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## ORIGINAL ARTICLE

# Efficacy of Expressed Breast Milk Versus 25% Dextrose Water in Reducing Procedural Pain in Neonates: Experience at a District Hospital

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### ABSTRACT

**Objective:** To compare the mean procedural pain score with EBM versus 25% dextrose water (DW) in neonates.

**Study Design:** Randomized Control Trial.

**Place and Duration of Study:** Neonatal Unit, District Headquarter (DHQ) Hospital, Gujranwala. Duration of study was 6 months from 01.01.2020 to 30.06.2020

**Material and Methods:** After meeting the inclusion and exclusion criteria, 100 infants were enrolled. Informed consent was taken from parents. Demographic information was collected. Infants were randomly divided into 2 groups. Group A was given expressed breast milk (EBM) and group B was given 25% dextrose water (DW). One minute after giving solution, infants underwent procedure. After 5 minutes of solution administration, infants were assessed for procedural pain score (NIPS). All the collected data was entered and analyzed on SPSS.

**Results:** Mean age of the infants was  $16.21 \pm 7.99$  days. Male to female ratio was 0.8:1. Arterial prick procedure was performed in 36 (36%) and NG tube was performed in 37 (37%) infants. Among expressed milk group, mean NIPS score at 5 minute was  $3.56 \pm 1.59$  whereas amongst 25% dextrose water group, mean NIPS score was  $5.02 \pm 1.46$  (p-value= $<0.001$ ).

**Conclusion:** EBM was more efficacious in terms of mean procedural pain score as compared to 25% DW in neonates.

**Key Words:** *Procedural pain score, Expressed breast milk, Dextrose water.*

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## INTRODUCTION

With increased development of Health care system, neonates are being exposed to procedural pain more frequently, either for diagnostic purpose or for preventive reasons. For example; heel prick, vaccination, sampling for

laboratory tests, nasogastric intubation, taking intravenous lines etc, all procedures are inherently painful. If this pain is controlled effectively in the newborn period, it will benefit the patients by improving physiologic, behavioral and hormonal outcomes.<sup>1</sup> Aforementioned reasons make

iatrogenic pain unavoidable and common in infants.<sup>2</sup>

Previously, it was thought that infants do not feel pain. But current research has proven it to be wrong. Pain initiates a series of behavioral and hormonal events which could result in deranged cognitive and neuronal development in early preterm babies.<sup>3</sup> Keeping in view the inevitability of painful procedures in neonates and infants and adverse short and long term effects of early procedural pain, it is important to find and adopt an effective pain relieving strategy during these painful procedures. Non-pharmacological pain relief, among many other techniques, can also be achieved with the help of sucrose or 25% dextrose water and/or breast milk.<sup>4-6</sup>

Some researches show expressed breast milk (EBM) to be superior to dextrose water (DW) or sucrose, and combination of breast milk and sucrose<sup>7,10</sup> while others suggest that opposite is true.<sup>5,8</sup> A lot of work needs to be done to evaluate the efficacy of non-pharmacological treatments and to find out which one is superior over the other, helping avoid the acute and long term consequences associated with procedural pain in infants along with lessening the adverse effects associated with pharmacological treatment, as prompt treatment of early infant pain is necessary to avoid the bad outcome.<sup>9</sup>

Rationale of this study is to compare the mean procedural pain score with EBM versus 25% DW amongst infants of less than 28 days of age. Literature showed that EBM can reduce procedural pain and ultimately neonate will have less cry, better breathing pattern and stay calm, more than that with DW. But controversial data has been retrieved from literature as well. Moreover, there is no local literature available which could help to decide whether to give EBM or DW to infants in order to keep the infant calm during procedure, hence this study was planned. This will help to improve our practice and knowledge and in future, we will be able to implement the use of better solution in infants undergoing some procedure. The objective of this study was compare the mean procedural pain score with expressed breast milk (EBM) versus 25% dextrose water (DW) in neonates (less than 28 days of age).

Procedural Pain was measured by using Neonatal Infant Pain Scale (NIPS) and score was noted after 5 minutes of procedure.

The hypothesis of the study was that there is a difference in mean procedural pain score with EBM versus 25% DW in neonates less than 28 days of age.

## MATERIAL AND METHODS

This was a randomized control trial, conducted at Neonatal unit of Pediatric Medicine Ward, DHQ-teaching Hospital, Gujranwala. This study was conducted over 6 months (01.01.2020 to 30.06.2020). A sample size of 100 neonate (50 in each group) was estimated by using 95% confidence level, 80% power of test and taking magnitude of mean procedural pain score i.e.  $3.2 \pm 1.58$  with EBM and  $6.85 \pm 2.41$  with 25% DW.<sup>10</sup> The sampling technique was non-probability, consecutive sampling.

Neonates (Infants, age <28 days), of either gender, born at gestational age >37 weeks (on antenatal record), undergoing venous or arterial puncture or NG intubation, in a state of quiet wakefulness (i.e. not crying), and who had their last oral feed not <30minutes before the procedure were included in the study. The exclusion criteria were neonates with any neurological or genetic disorder (on clinical examination) or on assisted ventilation or those receiving any sedatives/analgesics (on medical record).

