### **Original Research Article**

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### Use of expressed breast milk for pain relief during venepuncture in neonates

Abinaya S., Vinoth S.\*, Ramesh S.

Department of Paediatrics, Rajah Muthiah Medical College and Hospital, Chidambaram, Tamil Nadu, India

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#### \*Correspondence:

Dr. Vinoth S, E-mail: rajkantmc@gmail.com

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#### ABSTRACT

**Background:** It is now known that repeated pain in neonatal period influences neurodevelopmental outcome. It is necessary to assess and manage neonatal pain with appropriate interventions. The objective is to study whether expressed breast milk effectively reduces neonatal pain after venepuncture in comparison to placebo using sterile water.

**Methods:** In this randomised controlled trial, neonates were randomised into two groups-expressed breast milk group and placebo group with 40 neonates in each group. Two minutes before venepuncture, 2 ml of test solution was administered. Mean Premature Infant Pain Profile (PIPP) score and mean cry time were recorded in neonates of both groups after venepuncture and compared.

**Results:** At 0-30 second, 1-1 ½ minute, 3-3 ½ minute, 5-5 ½ minute after venepuncture, neonates in placebo group had mean PIPP score of 11.475, 10.125, 9.125, 7.575 respectively. At the same time intervals, mean PIPP score was 9.375, 7.825, 6.475, 5.05 in neonates of expressed breast milk group. Mean cry time after venepuncture was 105.65 seconds and 75.825 seconds in the placebo group and expressed breast milk group respectively.

Conclusions: Compared to placebo, expressed breast milk significantly reduced mean PIPP score and cry time in neonates.

Keywords: Cry time, Expressed breast milk, Venepuncture

#### **INTRODUCTION**

Neonates are subjected to painful procedures from early life. Assessment and management of neonatal pain is important for ethical issues and also because repeated and sustained noxious stimuli has short term and longterm sequelae. It may lead to permanent changes in brain processing and maladaptive behaviour later.<sup>1</sup>

Simons et al conducted a study in 151 neonates and observed that on an average  $14\pm4$  painful interventions were done during the first 14 days of life in a neonate.<sup>2</sup> An update from American Academy of Pediatrics and Canadian Society of pediatrics recommends

implementation of strategies to decrease the number of painful procedures. They also suggest having a pain assessment and management protocol including pharmacologic and non-pharmacologic methods.<sup>3</sup> In France, a prospective trial conducted in 2008 found that only 21% of infants were given specific pharmacologic or non-pharmacologic analgesia before painful procedures while ongoing analgesia was used in only 34% of neonates.<sup>4</sup>

Due to the inability of the neonate to express pain verbally it is necessary for the caregivers to be able to recognise and assess pain.<sup>5</sup> Crying is considered as an important indicator of a child's pain.<sup>6</sup> Grunau and Craig

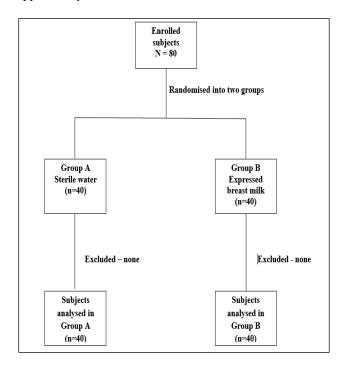
have demonstrated that cry following pain is most sensitive to noxious stimuli.<sup>7</sup> The duration of cry has been used to assess pain in various studies.<sup>8</sup> Various pain assessment scales have been developed that relies on physiological and behavioural responses to pain. Premature Infant Pain Profile (PIPP) is a multidimensional pain scale including physiological and behavioural indicators of pain. It is a validated pain scale used in many studies.<sup>9</sup>

One extensively researched method to reduce neonatal procedural pain is oral administration of sweet tasting solutions. Sucrose and dextrose have been described as analgesic for procedural pain.<sup>10</sup> Similarly, use of breast milk which is a safe, economic natural sweet solution to reduce neonatal pain response has been studied.<sup>11</sup> This study was conducted to assess whether expressed breast milk effectively reduced neonatal pain during venepuncture with the help of PIPP scale.

#### **METHODS**

Study area and population: Term neonates admitted in RMMCH, Chidambaram, Tamil Nadu were enrolled in this randomised controlled trial after getting consent from parents. 40 neonates were enrolled in each group.

