Behavioral Response to Pain in Drowsy and Sleeping Neonates: A Randomized Control Study

SHEILA S MATHAI, AMIT NARESH AND SATHYAJIT SAHU

From INHS Asvini (Naval Hospital), Colaba, Mumbai, India.

Correspondence to:
Dr Sheila S Mathai,
Professor and Head of Department (Pediatrics),
INHS Asvini (Naval Hospital),
Colaba, Mumbai 400 005, India.
sheilamathai@yahoo.com
Received: May 24, 2010;
Initial review: September 8, 2010;
Accepted: September 15, 2010.

In a randomized controlled design, 100 healthy, term neonates in the first week of life, undergoing heel prick for routine screening were randomized to receive a heel prick in either the drowsy/sleeping state or the awake (but not fussy or crying) state. 48 babies in sleeping or drowsy states and 47 in the awake states were analyzed. Infants in the drowsy/sleeping states scored significantly lower on the Neonatal Infant Pain Score (NIPS) (median score 5) at 30 seconds post stimulus compared with infants in higher states of alertness (median score 6). They also had a shorter total duration of cry (29.17sec ± 8.95 *vs* 32.67 sec ± 9.82). However, there was no difference in the NIPS score between the two groups at 45 seconds post stimulus. We concluded that babies in the drowsy/sleeping states of alertness at the time of a painful stimulus appear to show a less intense behavioral response to pain as compared to those in the awake state.

Key words: Neonate, Pain, Response, Sleep.

Published online 2011 Feb 28*. *PII: S097475591000430-2

Most pain scores commonly used in neonates do not take into consideration the state of alertness of the baby at the time of the painful stimulation and, if they do, they do not score an awake or sleeping state prior to stimulus differently [1]. Though there are a few studies that suggest that babies who are more alert manifest a more robust response to pain, these findings are not definite enough to make recommendations [2]. This study was carried out to determine if the initial state of alertness at the time of the noxious stimulus made a significant difference to the behavioral response to the pain of a heel prick in healthy, term neonates.

METHODS

One hundred healthy, term, appropriate for gestation age neonates, undergoing heel prick for newborn screening, were enrolled during the first week of life. All neonates were on breastfeeds and not on any medication or phototherapy. Infants less than 2000 grams, those with inherent neurological problems, those who had suffered birth asphyxia or had major congenital anomalies were excluded.

The sample size was based on the assumption that neonates would score between 3 and 7 on Neonatal Infant Pain Scale (NIPS) scores during a heel prick. To demonstrate a difference in the pain scores of at least 20% with a significance level of 5% and power of 80%, the sample size was calculated to be at least 45 in each of the two study groups. Hospital Ethics Committee approval was taken to conduct the study. Informed consent was taken from parents.

Simple randomization was done by random number tables and allocation was concealed by numbered envelopes. Neonates were randomized to receive the heel prick in either the awake or the asleep/drowsy state of alertness.

In Group A, heel prick was administered in drowsy/sleeping states of alertness (Brazelton States

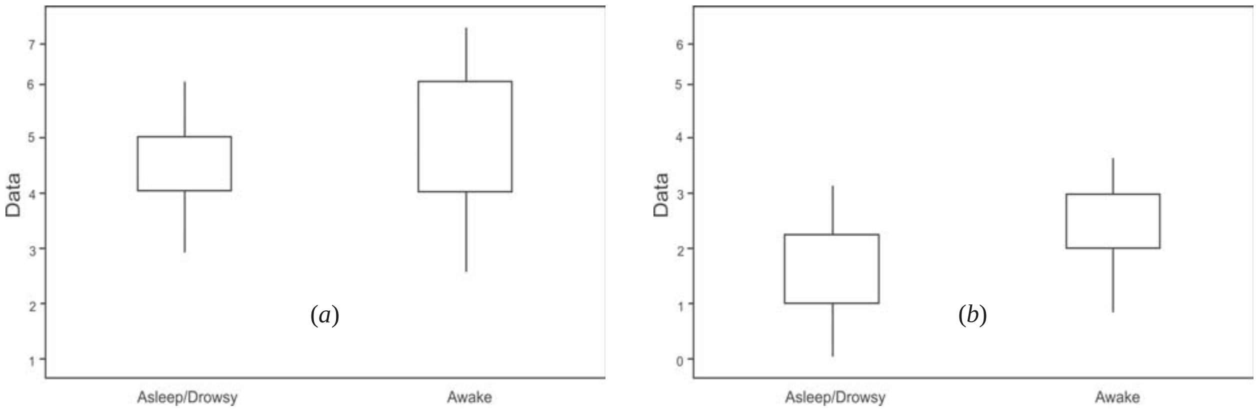

FIG. 1 *Box and Whisker plots showing difference between pain scores at (a) 30s and (b) 45s after stimulus in the two groups.*

1, 2 and 3) [3]. These states were determined to be present if the infants' eyes were completely or partially closed and there was no significant limb movement when unwrapped. In Group B, heel prick was administered in the quiet alert/active alert states of alertness (Brazelton States 4 and 5). These states was determined to be present if the infant's eyes were definitely open and there were at least some limb movement when unwrapped but the baby was not fussy or crying.

