Abstract: This study has been undertaken to examine the effect of breast feeding on immunization pain among infants within six months of age in a selected immunization clinic of West Bengal. Post test only control group design was adopted. Forty healthy infants returning to the immunization clinic for their second dose of injection DPT vaccine and above, were selected using purposive sampling technique. Then they were divided into experimental group and control group. Breast feeding was started two minutes before, during, and after administration of vaccine (DPT second dose) in experimental group. The control group was administered the vaccine without breast feeding. Unstructured interview schedule was used to collect background data. Pain responses of infants (immediately after and two minutes after) were assessed by using Modified Riley Infant Pain Assessment Scale in terms of intensity of pain and duration of crying. Result showed that mean immunization pain scores were statistically significant as evidenced by calculated ‘t’ value (t=6.22 and 7.26, immediately after and two minutes after administration of vaccine). The crying time was significantly shorter in the experimental group (mean = 43.55 seconds,) than in the control group (mean = 95.95 seconds, ‘t’=5.25). There was no relationship (p ˃0.05) between Immunization pain score and time of last feeding before starting treatment as evidenced by calculated ‘r’ value (0.55 and 0.59, in experimental group and control group, respectively).

Perception of pain among infants had serious consequences in future. So, nursing personnel of sub centre and immunization clinic of hospitals might practice application of providing breastfeeding during administration of vaccine among infants to reduce immunization pain and protocol could be established in pediatric ward in reducing procedural pain regularly.

Index Terms – Breast feeding, Immunization pain, Immunization clinic, Infant

I. INTRODUCTION

Newborn and infants often experience many painful procedures such as immunization, venepuncture, intramuscular injections, heel lancing, etc.\(^1\) Today, one of the most prevalent procedures in infants is vaccination during first year of life.\(^2\) Routine immunization injections are the common painful procedures in childhood.\(^3\) When routine procedures such as intramuscular injections and vaccinations are performed on infants, it is assumed that such procedures cause a certain degree of pain.\(^4\)

Infant injection related pain remains to be largely untreated. Untreated pain has immediate and measurable negative effects, most notable of which are child distress and parents distress.\(^3\) Preliminary data suggests that untreated pain in early life may also cause deleterious effects on the developing central nervous system. Various simple methods have shown to effectively reduce the pain response of newborn undergoing routine procedure.\(^6\)

Considering the short-term and long-term negative effects of uncontrolled pain and undeniable necessity of vaccination, an effective and secure pain controlling method seems necessary.\(^7\) Non pharmacological methods include breastfeeding,\(^7,8\) sweet solutions (oral sucrose, glucose), pacifier and skin-to-skin contact. In addition, various tastes and flavors of milk produce analgesic as well as milk protein and fat can reduce crying, grimacing, heart rate, and other physiologic pain index in premature and full-term infants.\(^8\)

Recent studies have demonstrated that certain tastes and flavors alleviate newborn pain. As little as 2 ml of milk, with its fat and protein components\(^8\) and sweet substances, reduces pain in infants and eliminates spontaneous crying.\(^10\) Although the infliction of pain during vaccination cannot be eliminated, nurses must seek ways to provide optimal comfort and security for patients during such procedures and should use methods that inflict the least amount of pain possible.\(^4\)

Immunization pain during vaccination is a common event in any immunization clinic. No similar study had been conducted in the past among the rural community of West Bengal. Breastfeeding is an effective analgesic, easily implemented and safe intervention against pain sensation in the newborn infants.\(^1\) So, the aim of this study is to assess the effect of breastfeeding on immunization pain among infants.
II. METHODOLOGY

Institutional Ethical committee permission was sought. Administrative permission was taken from Block medical officer of health. Anonymity and confidentiality were maintained. Informed consent was obtained from each mother of newborn participated in this study.

The objectives of the study were

1. To assess the immunization pain of infants in experimental and control group.
2. To compare the immunization pain between the experimental and control group.
3. To find out the relationship between intensity of Immunization pain of participants and time of last feeding before starting procedure.