Term neonates who were taking breastfeeds and required venepuncture for blood investigations were selected. Sick neonates, neonates with birth asphyxia, congenital malformations, feeding intolerance and those who were on sedatives were excluded from the trial. The study was approved by the Ethical committee of the Institution.





Method of study: Randomisation was achieved with closed envelope method where envelopes with group codes were used and the neonates were randomly divided into two groups-placebo group and expressed breast milk group. Sterile water from sterile ampoules was used as placebo and discarded after a single use. Expressed breast milk from mother collected in a sterile container was used (Figure 1).

The neonates were placed in a radiant warmer in a quiet room. A pulse oximeter probe was connected to the foot of the neonate. The baseline heart rate and oxygen saturation of the neonates were recorded.

Two ml of the test solution of the group selected was given on the anterior aspect of the tongue of the neonate by a sterile syringe by the principle investigator. After two minutes, venepuncture was done on the dorsal aspect of hand by a trained neonatal nurse. During the procedure, another trained neonatal nurse blinded to group allocation recorded the heart rate, oxygen saturation and cry time. Cry time was defined as the total duration of audible cry after the needle was introduced into the neonate's hand and was measured in seconds. An independent blinded observer noted down the facial responses of neonates after venepuncture. At 0-30 sec, 1-1 <sup>1</sup>/<sub>2</sub> min, 3-3 <sup>1</sup>/<sub>2</sub> min, 5-5 <sup>1</sup>/<sub>2</sub> min after venepuncture, the maximum heart rate, minimum oxygen saturation and duration of facial responses were noted and PIPP score was calculated. The data collected were recorded in a proforma.

#### Data analysis

The data was analysed using SPSS version 21.0. Statistical analysis using T test was done to find whether expressed breast milk significantly reduced PIPP score and cry time compared to placebo taking p value <0.05 as statistically significant.

#### RESULTS

The distribution of the descriptive characteristics of neonates like gender, mode of delivery, gestational and postnatal age and birth weight was found to be comparable between the two groups (Table 1).

#### Table 1: Baseline characteristics of study population.

Parameters	Placebo group (n=40)	Expressed breast milk group (n=40)
Vaginal delivery	20	17
Caesarean section	20	23
Male	22	20
Female	18	20
Mean gestational age (weeks)	37.9	38.4
Mean birth weight (kg)	2.83	2.87

# Table 2: Mean PIPP score (mean (SD)) in the study population of the two groups.

PIPP score at various	Mean PIPP score (Std deviation)		
time intervals after venepuncture	Placebo group	Expressed breast milk group	
PIPP at 0-30 sec PIPP 1	11.475 (1.04)	9.375 (1.44)	
PIPP at 1-1 <sup>1</sup> / <sub>2</sub> min PIPP 2	10.125 (0.99)	7.825 (1.48)	
PIPP at 3-3 <sup>1</sup> / <sub>2</sub> min PIPP 3	9.125 (1.32)	6.475 (1.36)	
PIPP at 5-5 <sup>1</sup> / <sub>2</sub> min PIPP 4	7.575 (1.38)	5.05 (1.32)	

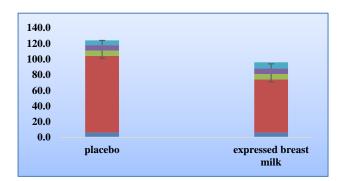
Neonates in expressed breast milkgroup had mean PIPP score of 9.375 at 0-30 sec, 7.825 at 1-1  $\frac{1}{2}$  min, 6.475 at 3-3  $\frac{1}{2}$  min, 5.05 at 5-5  $\frac{1}{2}$  min after venepuncture. Whereas neonates in placebo group had mean PIPP score of 11.475 at 0-30 sec, 10.125 at 1-1  $\frac{1}{2}$  min, 9.125 at 3-3  $\frac{1}{2}$  min and 7.575 at 5-5  $\frac{1}{2}$  min after venepuncture (Table 2). Comparison of the difference in mean PIPP score between neonates of placebo and expressed breast milk groups at various time intervals after venepuncture showed statistically significant difference. Neonates in expressed breast milk group had significantly lower PIPP score (Table 3).