Each neonate was tested for response to pain by two observers. After unwrapping and gently cleaning the heel but before administering the painful stimulus, the first observer ensured that the neonate was in the correct state of alertness of the group allotted. Baseline scoring on Neonatal Infant Pain Scale (NIPS) [4] was done by this observer who then also administered the heel prick. This was done with a standard lancet so that a 3-4 mm drop of blood was visible on the skin without squeezing. If the blood was inadequate it was assumed that the heel prick was not deep enough and the test was abandoned. No infant was pricked twice. If the infant was not in the correct state of alertness within 30 minutes of being randomized, the test was abandoned. The first observer also noted the duration of cry with the help of a stopwatch. The time from the start of the cry to the first inspiration (first phase of cry) and total duration of crying were both recorded. The second observer, who was blinded to the group assignment, stood behind a screen till the heel prick was given. He then entered the test area and did the pain scoring at 30 and 45 seconds. Validity of measurement and internal consistency was done by randomly video-recording 10% of cases and rescoring by the same observers. Parametric data were recorded as mean and SD and Student's *t* test was used for comparison. Pain scores were analyzed as non-parametric data and medians were compared by Mann Whitney test.

RESULTS

After randomization, 5 children were excluded from analysis as they could not be tested satisfactorily due to various reasons including inability to get the baby into the correct state of alertness (3 cases) and inability give a deep enough heel prick to get an adequate sample (2 cases). Finally, 95 babies were analyzed (Group A: 48; Group B: 47).The two groups were equally matched in demographic parameters except that there were more boys than girls in the awake group (***Table* I**).

Awake infants (Group B) had higher median NIPS scores than Group A infants immediately before the stimulus (3 *vs* 2) and 30 seconds post stimulus (6 *vs* 5). However, at 45 seconds there was no difference in the median scores in the two groups (2 in both groups). Total duration of cry was found to be lesser in babies who were asleep or drowsy at the time of stimulus (29.2±8.95s *vs* 32.7±9.82s). However the duration of first phase of cry (time from onset of cry to the first inspiration) was longer in sleeping or drowsy babies as compared to awake infants (4.1±1.24s *vs* 2.9±1.18s).

TABLE I DEMOGRAPHIC DATA OF STUDY GROUP

Parameters	Asleep /Drowsy (*n* = 48)	Awake (*n* = 47)
Male: Female	1.04:1	1.23:1
Birth weight (kg),*	2.93 (0.35)	2.92 (0.46)
Gestational age (wks),*	38.65 (1.06)	38.83 (1.04)
Age at study (hrs),*	46.33 (35.67)	38.39 (34.86)
Time from last feed (min),*	31.56 (24.19)	26.85 (30.58)
Type of delivery (vaginal/LSCS)	33/15	34/13

** Values in mean (SD)*

DISCUSSION

It has been observed that the state of alertness at the time of a painful stimulus may affect pain scores in neonates. A few studies have shown that more highly aroused, awake infants appear to respond more intensely to pain as compared with sleepy infants [5, 6]. The NIPS score is one of the few scores that takes the state of alertness of the baby into consideration The baby is scored 0 if he is either asleep or awake and 1 if he is 'fussy' Both sleep and awake are scored the same [4]. Some workers have shown that restraining a baby during administration of a painful stimulus results in a decreased pain score and that handling infants before a painful stimulus results in infants having a higher score [7]. However, to date, there are no recommendations regarding consideration of the state of alertness at the time of the painful stimulus when assessing pain by behavioral scores. This may lead to fallacious interpretation of results when assessing the effects of pain relieving strategies in neonates. Sleepy or drowsy babies may be interpreted as experiencing less pain as compared to alert ones when exposed to the same intensity of painful stimulus, This may lead to bias in the assessment of the effect of interventions for pain [8].

Our study shows that the state of alertness at the time of the painful stimulus made a significant difference in the behavioral response to heel-prick in term neonates. This was collaborated by the duration of cry which was also different in the different states. The duration of first phase of cry (*i.e.* from the start of crying to the first inspiration) which was longer in sleeping or drowsy babies could suggest irritation at being woken up rather than actual pain.

We recommend that all interventional studies using only behavioral pain scores should take into consideration the state of alertness at the time of the painful stimulus, when interpreting pain in neonates.

WHAT THIS STUDY ADDS?

- Lower states of alertness appear to result in lower behavioral pain scores in neonates.

Acknowledgment: Mr Ranjan Samanta, BSc (Economics and Statistics) for statistical analysis of data.
Contributors: SSM conceived and designed the study and revised the manuscript for important intellectual content. She will act as guarantor of the study. AN, and SS collected data and assisted in drafting and analysis. The final manuscript has been approved by all authors.
Funding: None. *Competing interests*: None stated.

REFERENCES

1. Duhn LJ, Medves MJ. Systematic integrative review of infant pain assessment tools. Adv Neonatal Care. 2004;4:2004.
2. Lawrence J, Alcock D, McGrath P, Kay J, MacMurray SB, Dulberg C. The development of a tool to assess neonatal pain.Neonatal Netw. 1993;12:59-66.
3. Brazelton TB, Nugent JK.The Neurobehavioural Assessment Scale. 3rd Edition. London: MacKeith Press.1995.
4. Lawrence J, Alcock D, McGrath P, Kay J, MacMurray SB, Dulberg C. The development of a tool to assess neonatal pain. Neonatal Netw. 1993;12:59-6.
5. Grunau RVE, Craig KD. Pain expression in neonates: facial action and cry. Pain. 1987; 28:395-410.
6. William AL, Khattak AZ, Garza C, Lasky RE. The behavioral pain response to heelstick in preterm neonates studied longitudinally: Description, development, determinants, and components. Early Human Dev. 2009;85:369-74.
7. Porter FL, Wolf CM, Miller JP. The effect of handling and immobilization on the response to acute pain in newborn infants. Pediatrics. 1998;102:1383-9.
8. Weissman A, Aranovitch M, Blaze S, Zimmer EZ. Heel-lancing in newborns: behavioral and spectral analysis assessment of pain control measures. Pediatrics. 2009;124:e920-8.