Hypothesis of the study were

- H1 - After providing breast feeding intensity of immunization pain in experimental group is different from intensity of immunization pain in control group at 0.05 level of significance.
- H2 – After providing breastfeeding mean duration of crying in experimental group is different from the mean duration of crying in control group at 0.05 level of significance.
- H3 – There is a relationship between intensity of immunization pain and time of last feeding before starting procedure at 0.05 level of significance.

Research Design: Quasi experimental research approach with time series post test control group design was adopted. Design is presented in Figure 1

Sample and sampling technique: In the present study a total of 40 infants were chosen as the sample by purposive sampling technique. Selection of experimental and control group was done by voluntary method. Randomized assignment in the groups was not followed due to ethical consideration. The mother who fed breast to their baby during last time immunization and willing to provide breast feeding during present immunization time, assigned to Experimental group. 20 infants were assigned to experimental group and 20 infants were assigned to control group by voluntary method. The following criteria were set for the selection of sample:

- The infants who came to the immunization clinic with their mother
- The infants who were breastfed
- The infants who were given injection DPT second dose
- The infants whose mothers agreed to participate in the experimental and control group

Theoretical Framework: The present study is based on Gate Control Theory (in 1965, by Ronald Meljack & Patrick Wall). The normal sensation of pain entering through the skin reaches the spinal cord by sensory nerve and then to the brain and pain sensation is perceived.

Gate Control Theory explains that ‘the substantia gelatinosa’, a functional unit of densely packed cells, which extends the length of spinal cord, is the site of transmission blocking action. It closes the gate to some impulses entering the spinal cord on their way so the pain impulses do not enter into the brain.

This potential blocking mechanism can result in little or no perception regardless of the intensity of the painful stimuli, and can be activated through touch stimuli of skin, distraction and the pleasure sensation of the infant.

In the present study breast feeding closes the gate by the action of holding, skin-to-skin contact, touch and pleasure sensation to the infants. Therefore it prevents the transmission of pain to the brain during administration of vaccine. Schematic presentation of Theoretical Framework is given in Figure 2
Data collection tools and techniques: Interview schedule on background information of infant was used to collect background sociodemographic data and, Modified Riley Infant Pain Assessment Scale was used to collect information related to intensity of immunization pain and duration of crying of infants. While reviewing literature different pain assessment scales i.e. Baker Wong’s, Facial Pain Scale, Neonatal Infant Pain Scale and Riley Infant Pain assessment tool were noticed. Among them Riley infant pain assessment scale was chosen and this tool was modified by subtracting two criteria i.e sleeping and response to movement/touch and adding one item i.e. duration of crying with this tool. Tools were tested for face validity & content validity by five experts. Content validity index (CVI) was 1.0 for interview schedule and CVI of modified Riley infant pain assessment scale was 0.96. modified Riley infant pain assessment scale had two components i.e., Part A - intensity of pain and Part B - Duration of crying.

In addition, Concurrent validity of Part A - intensity of pain was established by administering the Modified Riley Infant Pain Assessment Scale simultaneously with Riley Infant Pain Assessment tool among ten infants when they were receiving injection DPT vaccine in the immunization clinic & comparing the result of two mean pain scores measured by these two pain scales by two observers. One observer was the experimenter & another observer was one trained person who was given prior training for observation on Modified Riley Infant Pain Assessment Scale. The mean pain score which was measured by the above mentioned pain scales was calculated. To test the significant difference between two means ‘t’ was calculated. The calculated value of ‘t’ = 0.27) showed non significant mean difference. So Part –A of Modified Riley Infant Pain Assessment Scale was valid.

Similarly the concurrent validity of duration of crying was established by recording the duration of crying by stop watch and by Video recording by two observers simultaneously, To test the significant difference between two means, ‘t’ had been calculated. The calculated value of ‘t’ = 0.24) showed non significant mean difference. So Part-B of Modified Riley Infant Pain Assessment Scale was valid.

