiveness of ice application on pain response prior to intravenous procedures among children at tertiary care hospital where there was no statistical significant between pain score and selected demographic variables (religion, residence, family type, previous experience with cold application) of children in control group where as there was significant association of pain scores with age of children ($X^2$=8.816), gender of children ($X^2$=5), and weight of children ($X^2$=4.909) in experimental group.13

The present study revealed that there was no statistically significant association between gender and pain level but the mean scores of female (6.50) was less as compared to male (6.72), it is concluded that female scored less pain as compared to male, as it is believed that females have more pain tolerance threshold. Current human findings regarding gender differences in experimental pain indicate greater pain sensitivity among females compared with males for most pain modalities, including more recently implemented clinically relevant pain models such as temporal summation of pain and intramuscular injection of algesic substances.

The present study depicted that there was no statistically significant association between weight of child and pain level but the mean scores of weight 7-9kg (6.44) was less as compared to weight 4-6kg (6.70) and it is proved that body mass differ to pain level . Increased body mass is inversely proportion with pain. Infant felt less pain as they have more body mass. More weight infant experience less pain as compared to low weight.

CONCLUSION

There is some expectation from children in future. Children experience pain during immunization. As a health care personal, we have to concern to apply non-pharmacological intervention to relief it. The aim of this study was to assess the effectiveness of local cold application on pain during IM injection among immunization children. The study was conducted in the Sahari Swasthya Kendra, Rajbiraj, Nepal on 160 children. The study also concluded that local cold application was effective in reducing pain during IM injections.

Strength of study

This study depicts importance of non-pharmacologic measure (local cold application) could be used to relief pain among children receiving immunization. The implication of this study is pivotal to nursing practice, administration, nursing research, and nursing education. Cold application can be used to relieve pain as it is simple, safe, easy, effective and cheap independent nursing intervention that relieve pain of immunized children with minimal or no risk to maintain children safety and comfort. Ice can be kept in immunization center so that either the nurse or parents can apply before injection to reduce pain.

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Analysis and Interpretation: Collected data were analyzed by using descriptive and inferential statistics which is presented in the form of tables.

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Declaration of interest statement: This is not an industry-supported study. None of the authors have potential conflicts of interest to be disclosed. All authors have seen and approved the manuscript.

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