Physiological Analgesia for BCG vaccination induced pain in Neonates

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Abstract: BACKGROUND Blood sampling, intravenous catheterization and vaccination are some of the common painful procedures in newborn. Pain may contribute to immediate hemodynamic fluctuations as well as late significant behavioral changes. Physiological measures (such as holding, swaddling, breastfeeding) and pharmacological measures (such as acetaminophen, sucrose and opioids) have been used to alleviate pain in newborn.

OBJECTIVES To assess the BCG vaccination induced pain response in healthy term neonates. To identify the least painful period in relation to the time of breast feeding.

METHODOLOGY This cross sectional study was performed at Coimbatore Medical College Hospital for 3 months. Term healthy, exclusive breastfed neonates receiving BCG vaccine were included. Neonates with any illness and on analgesic or sedative drugs prior to vaccination were excluded. Vaccine was administered by trained nurses and an observer performed Neonatal Infant Pain Scale (NIPS) scoring without the knowledge of feeding schedule. NIPS is a validated score for assessing the pain response. Scores range from 0 to 7 and scores above 4 indicates moderate to severe pain.

RESULTS A total of 113 neonates were assessed for pain. NIPS scores were significantly less in the time period between 30 to 60 minutes after breast feeding (P value -0.001). In general, alert status did not significantly influence pain but sleeping neonates scored less during the time between 30 to 60 minutes from breast feeding (P value-0.002). In hungry neonates and immediately after fed state scores were high.

CONCLUSION Less painful period is between 30 to 60 minutes from breast feeding. All elective procedures may be performed in this period however this results needs to be confirmed in different settings and procedures.

Keyword: pain response, neonates, vaccination, breastfeeding

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Introduction:

Pain is an “unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such “IASP”. Blood sampling, intravenous catheterization and vaccination are some of the common painful procedures in newborn. In the past there was a common belief that newborn babies do not have the pain sensation because of their immature nervous system. However today it has been proved that myelination of sensory system is complete weeks before birth. In fact the newborns are hypersensitive to pain as the Descending pain modulation system is not well developed in them. Pain may contribute to immediate hemodynamic fluctuations as well as late significant behavioral changes in the newborn. The long term effects of pain include neurodevelopment sequeales and altered pain behaviors. Grunau and Gaig have found that the first cry associated with pain is the sensitive indicator of noxious stimuli. Studies have shown that physiological measures such as holding, swaddling, breastfeeding and pharmacological measures such as acetaminophen, sucrose and opioids can be used to alleviate pain in newborn.

Among these measures the breast milk is the natural and purest form available for the babies. There is increasing evidence that breast milk can cause good analgesic effect. Breast milk is the most acceptable and simple method of inducing analgesia for minor procedures such as vaccination, venepuncture and heel prick.

Objectives:

To assess the BCG vaccination induced pain response in healthy term neonates.

To identify the least painful period in relation to the time of breast feeding.

Materials and Methodology

This cross sectional study was performed at Hospital for 3 months (January-march 2012). Term healthy, exclusive breastfed neonates receiving BCG vaccine were included. Neonates with any medical illness and on analgesic or sedative drugs prior to vaccination were excluded. Institution ethics committee approved the study. Study participants enrolled after obtaining informed written consent from the caregivers.

Data collected were demographic factors, time of breast feeding, and pain response using Neonatal Infant Pain Scale (NIPS) Scoring. The Neonatal Infant Pain Scale (NIPS) is a behavioral scale and can be used for both full-term and pre-term infants. It is composed of six (6) indicators.

- Facial expression
- Cry
- Breathing patterns
- Arms
- Legs
- State of arousal

Each behavioral indicator is scored with 0 or 1 except "cry", which has three possible descriptors therefore, being scored with 0, 1 or 2. Infants were observed at one minute and 5 minutes after injection.

Total pain scores range from 0-7. Pain Level 0-2 = mild to no pain 3-4 = mild to moderate pain >4 = severe pain administered intradermaly at left arm by trained nurses.
an observer performed NIPS scoring without the knowledge of feeding schedule. The study group were divided into three groups based on their time since breastfeeding: Group I - less than 30 min from last breastfeeding, Group II - between 30 to 60 minutes from breastfeeding, Group III - after 60 minutes from breastfeeding.

Chi square test and student t test were used for analysis.

**Results:**

A total of 113 neonates were included in the study. The postnatal age, sex ratio, APGAR score, time since last feed, and birth weight were comparable in all three groups (figure 1). Figure 1- demographic characteristics of study population NIPS scores at one minute among the groups, group I mean -4.73 (SD- 1.04), group II mean- 3.12 (SD- 0.82) and group III mean - 5.41 (SD-1.12). These values were statistically significant (p-0.001). Values were depicted in figure 2 with 25th and 75th percentiles and median (FIGURE 2).

Figure 2 NIPS Score with median and percentiles NIPS scores after five minutes of procedure among the groups, group I mean- 0.88 (SD- 1.64), group II mean- 0.70 (SD- 1.02) and group III mean - 0.91 (SD-1.42). These values also were statistically significant (p-0.001). From these values it is evident that newborn babies pain behavioral response were significantly less in group II (between 30 to 60 minutes from breastfeeding) when compared to other groups. In general, alert status did not significantly influence pain behavioral response among three groups. The sleeping neonates in group II scored significantly less as compared to other two groups sleeping newborns (P value-0.002)(FIGURE 3 & 4).
Figure 3-NIPS Score in sleeping newborns
Figure 4- NIPS Score in alert newborns In hungry neonates and immediately after fed state NIPS scores were high. The mean crying time was 14 seconds in group 1, 8 seconds in group II and 17 seconds in group III. (P=.0001). No gender differences were found.

Discussion:
The study was done to find the least painful period following breastfeeding for painful procedures in neonates. It was found that NIPS pain scoring was least in study group II who were between 30 to 60 min after breastfeeding. Several physiological measures such as holding, swaddling, breastfeeding and pharmacological measures such as acetaminophen, sucrose and opioids have been used to alleviate pain in newborns caused by minor procedures. Breastfeeding was associated with reduction in changes in the heart rate, duration of crying and percentage time crying when compared to placebo/no intervention/positioning in neonates. The results of Gray et al (2002) showed that breastfeeding effectively caused a reduction in pain intensity and it also prevented the increase in heart rate following the procedure. The findings of Gray’s study were in accordance with this study in terms of effectiveness of breastfeeding as analgesic and reducing the crying time. In 1997, Blass published a study which aimed to determine whether breastmilk and its components could reduce the duration of cry in newborn during and after taking of blood samples for determination of phenylketonuria in neonates. Efe and Ozer found that breastfeeding was an effective way of relieving pain during neonatal immunization, and Efe and Savaser found no difference in the analgesic effect of breastfeeding and administration of sucrose during venipuncture. Furthermore, the analgesic effect of non-nutritive sucking along with cuddling can be used as a consoling measure. The Cochrane review conducted recently have shown that breast milk or breast feeding during procedures was effective in reducing pain in neonates than placebo, holding position or no measures taken. Finally, the findings of this study showed that breastfeeding caused reduction in pain and crying time in neonates immediately after the vaccine injection. According to the findings of this study and considering the fact that breastfeeding is a safe and free method accepted by mothers and health professionals, the timing of the elective minor procedures in the newborn nursery may be done between 30 to 60 minutes after breast feeding.

Conclusion
Our study suggests that the least painful period is between 30 to 60 minutes after breast feeding, especially if the neonate is sleeping. All elective minor procedures may be performed during this period; however this results needs to be confirmed in different settings and procedures with robust number and methodology.
References:


