Clinical, Physiologic, and Biologic Impact of Environmental and Behavioral Interventions in Neonates During a Routine Nursing Procedure

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Abstract: **The aim of this randomized crossover study was to evaluate the impact of environmental and behavioral interventions (EBI) on behavioral, physiologic, and biologic stress response during a weighing procedure in neonates. Three groups of 15 neonates included (A) gestational age (GA), ≤32 weeks; (B) GA, 32 weeks, 1 day to 36 weeks, 6 days; and (C) GA, ≥37 weeks. Each neonate experienced 2 weighing procedures with and without EBI. Pain was evaluated by using the Neonatal Infant Pain Scale (NIPS) and the Neonatal Pain and Discomfort Scale (EDIN). Heart rate and oxygen saturation were recorded. Salivary samples were obtained for cortisol assay. Cerebral tissue oxygenation index (TOI) was recorded with near-infrared spectroscopy. A significant decrease of NIPS and EDIN was observed with EBI versus control. Mean heart rate was lower with EBI. No difference in cortisol level changes was observed. For groups A and B, a trend of increased TOI was observed with EBI. We concluded that EBI during a nursing procedure provides a decrease in pain scores in preterm and term neonates with changes in heart rate.**

Perspective: ***This study evaluates the impact of combined environmental and behavioral interventions on pain responses in neonates during a weighing procedure. The results indicate a decrease in behavioral pain scores and in heart rate for preterm and term neonates and a trend in increased brain oxygenation depending on gestational age.***

Key words: *Procedural pain, infant, neonate, developmental care, cortisol, NIDCAP.*

Perinatal brain vulnerability increases the risks of early painful events.[4] Repeated painful procedures in hospitalized neonates might lead to short-term and long-term consequences.[20,26] Allodynia defined by the International Association for Study of Pain as "pain due to a stimulus that does not normally provoke pain"[23] has been demonstrated in animal models of early development. Fitzgerald and de Lima[17] suggested that the same mechanism could occur in neonates undergoing intensive care. Porter and al[31] reported an increase in neonatal pain response with handling and immobilization. It can be hypothesized that noninvasive routine nursing procedures in neonatal intensive care units (NICUs) can provoke pain behaviors.[15]

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Treating procedural pain in NICU is now a widely accepted goal. Pharmacologic strategies including opioids and sedatives cannot be routinely used for noninvasive procedures because some concerns exist about their potential side effects.[5] Environmental and behavioral interventions (EBI), commonly called nonpharmacologic strategies, are of interest alone or in combination with pharmacologic treatment.[16] These strategies include kangaroo care, swaddling, maintaining flexed position, rocking, non-nutritive sucking, and touch. Most of the studies on EBI have been conducted in full-term or near-term neonates, with single intervention, for single invasive procedures such as a heel stick.[13,24] Als et al[1] have developed and tested a family-centered, developmentally supportive approach to newborn intensive care referred to as Newborn Individualized Developmental Care and Assessment Program (NIDCAP). Heller et al[22] have reported a decrease in amount of sedatives used in severely ill preterm neonates with NIDCAP as compared with control. A recent trial demonstrated a decrease in physiologic and behavioral responses to diaper change in preterm neonates by using EBI in a NIDCAP-reliable NICU.[33]

The main purpose of this study was to determine the impact of combined EBI on physiologic, behavioral, and biologic responses in preterm and full-term infants dur-

Table 1. Clinical Characteristics of the Study Population (Mean ± Standard Deviation)

	Group A (n = 15)	*Group B (n = 15)*	*Group C (n = 15)*
GA (wk)	30.1 ± 1	34.2 ± 1	39.1 ± 1
Birth weight (g)	1232 ± 243	2140 ± 481	3458 ± 403
Antenatal steroids (n)	14	5	0
Surfactant (number of subjects)	9	1	0
Indomethacin (n)	2	0	0
Caffeine (n)	15	1	0
Age at inclusion (days)	4.8 ± 1.85	3.4 ± 1.64	3.13 ± 1.68
CPAP (n)	11	3	0
CPAP during study procedure (n)	4	2	0
Invasive procedures before inclusion (n)	7.7 ± 2.15	6 ± 2.87	6.33 ± 2.9
Weighing procedures before inclusion (n)	1.73 ± 0.7	1.66 ± 0.6	2.2 ± 1

Group A, GA ≤32 wk; group B, GA 32 wk, 1 day to 36 wk, 6 days; group C, GA ≥37 wk.

