

## Original Article

## Breast milk vs. non-nutritive sucking to reduce pain from minor invasive procedures in neonates

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### Abstract

**Background** Neonates undergo many uncomfortable, invasive minor procedures during their first hospital stay. Non-pharmacological interventions may provide valuable alternatives for pain relief in neonates during minor procedures.

**Objective** To compare the analgesic effect of orally administered breast milk vs. non-nutritive sucking (NNS) in neonates who underwent minor invasive procedures.

**Methods** A randomized, open trial was performed at the Haji Adam Malik Hospital from September to December 2009. Subjects were 96 healthy, term infants who received injections of either intramuscular hepatitis B immunization or vitamin K. Subjects were randomly allocated into two groups, those were the breast milk group (n=48) and the NNS group (n=48). Breast milk and NNS were given two minutes before the injection. The events were recorded by video recorder. Transcutaneous heart rate, oxygen saturation and crying times were recorded. Two observers used the premature infant pain profile (PIPP) scale to evaluate all subjects.

**Results** In the breast milk group, there was significant reduction in mean PIPP score (P=0.001) and mean crying time (P=0.03) compared to the NNS group. There were no significant differences in mean PIPP score and crying times between males and females (P=0.4 and P=0.5, respectively). However, there was a significantly lower mean PIPP score for vitamin K injection than for hepatitis B immunization (P=0.002), although mean crying times were not significantly different (P=0.06). We observed significantly less O<sub>2</sub> desaturation at 150 seconds post-injection in the breast milk group compared to that of the NNS group. However, there was no significant difference in heart rate between the two groups throughout the observation period.

**Conclusion** Breast milk administered before an invasive minor procedure effectively reduces pain in neonates. Breast milk administered to neonates prior to injection has reduced mean PIPP scores, crying times, and O<sub>2</sub> desaturation, compared to neonates who received NNS in the form of pacifiers. [Paediatr Indones. 2013;53:204-8].

**Keywords:** breast milk, non-nutritive sucking, pain, invasive minor procedure, neonates

Pain is defined by the *International Association for the Study of Pain* (IASP) as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. The definition also states that pain is always subjective and learned through experience related to injury in early life.<sup>1</sup>

Routine medical care of neonates includes blood sampling during the first day of life, as well as injection of vitamin K or vaccines. These procedures are performed in both healthy and ill neonates.<sup>2</sup> The ability of neonates to perceive and react to pain has been acknowledged.<sup>3</sup>

Neonates are incapable of verbal self-reporting, but they provide behavioral and physiological cues to indicate the presence of pain.<sup>4</sup> Treating pain in neonates is essential, both for ethical reasons and because pain can lead to decreased oxygenation, hemodynamic instability, and increased intracranial pressure. Interventions for treating pain may be pharmacologic or non-pharmacologic.<sup>3</sup> Non-pharmacologic pain management includes swaddling, facilitated tucking, nesting, holding, skin-to-skin

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contact, non-nutritive sucking (NNS), as well as consuming sucrose solutions or breastmilk.<sup>1,5</sup>

Evaluation of pain in neonates is difficult and relies on infant reactions, such as changes in behavior, modifications in physiological variables, or release of stress hormones to infer pain. Assessments that rely on various behavioral changes appear to be more accurate for pain evaluation in neonates.<sup>3</sup> A commonly used test is the *Premature Infant Pain Profile* (PIPP) scale.<sup>1</sup> The PIPP scale is a validated, 7-indicator scale for assessment of acute pain in preterm and term infants. PIPP uses measurements of gestational age, behavioral state, heart rate, oxygen saturation, and three facial actions (brow bulge, eye squeeze, and nasolabial furrow) to yield a pain score. The score ranges from 0 (no pain) to 21 (maximum pain).<sup>6</sup>

We aimed to compare the analgesic effect between orally administered breast milk vs. NNS in neonates who underwent minor invasive procedures.

## Methods

We conducted a randomized, controlled, open trial in Haji Adam Malik Hospital, Medan, Indonesia from September to December 2009. All neonates admitted to the special care nursery were recruited by consecutive sampling.

Neonates with normal gestational age, no contraindication to taking substances orally, and appearance, pulse, grimace, activity, respiration (APGAR) scores greater than 7 at the 1<sup>st</sup> and 5<sup>th</sup> minutes after birth were eligible for the study. We excluded neonates from high risk pregnancies, who were delivered from mothers under general anesthesia, from mothers with drug abuse problems, as well as those with congenital anomalies, and sepsis. Informed consent was obtained from subjects' parents or guardians. This study was approved by the Ethics Committee for Research at the University of North Sumatera.

