Breast Milk for Neonatal Vaccination Pain

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Abstract

A prospective, double blinded (care giver, researcher) randomised experimental study was conducted at the postnatal ward of a tertiary care hospital at Puducherry to identify the effect of twin intervention on pain among neonates receiving Bacillus Calmetteguaorine (BCG) vaccine. The outcome variable of pain level was assessed by using the Neonatal and infant pain Scale (NIPS) in terms of behavioural changes in behaviour and haemodynamic behaviour and variables like respiratory rate (RR), heart rate (HR), oxygen saturation (SpO_2). One hundred and forty-five neonates fulfilling the inclusion criteria were randomly recruited into the study after informed parental consent. One ml of expressed breast milk (EBM) was given to the neonates by sterile syringe 2 min before BCG vaccination and the newborn kept in facilitated tucking position (FT) during vaccination procedure. The behavioural changes of neonates, duration of cry time and selected physiological parameters were recorded before BCG vaccination and after at 0, 3 and 5 min. It was found that the twin Intervention was effective in reducing the level of pain. The mean pain level for EBM group was 3.089 and for control study group it was 3.6. The median crying time was 53.511seconds in EBM at $p<0.001$ which is less when compared with the control group. To conclude, the "twin intervention" (FT& EBM) significantly reduces pain in neonates while they receive BCG vaccination.

Every client has a right to have his or her pain to be assessed and treated. It is an ethical as well as humanitarian obligation towards our most vulnerable population. Pain is the fifth vital sign. Identification of presence of pain among neonates is difficult as they cannot express verbally. Pain assessment is the first step towards relieving pain effectively in neonates. The nurses are the ones who identify the pain and alleviate it.

Some interventional procedures produce pain in neonates causing anxiety, stress and also short- or long-term adverse effects in neonates. These procedures are necessary to lead a healthy life and it is done without forgetting that they cause pain. Vaccination produces intentional pain in children which brings down the mortality and child morbidity rate of the nation.

Vaccination is the one of the painful procedure given to neonates in the developing countries like India. Most women (90%) breastfeed their neonates in India. Despite such advantage unfortunately health care centres do not use breast milk as a non-pharmacological intervention for pain relief for immunisations or other practices.

Breastfeeding is a developmentally superior alternative to oral sucrose, glucose or any other analgesics for mild to moderate level of pain in infants as it is naturally available at any time and is rich in its nutritive value and also free from microorganism. Compared to artificial formulas, breast milk contains a higher concentration of tryptophan, a precursor of melatonin. Melatonin is shown to increase the concentration of beta endorphins and could possibly be one of the mechanisms for the nociceptive effects of breast milk. Use of breast milk as an analgesic has additional benefits such as promotion of breast-feeding, also bonding the mother and the child, and eventually improving breast-feeding rates without additional cost to the health care system. So administering analgesics to neonates should be the last option to in newborns if it is undergoing any painful procedure which causes mild to moderate pain. Despite such advantage unfortunately health care centres do not use breast milk as a non-pharmacological intervention for pain relief for immunisations or other practices

The pain management intervention used should

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be simple, practicable, cost effective and safe. Administration of breast milk as a study intervention could be easily adopted from the perspectives of health care providers and parents.

Review of Literature

A randomised controlled trial conducted by Ou-Yang et al (2012) to determine the effect of expressed breast milk on procedural pain due to heel lancing in preterm neonates. Pre-term neonates were given 5 ml of distilled water as placebo (water, n=44), 25 percent glucose water (glucose, n=39) or milk (n=40) 2 min before heel lance. There was a significant difference in the median duration of first cry among the groups: water = 70.5 sec, glucose = 2.0 sec, milk = 29.5 sec. The duration of first cry was significantly shorter in the glucose group compared with the water group. Pain scores were significantly lower in the glucose and milk groups compared with the water group 1, 2 and 3 min after heel lancing ($p < 0.05$). The study concluded that there was no significant difference in cry time but there was reduction in the pain score in breast milk group. Thus the milk may be used to reduce pain associated with heel lancing in preterm neonates.