Abbreviations: GA, gestational age; CPAP, continuous positive airway pressure.

ing a weighing procedure. We also considered the impact on brain oxygenation by using near-infrared spectroscopy (NIRS).

Methods

Subjects

The study was conducted in a NIDCAP-reliable NICU (NIDCAP training level II; National NIDCAP Training Center, Boston, Mass) at a university hospital. Forty-five patients (18 female and 27 male) younger than 7 days old were studied (Table 1). Three groups were formed according to gestational age (GA): group A with GA ≤32 weeks, group B with GA 32 weeks, 1 day to 36 weeks, 6 days, and group C with GA ≥37 weeks.

Criteria for exclusion were treatment with muscle relaxant, sedative, antiepileptic, or analgesic drug (except sucrose) during the last 24 hours, a congenital defect, a neurologic abnormality including convulsion, intraventricular hemorrhage grade higher than II according to the Papile scale, and periventricular leukomalacia. None received postnatal steroids. This study was approved by the Institutional Research Ethics Committee, and written informed consent from parents was obtained for each patient.

Procedure

All neonates were observed during a weighing procedure. Each neonate was his own control (randomized crossover design) and was weighed twice at 24-hour intervals at the same time of the day, once with EBI and once without. Ordering of conditions was determined randomly by a computer-generated program. The weighing procedure was performed by the nurse in charge of the neonate at the time of the procedure. Some of the nurses were certified to use the NIDCAP assessment tool (NIDCAP training level I; National NIDCAP Training Center). All nurses have received basic education on the NIDCAP approach including the use of EBI. According to the NIDCAP model, EBI included attenuated noise and light with closed doors and covered incubator, lateral posture with head, back, and feet contacting supportive bedding, and opportunity for grasping or sucking. Before the weighing, the neonate was wrapped up, allowing a continuous postural support during transport out of the incubator and during the weighing. The control weighing was performed without specific protection for light or noise, supine posture without swaddling, or any postural support.

Fig 1 summarizes the experimental sequence.

Measures

Behavioral Indices of Pain

Two pain scales were used. The Neonatal Infant Pain Scale (NIPS) developed by Lawrence,[25] ranging from 0 to 7, integrates one physiologic parameter (breathing patterns) and different behavioral components: facial expression, limb activity, cry and state of arousal. Inter-rater reliability and internal consistency reported by Lawrence ranged from 0.92 to 0.97 and 0.87 to 0.95, respectively. The Neonatal Pain and Discomfort Scale (EDIN), a behavioral pain and stress scale developed by Debillon and al,[14] ranging from 0 to 15, was used to evaluate chronic pain and stress. Inter-rater reliability and internal consistency reported by Debillon et al ranged from 0.59 to 0.74 and 0.86 to 0.94, respectively.

The NIPS and EDIN were assessed 2 minutes before and 5 and 30 minutes after the weighing procedure. The NIPS was also assessed during weighing. To avoid any interference with the nurse, only 3 items from the EDIN (facial activity, body movements, and quality of sleep) were scored. Video recordings were performed 2 minutes 30 seconds before, during, and until 5 minutes after the weighing and then 30 minutes after the weighing during 1 minute by using a camera (JVC compact VHS Camcorder, JVC, Japan). Pain scores were independently assessed by 2 coders by using the Video-pro Observer (Noldus, Wageningen, The Netherlands), allowing flashback and slowing down. Individual scorings were compared. Inter-rater reliability was 0.6 and 0.55 for NIPS and EDIN, respectively. A third joint coding was performed for scores with difference higher than 1.

Physiologic Measures

Heart rate and transcutaneous oxygen saturation were continuously monitored (Hewlett-Packard HP M2360A or HP viridia 24C or Agilent monitor M3046A, Palo Alto, Calif). These 2 parameters were collected 2 minutes before the weighing, just before and after weighing, and 5 and 30 minutes after the weighing.