#### Table 3: Comparison of difference in mean PIPP score between the groups.

PIPP at various time intervals after venepuncture	Groups	Difference in mean PIPP score	t value	p value
PIPP at 0-30 sec PIPP 1	placebo versus expressed breast milk	2.100	7.468	0.000
PIPP at 1-1 <sup>1</sup> / <sub>2</sub> min PIPP 2	placebo versus expressed breast milk	2.300	8.153	0.000
PIPP at 3-3 <sup>1</sup> / <sub>2</sub> min PIPP 3	placebo versus expressed breast milk	2.650	8.835	0.000
PIPP at 5-5 <sup>1</sup> / <sub>2</sub> min PIPP 4	placebo versus expressed breast milk	2.525	8.379	0.000

#### Table 4: Comparison of differences in mean cry time between the groups.

Mean cry time after venepuncture	Groups	Difference in mean cry time (sec)	t value	p value
Cry time	Placebo versus expressed breast milk	29.8250	17.119	0.000



## Figure 2: Distribution of cry time (sec) of neonates after venepuncture.

Mean cry time after venepuncture was 105.65 sec and 75.825 sec in the placebo group and expressed breast milk group respectively (Figure 2). There was a significant difference in mean cry time between the neonates of placebo group and the expressed breast milk group with p value <0.05 (Table 4).

#### DISCUSSION

It is recognized that neonates are capable of perceiving neonatal pain during various procedures. Use of sweet solutions for neonates undergoing painful procedures has been investigated over the recent past. Small amounts of sweet solutions administered on the neonate's tongue have been found to increase the release of endogenous opioids. The effect of sweet solutions on pain is mediated by their orogustatory effect (taste) and hence intraoral route of administration is used.<sup>5</sup>

Premature Infant Pain Profile is a validated multidimensional pain scale used in many studies.<sup>9</sup> Sucrose was the most widely researched and used sweet solution.<sup>10</sup> Expressed breast milk has lactose and high concentration of tryptophan, precursor of melatonin. Melatonin has been shown to increase beta endorphins concentration.<sup>11</sup>

Recently use of other sweet solutions like dextrose and expressed breast milk are also being studied.<sup>12</sup> Present study was done to determine the efficacy of expressed breast milk in relieving pain after venepuncture with the help of PIPP score and cry time.

In the present study, it was found that the mean cry time and the mean PIPP scores at 0, 1, 3, 5 minutes after venepuncture were significantly lower in neonates belonging to expressed breast milk group as compared to the placebo group. Yang O et al conducted a trial to assess efficacy of expressed breast milk in reducing pain after heel lancing in preterm neonates. They concluded that pain scores were significantly lower in breast milk group compared to placebo group.<sup>13</sup>

Rosali et al studied the efficacy of expressed breast milk in reducing pain during Retinopathy of Prematurity (ROP) screening. The expressed breast milk group had significantly lower PIPP score of  $12.7\pm1.69$  as compared to the control group PIPP score of  $15.5\pm1.78$  during the procedure. This significant difference between the two groups was found to persist at 1 min and 5 min after the procedure.<sup>14</sup>

Upadhyay et al studied efficacy of expressed breast milk for pain reduction using Neonatal Facial Coding System (NFCS) scale. Lower pain scores and shorter crying time were observed in infants receiving expressed breast milk.<sup>15</sup> Sabety et al aimed to study the effects of 2 ml of 50% oral glucose, topical lidocaine, 2 ml of expressed breast milk, and nothing per oral for reducing pain before painful procedures. Expressed breast milk was found to significantly reduce Douleur Aigue Nouveau-ne (DAN) score and crying time.<sup>16</sup> Studies were conducted comparing breast milk with other sweet solutions. Ozdogan et al observed lower Neonatal Facial Coding System (NFCS) scores in infants receiving sucrose and breast milk. But no significant difference was found between the two groups.<sup>17</sup> A study by Rodrigues L et al compared the efficacy of 25% dextrose and expressed breast milk during nasopharyngeal suctioning in preterm neonates on CPAP using PIPP score. There was no significant difference in mean PIPP scores between the expressed breast milk and 25% dextrose groups concluding that both expressed breast milk and 25% dextrose were equally effective in reducing neonatal pain.<sup>18</sup>

The present study has shown that expressed breast milk given before venepuncture reduces neonatal pain response significantly.

#### CONCLUSION

Expressed breast milk is an easily available economic sweet solution. From the present study, it is evident that expressed breast milk can be used effectively as a procedural analgesia.

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