A prospective, double blinded randomised controlled comparative study by Malngiang et al (2016) to identify the effect of oral glucose versus expressed breast milk (EBM) to reduce pain in newborns undergoing skin pricking procedures was assessed by using the neonatal infant pain scale (NIPS) and changes in heart rate and duration of crying. 150 babies were randomly divided into 2 groups, 2 ml of 10% oral glucose or expressed breast milk was given 1 min before the procedure orally. During the blood sampling procedure - heart rate, crying time and the NIPS scores were noted. The NIPS score for expressed breast milk group was higher (4.77) than that of oral glucose group (3.67 at $p<0.001$). Crying time for the Breast milk group's babies was significantly longer than crying time (9.48) for the oral glucose group's babies (6.40 at $p<0.001$). Oral glucose group had 1.5% more chance of having higher heart rate in comparison with the heart rate of those assigned to expressed breast milk group (OR=1.015). The mean heart rate before blood sampling for the EBM group was 124.99 per min which was significantly less than the corresponding figure for oral glucose group -126.69 per min ($p=0.002$).

Methods

This prospective randomised experimental study was conducted in the post-natal ward of a tertiary care hospital in Puducherry, South India during January 2013 to January 2014. The objective of the study was to identify the effect of facilitated tucking and oral administration of 1 ml of expressed breast milk with control group for pain management among neonates of study groups who received Bacillus calmette-guaorine (BCG) vaccine. The control group neonates received the routine care of FT as per the hospital policy during vaccination procedure. The research hypothesis formulated in study is neonates of study groups had significant variation on haemodynamic variables and outcome variables in response to the painful stimulus with twin intervention.

The sample size was calculated using nMaster 2.0, which is a user friendly, affordable and power software package used to calculate the sample size and 100 neonates were included into the study. Newborns ≥ 37 weeks of gestation receiving BCG vaccination were included in the study after informed parental consent. Neonates who were sick, had perinatal asphyxia (Apgar score <5 at 5 min), having congenital malformations or were on opioid analgesics, sedatives or phenobarbitone, mothers who cannot express and give 1 ml of breast milk to use for study purpose, mothers/neonates with known HIV or other immunosuppressive disorders were excluded. All neonates who cried before BCG vaccination or passed stool/urine during sampling were excluded from analysis. The study was ethically cleared by the Institutional ethical review board of Pondicherry Institute of Medical Sciences.

The eligible neonates were randomised and included into the study using computer generated random numbers. The envelopes were exclusively accessed by the Research assistants. The data were collected in three phases: 1-Preparatory Phase, 2-Interventional Phase, 3-Post-interventional phase

Preparatory Phase: Neonates receiving BCG vaccination were taken to a quiet vaccination room. It was ensured that time interval between the procedure and previous breast milk intake was at least one hour to prevent the analgesic effect of breast milk by the previous feed. The neonate's baseline physiological data like respiratory rate (RR), heart rate (HR) and oxygen saturation (SpO_2), were monitored by a research assistant using pulse oxymeter (MASIMO).

Interventional Phase: One ml of breast milk was administered to the neonates of study group through a sterile disposable syringe from one corner of the mouth by research assistant. The excess amount of breast milk in the neonatal mouth and the syringe was cleared before the entry of blinded researcher into the vaccination room and thus the researcher was masked from the test solution. The newborn was

kept in facilitated tucking position by bringing the extremities of the neonates flexed and close to trunk, midline position close to the newborns' body while the newborn in lateral position during vaccination procedure. The neonates of the control group were given routine care. The BCG vaccinations were done throughout the study by a trained paediatric nurse who had adequate experience in neonatal care in order to minimise variation in pain during Vaccination.

Post-interventional phase: The primary outcome of the study, pain was measured using the NIPS score (total score: 0-7, mild pain 0-2, moderate pain 3-4). The secondary outcome was duration of cry using audio-recorder (i.e.) beginning immediately after injection to cessation of crying up to 3 minutes.

Statistical analysis was done with ANOVA (analysis of variance) to assess the effect within the groups with SPSS 21.00 version. Post-hoc analysis was done using inferential statistical method. Crying time was analysed by independence sample test. Repeated measures ANOVA were used to compare the heart rate and SpO_2 over time and its interaction with the intervention group. A p-value of 0.001 was considered a statistically significant level of difference.

