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ORIGINAL ARTICLE

Postural support improves distress and pain during diaper change in preterm infants

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Objective: To determine the effects of a postural support protocol on the physiological and behavioral stability of preterm infants while undergoing a diaper change.

Study Design: Forty-seven newborns having a birth weight $\leqslant$2000 g and gestational age $\leqslant$35 weeks were included in this randomized, crossover clinical trial in a Neonatology Intensive Care Unit. The infants were observed as his or her own control and evaluated with and without the use of the proposed intervention, which was positioning the baby in a nest produced with rolled-up towels. During the observations, as control, the care model used by the unit was considered.

Result: All babies displayed increased distress and pain scores during diaper changes. This was significantly less for babies nested compared with non-nested babies ($P<0.0001$).

Conclusion: Diaper change is a distressing procedure for preterm infants. Providing postural support during diaper changes reduces the signs of distress and pain.
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Introduction

Developmental care in Neonatal Intensive Care Unit (NICU) is becoming a worldwide standard. This concept is a comprehensive approach in which caregiving is based on the individual behavior of the infant and refers to the impact of the NICU on the infant's environment and their family.[1]

Aspects of developmental care include handling and positioning of the infant. Observations of neonatal unit procedures have shown that a preterm baby, when handled for reasons such as diaper change, hygiene, feeding, or for diagnostic or therapeutic procedures, can react negatively for several minutes until it becomes exhausted. This results in an unnecessary expenditure of energy that can, at a later time, turn into physiological (bradycardia, tachycardia, drop in the O_2 saturation and apnea) or behavioral (flaccidity, fatigue and difficulty in sleeping) instability, and signs of distress and pain.[1–6] Use of rolled-up towels or sheets have been proposed to form a 'nest' in order to provide postural, behavioral and physiological stability to the newborn.[2–6]

A recent meta-analysis evaluated the effects of many elements of developmental care and concluded that more consistent effects of specific interventions, such as a postural support, on short- and long-term clinical outcomes were required.[7]

The objective of the present study was to determine the effects of postural support on the physiological and behavioral stability of preterm infants when undergoing a diaper change. The hypothetical basis is that a postural support (nest) provides more physiological stability and less distress and pain reactions during routine care.

Methods

This was a randomized, crossover clinical trial, in which each baby was observed as his or her own control. All of the babies hospitalized in the NICU of Hospital de Clínicas in Porto Alegre–Brazil, between April to October, 2004 with a birth weight $\leqslant$2000 g and gestational age $\leqslant$35 weeks, were eligible for the study, but were excluded if the following criteria were met: (1) sedation; (2) cardiovascular disorders; (3) probable transfer out of the NICU; (4) born at another facility and admitted to our NICU over 24 h of age; (5) serious malformations and (6) evidence of intrauterine infection.

Group assignments were made sequentially by a randomized series of sequential, sealed, opaque envelopes, labeled on their outside with numbers from a table of random numbers. Half of the babies were randomly selected to group 1; they received the intervention on the first day, leaving the second day as a control, which was repeated successively for 6 days. The other half, group 2

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Figure 1 Diaper change with nest (image authorized by parents).

Figure 2 Diaper change without nest (image authorized by parents).

received the control and intervention in an inverse sequence. All babies were observed placed in the incubator during a single diaper change in each way (with nest and without nest), on alternate days and were evaluated exclusively by the same chosen by sort evaluator. The evaluations could be made at any time during 24 h.

All babies were evaluated with and without the use of the proposed intervention, which was positioning the baby in a slightly flexed posture, preferably in a side-lying position with the limbs directed to the midline and set in a 'nest', earlier produced with rolled-up towels, in order to provide support all around the baby's body: head, back, limbs and feet. (Figure 1) On the 'nest' day, this postural support was used as regular care throughout the day (i.e. mechanical ventilation, phototherapy, use of catheter etc). The exclusion criteria were chosen in order to avoid bias if the nesting condition could not be maintained for the entire day. Despite the use of prophylactic or early exogenous surfactants in this hospital service, respiratory distress syndrome was diagnosed in $\sim$35% of the studied babies.