The required sample size was estimated to be 48 neonates for each group. We collected the following demographic data from subjects: age, sex, type of injection, delivery mode, body weight, and APGAR scores. Neonates were randomly assigned to 2 groups, the breast milk group or the NNS group, using a random number table. They received injections, either intramuscular hepatitis B immunization or vitamin K,

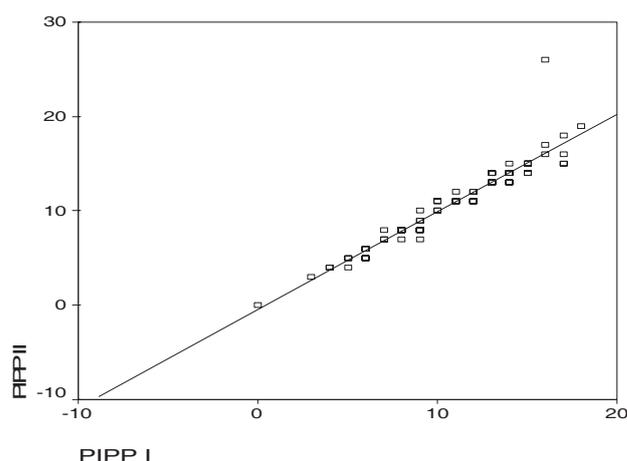
by the clinician in charge of the neonates. Two minutes before the injection, subjects received 2 mL of breast milk or a pacifier. Primary measurements included heart rate, oxygen saturation, PIPP scale score, and crying times. Infants were recorded on videotape.

The comparison of breast milk vs. NNS for reducing pain in neonates was analyzed by Chi square test, where numerical data was analyzed using independent T-test. Data was considered to be statistically significant for  $P < 0.05$  and 95% confidence intervals. Interobserver compatibility for PIPP scale evaluaters was analyzed by Kappa coefficient test for interrater agreement, with significance accepted to be between 0.8 to 1. The correlation between two observers was also analyzed with Pearson's correlation test. Data was processed and analyzed with SPSS version 13.0 software.

## Results

We evaluated 96 neonates who fulfilled the inclusion criteria. No subjects dropped out of the study. Each group consisted of 48 neonates. Subjects from both groups had similar baseline characteristics, including age, sex, type of injection, delivery mode, body weight, and APGAR scores (**Table 1**).

There was good agreement between the two observers for PIPP scale evaluations, as measured by Kappa coefficient, with  $K = 0.8$  (**Figure 1**).



**Figure 1.** PIPP scale measurements between the two observers by Kappa test

Pearson's correlation test revealed that  $r = 0.9$  ( $P=0.01$ ), indicating a strong interobserver correlation (Table 2).

We observed no significant differences in mean PIPP scores or mean crying times between males and females ( $P = 0.4$ ). Hepatitis B injections caused

higher pain level in terms of higher mean PIPP score than that of vitamin K injections, however, mean crying times did not significantly differ. Furthermore, neonates who received breast milk had significantly lower mean PIPP score and mean crying time than that of the NNS group (Table 3).

**Table 1.** Baseline characteristics of subjects

Characteristics	Breastmilk group (n=48)	NNS group (n=48)
Gender, n (%)		
Male	18 (37.5)	25 (52.1)
Female	30 (62.5)	23 (47.9)
Injection type, n (%)		
Vitamin K	20 (41.7)	15 (31.2)
Hepatitis B	28 (58.3)	33 (68.8)
Delivery mode, n (%)		
Vaginal	24 (50)	27 (56.3)
Caesarean	24 (50)	21 (43.7)
Mean gestational age (SD), weeks	36.3 (3.7)	36.9 (4.1)
Mean age (SD), days	1.9 (1.2)	1.7 (1.0)
Mean birth weight (SD), grams	3,134.6 (356.3)	3,165.4 (467.8)
Mean weight (SD), grams	3,115.6 (361.2)	3,133.8 (469.9)
Mean APGAR score at 1 <sup>st</sup> minute (SD)	8 (0.9)	8.4 (0.8)
Mean APGAR score at 5 <sup>th</sup> minute (SD)	9.8 (1.6)	10 (1.5)

**Table 2.** Compatibility in PIPP scale measurements between the two observers by Pearson's correlation test

PIPP I *		PIPP II **			Total
		Mild pain	Moderate pain	Severe pain	
PIPP I *	Mild Pain	15	0	0	15
	Moderate Pain	0	42	0	42
	Severe Pain	0	0	39	39
Total		15	42	39	96

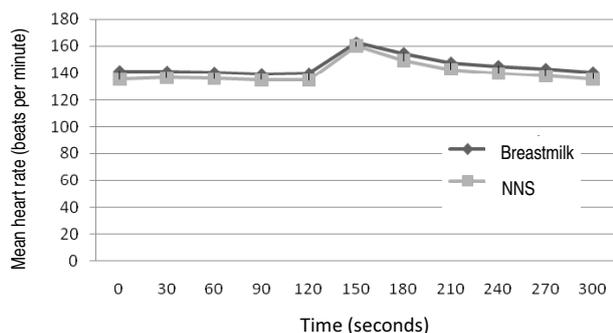
\* PIPP I : PIPP scoring by the first observer