Results & Discussion

Gestational age of the neonatal participants ranged from 37 weeks to 37.6 weeks in the study and control groups. Female neonates were found to be more in both the groups compared to the male neonates as the study group comprised of 19 (42%) male neonates and in control group there was 48 (44.7%) of male neonates. Most of the neonates' weight ranged from 2.5-3 kg (i.e. 90% in study group and 83% in control group).

The average birth weight of the neonates in the study group was 2.9 kg. The neonates born through spontaneous vaginal delivery i.e. 32 (61%) and remaining 26 (39%) born through assisted type of delivery like forceps and vacuum delivery and none born through caesarean section. The mean Apgar score of the neonates at 0 min was 7.7 and at 5 min - 8.7.

When both groups were compared using the group averages for all the physiological parameters, no significant differences in mean were found among the heart rate of the study group neonates and oxygen saturation before BCG vaccination. There was highly statistical significance identified among the study groups with regard to respiratory rate and oxygen saturation at p <0.001 level. There was no statistical significance found among the neonates heart rates of breast milk group and control group in terms of their heart rate (Table 1 - 3).

The Neonatal and Infant Pain Score (NIPS) was used to score pain perception of newborn and it was found that in study group 27.40 percent neonates had moderate pain 16.10 percent had mild pain. In control group more than half of the neonates (58%) had moderate pain, which shows that more number of neonates had reduction in the degree of pain from

Table 1: Comparison of respiratory rate between control group and breast milk group

Respiratory rate	Control group [n = 100] Mean ± SD	Breast Milk [n = 45] Mean ± SD	t-value	p-value	95% CI	
					Lower	Upper
Before BCG vaccination	60.72± 2.503	59.422±3.237	2.629	0.009 ***	0.3221	2.2734
After BCG - at 0 min	58.64±3.422	70.733±3.063	-20.32	0.000 ***	-13.269	-10.917
After BCG - at 3 min	70.95±3.398	68.533±2.351	4.324	0.001 ***	1.312	3.5213
After BCG - at 5 min	69.88±5.969	57.111±3.207	13.485	0.000 ***	10.8972	14.6406

*** Very highly statistical significance difference at 99.9% (p<0.001)

Table 2: Comparison of heart rate between control group and breast milk group

Heart Rate	Control group [n = 100] Mean ± SD	Breast milk group [n = 45] Mean ± SD	t-value	p-Value	95% CI	
					Lower	Upper
Before BCG vaccination	131.52±6.788	131.244±6.853	0.225	0.822 NS	-2.14	2.6911
After BCG - at 0 min	129.62±2.044	130.622±2.887	-2.39	0.018 NS	-1.831	-0.174
After BCG - at 3 min	128.5±4.700	128.044±3.778	0.572	0.568 NS	-1.119	2.029
After BCG - at 5 min	129.4±3.798	129.289±5.802	0.137	0.891 NS	-1.489	1.712

NS – No statistical significance

Table 3: Comparison of oxygen saturation between control group and breast milk group

Oxygen Saturation	Control Group [n = 100] Mean ± SD	Breast milk group [n= 55] Mean ± SD	t-Value	p-Value	95% CI	
					Lower	Upper
Before BCG vaccination	97.06±1.377	97.422±1.197	-1.524	0.13 NS	-0.832	0.1075
After BCG - at 0 min	97.41±1.239	96.598±1.416	3.49	0.001 ***	0.3522	1.2722
After BCG - at 3 min	97.57±1.103	96.807±1.362	3.577	0.000 ***	0.3414	1.1852
After BCG - at 5 min	97.77±0.789	96.131±1.141	10.006	0.000 ***	1.3151	1.9626