Out of 100, 50 infants, in each group, fulfilling selection criteria were enrolled in the study from Neonatal Unit of Pediatric Medicine Ward, DHQ Hospital Gujranwala. Informed consent was obtained from parents. Demographic details, name, age, gender, gestational age and weight of babies were noted. Infants were randomly allotted to two groups by lottery method. In group A, infants were given 3 ml of EBM from mother's breast in milk container 1 minute before the baby underwent a painful procedure. In group B, infants were given 3 ml solution of 25% DW orally. After 1 minute of solution intake, infant underwent a procedure. All procedures were carried out by the researcher. After 5 minutes of either solution administration, infants were assessed for

procedural pain score (as per operational definition). All this data was recorded on proforma.

Data was entered and analyzed in SPSS 23. Quantitative variables such as age, weight, gestational age at birth and procedural pain score were demonstrated as mean  $\pm$  SD. Qualitative variables like gender and procedure performed were exhibited as frequencies and percentages. Both groups were compared for mean procedural pain score by using independent sample t-test. P-value  $\leq 0.05$  was taken as significant. Data was stratified for age, gender, weight, gestational age at birth and procedure performed. Post-stratification, both groups were compared for mean procedural pain score by using independent sample t-test for each strata. P-value  $\leq 0.05$  was taken as significant.

## RESULTS

In this study 100 infants were enrolled. Mean age of the infants was  $16.21 \pm 7.99$  days with minimum and maximum ages of 2 and 28 days respectively. Among EBM group, mean age was  $16.06 \pm 8.00$  days while among 25% DW group, mean age of the infants was  $16.36 \pm 8.06$  days. With reference to gender, 45 (45%) were male while 55 (55%) infants were female. Male to female ratio was 0.8:1. In EBM group 25 (50%) infants were male and in 25% DW group 20 (40%) infants were male. Similarly in EBM group 25 (50%) infants were females and in 25% DW group 30 (60%) infants were female (table 1).

**TABLE 1: Distribution according to age, gender, gestational age, birth weight and procedure performed (n=100)**

	N	100	Expressed Breast Milk (n=50)	25% Dextrose Water (n=50)
Age (days)	Mean	16.21	16.06	16.36
	SD	7.99	8.00	8.06
	Minimum	2	-	-
	Maximum	28	-	-
Gender	Male	45	25 (50%)	20 (40%)
	Female	55	25 (50%)	30 (60%)
	Mean	39.04	39.02	39.06
Gestational Age at Birth (weeks)	SD	1.32	1.421	1.24
	Minimum	37	-	-
	Maximum	41	-	-
Weight at Birth (kg)	Mean	3.44	3.43	3.46
	SD	0.615	0.62	0.613
	Minimum	2.50	-	-
Procedures Performed	Maximum	4.50	-	-
	Arterial Prick	36	15 (30%)	21 (42%)
	NG Tube	37	21 (42%)	16 (32%)
	Lumber Puncture	27	14 (28%)	13 (26%)

Mean gestational age at birth of the babies was  $39.04 \pm 1.32$  weeks with minimum and maximum gestational ages of 37 and 41 weeks respectively. Among EBM, mean gestational age was  $39.02 \pm 1.421$  weeks whereas in 25% DW, mean gestational age was  $39.06 \pm 1.24$  weeks. Mean weight of the infants was  $3.44 \pm 0.615$  kg with minimum and maximum weights of 2.50 and 4.50 kg respectively. Among EBM, mean weight of the

infants was  $3.43 \pm 0.62$  kg where as in 25% DW group, mean weight was  $3.46 \pm 0.613$  kg (table 1).

As far as frequency of procedures performed is concerned, arterial pricks were performed in 36 (36%), NG tube was passed in 37 (37%) and lumber puncture was done in 27 (27%) neonates. Further stratification revealed that in EBM group, arterial pricks were performed in 15 (30%), whereas among 25% DW group, arterial pricks were performed in 21 (42%) neonates. In EBM,

NG tube was passed in 21 (42%) whereas among 25% DW group, it was passed in 16 (32%) neonates. Similarly in EBM, lumbar puncture was performed in 14 (28%) whereas among 25% DW group, it was performed in 13 (26%) neonates (table 1).

In the present study, mean NIPS at 5 minutes of the procedure was  $4.29 \pm 1.69$  with minimum and maximum NIPS score of 1 and 7 respectively.

Among EBM, mean NIPS at 5 minutes was  $3.56 \pm 1.59$  whereas among 25% DW group, it was  $5.02 \pm 1.46$ . Statistically significantly lower pain score was found in EBM as compared to 25% DW group (p-value <0.001) table 2. Similarly, statistically significant difference was found between the study group and NIPS at 5 minutes stratified by age, gender, gestational age, weight and procedure performed, respectively (p-value <0.05) table 3.