\*\* PIPP II : PIPP scoring by the second observer

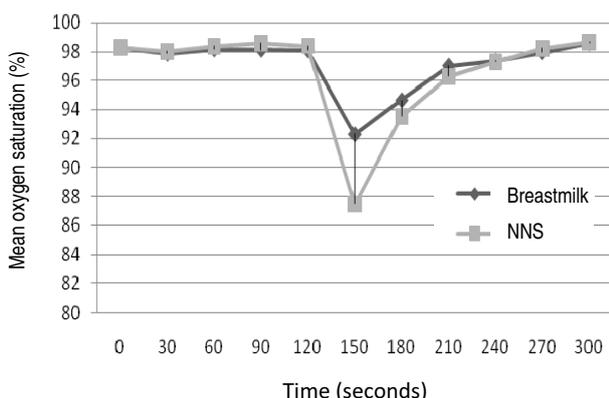
**Table 3.** PIPP scores and crying times according to breast milk vs. NNS, gender, and injection type

Groups	PIPP Score (SD)	Crying time (SD), min
Breast milk (n=48)	9.3 (3.6)	19.1 (17.1)
NNS (n=48)	12.5 (3.3)	29.4 (28.1)
P value	0.001	0.03
95% CI of differences	-14.6 to -1.8	-19.7 to -0.9
Male (n=43)	11.3 (3.8)	22.3 (23.6)
Female (n=53)	10.6 (3.9)	25.9 (23.7)
P value	0.4	0.5
95% CI of differences	-0.4 to -0.9	-4.1 to 0.9
Vitamin K (n=35)	9.3 (3.9)	18.3 (17.7)
Hepatitis B (n=61)	11.8 (3.5)	27.7 (26.0)
P value	0.002	0.06
95% CI of differences	-19.3 to -0.4	-18.3 to 0.6

We observed no significant differences in mean heart rates between the breast milk and NNS groups, at 150 seconds, or 30 seconds after a minor invasive procedure ( $P = 0.4$ ), by independent T-test (Figure 2). However, there was significantly higher oxygen saturation in the breast milk group than in the NNS group observed at 150 seconds ( $P = 0.001$ ), (Figure 3).



**Figure 2.** Mean heart rates of the two groups before and after injection



**Figure 3.** Mean oxygen saturation of the two groups before and after injection

## Discussion

In this study, we found no significant differences between males and females in PIPP scores or crying times, consistent with a previous study of similar results, although females had more expressive facial features than males.<sup>7</sup>

A significant change in a physiological parameter was the decreased oxygen saturation at 150 seconds post-injection in the NNS group. However, the lack

of a significant difference in heart rate between the breast milk and NNS groups may have been due to the insensitivity of the instrument used to measure heart rate. However, a study in Turkey revealed no significant differences in the breast milk group which was administered during the vaccination process, but this result was due to instrument insensitivity.<sup>8</sup> An Indian study compared neonates who received either expressed breast milk or a distilled water placebo in terms of their reactions to pain. The breast milk group had significantly lower heart rate,  $O_2$  desaturation and crying time than the placebo group.<sup>9</sup> As such, giving neonates breast milk before they undergo minor invasive procedures may be a simple and effective method for pain reduction.

A previous study reported no significant difference in crying time between groups who received either colostrum or NNS.<sup>10</sup> In contrast, we found that neonates who received breast milk had significantly decreased crying time than neonates in the NNS group. Previous studies also concluded that breast milk was effective for reducing pain in neonates undergoing minor invasive procedures, as shown by a spontaneous decreased crying time and heart rate.<sup>11-13</sup> This procedure can be recommended for reducing pain in neonates undergoing minor invasive procedures.<sup>14</sup>

We used the PIPP scale as it was shown to be valid scale according to the *International Pain Consensus*, and equal to other scales such as the *Neonatal Facial Coding System* (NFCS), the *Neonatal Infant Pain Scale* (NIPS), the *Pain Assessment in Neonates* (PAIN), the *Infant Body Coding System* (IBCS) and other pain assessment scales in neonates.<sup>15,16</sup>

A limitation of our study was that observers were not blinded to subjects' groups when they evaluated the video recordings. Nevertheless, high agreement among observers during their initial evaluations indicated objectivity. A second limitation was the insensitivity of the pulse oximeter in measuring heart rate. However, the PIPP scale showed a significant difference between the two groups, so this limitation did not lead to bias.

In conclusion, breast milk administered before an invasive minor procedure effectively reduces pain in neonates, in terms of lower PIPP score and crying time, as well as higher oxygen saturation, compared to non-nutritive sucking.

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