*** Very highly statistical significance difference at 99.9% (p<0.001)

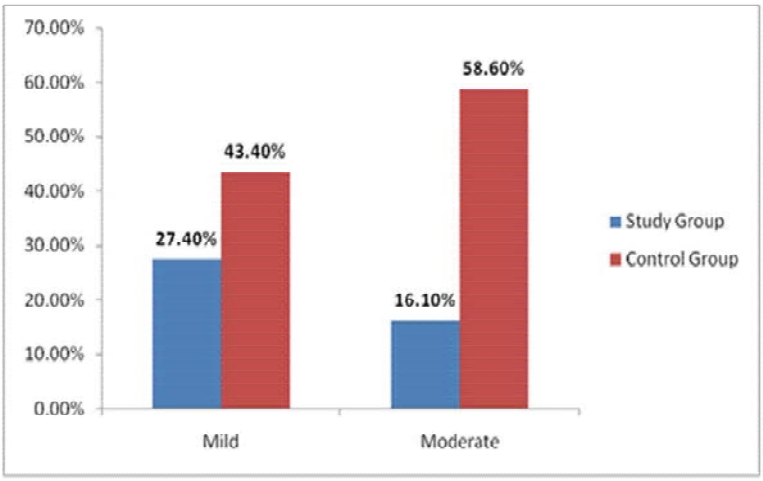

Figure 1: Level of pain among study and control group

mild to moderate level of pain in the study group. Thus the effectiveness of breast milk for pain management is increased. There is significant difference in the NIPS score both in study and control group (Fig 1).

There was significant reduction in cry time when comparing the study group (53.511 ± 3.0646) to the control group (60.940 ± 3.434) (mean ± SD). No adverse events were observed in neonates of any groups (Table 4).

The study revealed that expressed breast milk and decreased pain response (behavioural and physiologic) in newborn babies as assessed by the NIPS score. The respiratory rate, heart rate and oxygen saturation changes at 0, 3, 5 minute after BCG vaccination and the analgesic effect persisted till 5 minutes after the procedure. According to Anand (2001) the analgesic effect of expressed breast milk is attributable to the oro-gustatory nature of sweet solution when given orally. Similar findings were observed by Reis et al (2003) sweet taste perception due to the higher concentration of tryptophan, a precursor of melatonin that increases the concentration of beta endorphins which reduces pain.

Nursing Implications

Practice:

· Study findings can be integrated into nursing care practice.

· Nurses need to have knowledge on assessment, management and prevention of complication related to pain.

· Paediatric nurses have a responsibility to meet the health/comfort needs of the child.

· Parents can be incorporated into the child care with regard to pain management.

Education:

· Assessment of pain using different types of pain assessment scales for different age groups.

· Student nurses can be given awareness on pain assessment and management and outcomes of neglected pain.

Administration:

· Formulating policies at the institutional level to standardise the procedure.

· Framing information brochure/protocols for the novice nurses.

· Novice nurses need to be educated on management of mild level of pain.

Research:

- Future studies should concentrate on other pain relieving measures such as direct breast-feeding, kangaroo mother care and non-nutritive sucking.
- Research about interventions that enhance holistic comfort in neonates be undertaken.
- Study can be conducted following different design and methodology.
- Different non-pharmacological methods can be clubbed together and used as study interventions.

Recommendations

· Other physical and psychological variables can be added as study outcome.

· Comparison can be done with other painful procedures like intravenous procedure and intradermal injection.

· Same study can be replicated on larger sample size.

· Objective assessment of salivary cortisol, serum cortisol can be included.

· Direct breast feeding before vaccination and facilitated tucking during vaccination can also be used as one of the nursing care intervention and its effectiveness can be measured.

Table 4: Level of pain evaluation using the primary outcomes NIPS Score and the cry time

Outcome variable	Control group [n = 100] Mean ± SD	Breast milk group [n=45] Mean ± SD	t-value	p-Value	95% CI	
					Lower	Upper
Cry time in seconds	60.940±3.434	53.511± 3.0646	12.447	0.000 ***	6.249	8.608
Total NIPS score	3.600±0.4924	3.089±0.7926	4.738	0.000 ***	0.297	0.724

*** Very highly statistical significance difference at 99.9% (p<0.001)

- Same twin intervention can be applied for the preterm neonates undergoing various other acute painful procedures.
- Two different types of pain assessment tool can be used and the results can be compared.

Conclusion

Pain in neonates should be recognised and treated. Very little pain management strategies' are used for invasive procedures especially during BCG and other vaccination procedures at OPDs. Twin intervention is effective in reduction of pain response among neonates during BCG vaccination. Educational programmes for pain management in newborns should be arranged to develop an institutional protocol. Further studies are needed to identify the more effective non-pharmacological / alternative interventions to minimise the pain. Evidences in this field may bring in the knowledge and confidence among health care professionals.

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