**TABLE 2: Descriptive statistics of NIPS at 5 minutes (n=100)**

	N	100	Expressed Milk (n=50)	Breast 25% Dextrose Water (n=50)	p-value
NIPS at 5 Minutes	Mean	4.29	3.56	5.02	<0.001
	SD	1.69	1.59	1.46	
	Minimum	1	-	-	
	Maximum	7	-	-	

**TABLE 3: Comparison of NIPS at 5 Minutes in both groups stratified for effect modifiers**

Variables	NIPS at 5 minutes	Study Groups		p-value
		Expressed Breast Milk	25% Dextrose Water	
Age (days)	≤14	3.09± 1.62	5.39±1.29	<0.001
	>14	3.96±1.48	4.81±1.53	0.035
Gender	Male	3.12±1.62	5.15±1.42	<0.001
	Female	4.00±1.47	4.93±1.51	0.025
Gestational Age (weeks)	37-39	3.58±1.54	4.73±1.53	0.005
	>39	3.53±1.71	5.45±1.28	<0.001
Weight (kg)	≤3	3.68±1.67	5.13±1.63	0.004
	>3	3.44±1.53	4.93±1.33	<0.001
Procedure Performed	Arterial Prick	3.67±1.72	5.10±1.30	0.012
	NG Tube	3.24±1.64	4.81±1.83	0.009
	Lumber Puncture	3.93±1.38	5.15±1.28	0.025

## DISCUSSION

Neonates admitted to Intensive Care Units have to experience multiple procedures, and most of them are unpleasant. Recurrent traumatic acts in preterm neonates would modify the threshold, cognition and endurance of pain during succeeding painful processes and may have adverse influence on development. EBM possess tryptophan which results in increased concentration of beta endorphins, which may cause relief from pain.<sup>11-13</sup>

In the present study, mean NIPS at 5 minutes was  $4.29 \pm 1.69$ . Among expressed milk group, mean NIPS at 5 minutes was  $3.56 \pm 1.59$  while it was

$5.02 \pm 1.46$  (p-value <0.001) in those who received 25% DW. Rosali et al<sup>10</sup> conducted a study on impact of EBM while screening for retinopathy of prematurity. The group who was administered EBM had much lower Premature Infant Pain Scores while performing a procedure ( $12.7 \pm 1.69$ ) compared with control group ( $15.5 \pm 1.78$ )  $p < 0.05$ .

Upadhyay et al<sup>14</sup> conducted a study on analgetic impacts of EBM in pain associated with various procedures in full term babies. Results of the study revealed that span of crying was much reduced in neonates who were administered EBM compared to those who were given 25% DW. Mean duration of crying in neonates with EBM

was reduced by 70.7 seconds. The modified neonatal facial coding system at 0, 1 and 3 minute was much reduced ( $p$ -value $<0.01$ ) among the EBM group as compared to DW. Administration of 5 ml of EBM ahead of venipuncture effectively reduces pain in full term babies.

Skogsdal et al<sup>15</sup> and Ors et al<sup>16</sup> observed that intensity of symptoms due to pain was reduced, when 1–2 ml EBM was consumed before a painful event, however, these outcomes were not proven statistically significant. This could be explained on the basis of composition of EBM, as breast milk contains sugar content of 7% only, which is lower than other dextrose containing liquids.

Gray et al observed that crying was substantially reduced during a heel prick, if baby was being breastfed at that time.<sup>17</sup> Carbajal et al noted pain scores were considerably reduced when performing venipuncture, while the baby was being breastfed.<sup>18</sup> Contrary to this, Sahoo et al<sup>5</sup> revealed that EBM substantially decreases the pain associated with procedures in babies, however, to a smaller degree when compared with those who were administered 25% DW. According to their findings, Mean Premature Infant Pain Profile Score in the three study groups were 5.22, 6.84 and 11.22 at 0-30 sec after venipuncture; 4.52, 6.34, and 10.88 at 1-1½ min; 3.96, 6.15 and 9.35 at 3-3½ min; and 3.12, 4.68 and 7.83 at 5-5½ min; respectively ( $p$ -value  $<0.001$ ). The median crying time was 10, 37.5 and 162 seconds in 25% DW, EBM and SW groups, respectively ( $p$ -value  $<0.001$ ).<sup>5</sup>

The analgesic impacts of EBM has been ascertained in articles on heel prick and venipuncture in the Cochrane meta-analysis. (Premature Infant Pain Profile scores 6–12). No un-toward impact like vomiting or apneic spells were observed with the administration of EBM.<sup>19</sup>

Few other studies conducted by Skogsdal, et al and Deshmukh, et al documented superior effect with solutions containing increased glucose levels (25-30%) compared to 10% DW or EBM.<sup>15, 20</sup> Another trial showed that there was significant difference ( $p=0.036$ ) in mean pain score i.e. 4.68 (3.8-5.5) with EBM ( $n=62$ ) while 3.12 (2.4-3.8) with 25% DW ( $n=50$ ), showing 25% DW as better option to reduce pain.<sup>5</sup>

## CONCLUSION

This study concluded that expressed breast milk is more efficacious in terms of mean procedural pain score as compared to 25% dextrose water in neonates.

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