Reliability was established by interrater method and percentage of agreement was obtained by two observers for interview schedule. Reliability of pain assessment scale was tested by interrater method (test of Equivalence). Pearson co-relation co-efficient r was calculated and it was 0.89 and 0.9 for Part A - intensity of pain and Part B - Duration of crying respectively. So valid tools were reliable for the purpose of the study.

Description of the pain assessment scale: Modified Riley Infant Pain Assessment Scale consisted two parts, Part – A comprised of intensity of pain & Part – B comprised of duration of crying. Intensity of pain comprised of 4 parameters like vocal, facial, consoladility & body movement. Each parameter had four findings scoring from 0 – 3. The scores of the 4 categories of items was added together for the total score. The maximum score was 12 & minimum score was 0. A score 0-1 indicated no pain, 2 – 4 indicated low pain, 5 – 8 indicated moderate pain & 9 – 12 indicate severe pain.

Description of treatment Protocol (Breastfeeding): It consisted of steps of protocol of breastfeeding. It was composed of four steps like position of mother, technique of holding the infant, way of sucking of breast by the infant and duration of breast feeding. All these steps were constructed to provide a comfortable position for breast feeding. The steps were

- Mother was seated on a comfortable chair with their infants in one side of the clinic
- Infant was supported by the mother’s forearm in slight head elevated position and with head, neck & back in straight line
- Mother’s breast was open, baby’s chin touched the breast, cheek touched the nipple and baby opened mouth so that nipple & most of the areola went into the mouth.

Breast feeding was started two minutes before the administration of vaccine and it was continued during and after the procedure.
IV. RESULTS AND DISCUSSION

Table 1
Distribution of participants according to their age and sex in experimental and control Group

<table>
<thead>
<tr>
<th></th>
<th>Experimental group ( n= 20)</th>
<th>Control group ( n = 20 )</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>Percentage</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 75 - 89 days</td>
<td>6</td>
<td>30</td>
</tr>
<tr>
<td>• 90-120 days</td>
<td>14</td>
<td>70</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Male</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>• female</td>
<td>10</td>
<td>50</td>
</tr>
</tbody>
</table>

The data presented in table 1 shows that majority of participants (90% in control group & 70% in experimental group) were in the age group of 90-120 days. The data also reveals that 60% of participants were male in the control group whereas in the experimental group numbers of male and female participants were equal.

Figure: 3 Distribution of participants according to time of last feeding before starting procedure.

Table 2
Mean, SD, Mean difference, SE, and ‘t’ value of Immunization pain of participants between experimental and control group

<table>
<thead>
<tr>
<th>Immunization pain</th>
<th>Experimental group</th>
<th>Control Group</th>
<th>Mean</th>
<th>SD</th>
<th>Mean</th>
<th>SD</th>
<th>Mean difference</th>
<th>$SE_M$</th>
<th>$t$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intensity of pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately after administration of vaccine</td>
<td>5.6</td>
<td>1.75</td>
<td>9.15</td>
<td>1.89</td>
<td>3.55</td>
<td>0.57</td>
<td>6.22**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Two minutes after administration of vaccine</td>
<td>0.9</td>
<td>1.48</td>
<td>6.35</td>
<td>3.03</td>
<td>5.45</td>
<td>0.75</td>
<td>7.26**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of crying</td>
<td>43.55</td>
<td>33.61</td>
<td>95.95</td>
<td>29.36</td>
<td>52.4</td>
<td>9.97</td>
<td>5.25**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* $t$ (38) =2.03 , $P < 0.05$

Data presented in Figure 3 reveals that the maximum number of participants were fed 30 minutes before starting procedure (immunization) both in experimental group and in control group.

The data presented in table 2 reveals that in the first observation the mean immunization pain score (5.6) of experimental group was significantly lower than the mean immunization pain score (9.15) in control group with a mean difference 3.55. The obtained difference between the Immunization pain scores of experimental and control group was found to be statistically significant as evident from ‘t’ value of 6.22 at df 38 at 0.05 level of significance. It was also significant in 0.01 level.
The data presented in the table further reveals that in the second observation the mean immunization pain score (0.9) of experimental group is lower than the mean immunization pain score (6.35) of control group with a mean difference 5.45. The obtained difference between the Immunization pain scores of experimental and control group was found to be statistically significant ($t\,(38) = 7.26; \ p < 0.05$). It was also significant in 0.01 level. Therefore, the obtained mean difference between Immunization pain scores was a true difference and not by chance. Hence null hypothesis $H_0$ had been rejected and research hypothesis $H_1$ had been accepted.

The data presented in the table further reveals that the mean duration of crying (43.55) of experimental group is shorter than the mean duration of crying (95.95) of control group with mean difference 52.4. The obtained difference between the duration of crying of experimental and control group was found to be statistically significant ($t\,(38) = 5.25; \ p < 0.05$). It was also significant in 0.01 level. Therefore, the obtained mean difference between duration of crying of experimental and control group was a true difference and not by chance.

<table>
<thead>
<tr>
<th>Percentage of Infant</th>
<th>No Pain</th>
<th>Low Pain</th>
<th>Moderate Pain</th>
<th>Severe Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Experimental Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately after administration of vaccine, Pain score</td>
<td>60%</td>
<td>30%</td>
<td>10%</td>
<td>0%</td>
</tr>
<tr>
<td>Control Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 minutes after administration of vaccine, Pain score</td>
<td>65%</td>
<td>30%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Figure 4: Distribution of the participants in terms of Intensity of immunization pain in experimental and control group.

Data presented in figure 4 highlights that immediately after administration of vaccine maximum infants of experimental group perceived moderate pain (60%) as compared to 65% of infants who perceived severe pain in control group. Data further revealed that two minutes after administration of vaccine 40% of infants in control group perceived moderate pain and rest of infants (30%) perceived severe pain but there was no infants in experimental group with moderate and severe pain score.

Table 3

<table>
<thead>
<tr>
<th>Relationship between immunization pain of participants and time of last feeding before starting procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>N = 40</td>
</tr>
<tr>
<td>pain score</td>
</tr>
<tr>
<td>Experimental group</td>
</tr>
<tr>
<td>Control group</td>
</tr>
</tbody>
</table>

The data presented in table 3 shows the relationship between intensity of immunization pain of participants and time of last feeding before starting procedure. Intensity of Immunization of pain is not significantly related with time and last feeding before starting procedure in experiment group as well as control group; so feeding was not influencing the immunization pain rather reducing of pain was related to breast feeding.

Discussion

The findings of this study reveal that there is a significant difference between intensity of immunization pain of experimental and control group ($t = 6.22$ immediately after administration of vaccine), which was supported by another study carried by Thomas, Shetty, Bagall1, who also reported a significant difference between pain score of experimental group and control group ($t = 5.307$) immediately after administration of vaccine. The finding of the present study were in accordance with the findings of Efe and Savasar study in which crying time was shorter in breast feeding group in comparison with the control group.
The duration of crying of the present study was shorter in experimental group (\( M = 43.55 \text{ secs} \)) than in the control group (\( M= 95.95 \text{ sec.} \)). These findings were in accordance with the findings of Efe and Zeynep study\(^{11}\) in which crying time was shorter in breast feeding group (\( M = 35.85 \text{ sec.} \)) in comparison with the control group (76.24 sec.).

**Conclusion:**

Providing breastfeeding during immunization is significantly effective in reduction of intensity of Immunization pain and duration of crying as measured by Modified Riley infant pain assessment scale. Breastfeeding and the component parts of taste, suckling, and contact are associated with significant reduction of intensity of pain and crying time in young infants during immunization injection. There is no cost for breastfeeding. Thus, it is concluded that breastfeeding can be easily and widely incorporated into the practice of standard infant injection in the paediatric ward, in the immunization clinic and other settings for reduction of pain due to administration of injection among infants.

**References :**