A training course was provided to the professionals involved in the daily care of the hospitalized babies in the neonatal unit (nurses and nursing technicians) in order to be certain that they understood and could execute and maintain the postural support ('nest') procedure during their routine tasks, and to provide a same model of diaper change for both groups, which means performing diapering in side-lying position for all babies, with and without the use of the proposed intervention. The diaper change in side-lying position was chosen earlier because of other research indicating that this position provided the best stability for preterm infants.[8] The routine of the unit was to change diapers 10 to 15 min before nursing, which was occurred every 2 or 3 h.

During the observations, the control condition was the care model usually used within the unit. This model utilized the side-lying or prone position with limbs very close to their body. However, the routine care model did not use postural support or supportive nest (Figure 2). At the time of this study, no developmental care aspects besides minimal postural support had been implemented.

Nine volunteer evaluators were trained by the main investigator, who herself was trained in an official course of developmental care in preterm infants in Brazil.[8] The inter-observer reliability among the evaluators and the main investigator was validated using the κ coefficient, which presented results between 0.7 and 1.00 ($P<0.05$).

An observation sheet was designed to record the effects of this postural support on the physiological and behavioral stability of the babies 5 minutes before, immediately after, 5 minutes after, and 10 minutes after the diapers were changed.

- Heart rate and arterial oxygen saturation using the equipment available at the bedside (Dixtal Biomédica; Brazil).
- Distress score stands for the presence or absence of specific movements (airplane, salute, finger splay, sitting on air and arch) as described by Als[3] and Holsti.[9]
- Pain scores stands for the presence or absence of 8 facial movements (brow bulge, eye squeeze, naso-labial furrow, open lips, grimace, tongue protrusion, chin quiver and lip purse) according to the Neonatal Facial Coding System.[10,11]

Each movement was coded as 1/0 (occurred/did not occur) during each event in both scores.

Observations during the exact moment of the diapering are not feasible because of the difficult evaluation of the babies during diaper change in side-lying position and due to the caregiver movements for hygiene. However, the observations were made immediately after diaper change in order to obtain the maximum information about the babies' reaction to the procedure.

Statistical analysis

A sample size of 48 babies was calculated in order to obtain a difference of 30% in relation to the signs of distress, with a statistical power of 80% and statistical significance of $P<0.05$. The characteristics of the babies evaluated and the babies not included were compared by means of the Student's *t*-Test for independent samples and analysis of variance followed by test of least significant differences (LSD). The baseline data of the babies studied were compared using the Student's *t*-Test for pair-wise samples.

The analysis to compare the results related to the physiological and behavioral stability between groups were summarized in scores by calculating the area under the curve and realized taking into

Table 1 Demographic characteristics during evaluation

	Group 1 N = *30*			*Group 2* N = *17*		
	Period 1 (with nest)	*Period 2 (without nest)*		*Period 1 (without nest)*	*Period 2 (with nest)*	P
Evaluation weight (g)	1369 ± 275	1408 ± 289	0.59	1484 ± 304	1520 ± 298	0.73
Age in days at evaluation	10 ± 8	12.5 ± 7.8	0.24	10.8 ± 10	13.5 ± 10	0.44

Data are presented as mean ± s.d.

Table 2 Results of the randomized crossover study comparing the behavior of preterm infants with or without the use of a nest during diaper change

	Group 1 N = *30*		*Group 2* N = *17*				
	Period 1 (with nest)	*Period 2 (without nest)*	*Period 1 (without nest)*	*Period 2 (with nest)*	P†	P‡	P§
HR	152 ± 14	153 ± 12	144 ± 14	155 ± 12	0.14	0.22	0.012
O_2 Sat	96 ± 2	96 ± 1	96 ± 2	96 ± 2	0.41	0.72	0.33
Distress score	3.7 ± 3.1	5.0 ± 3.9	5.2 ± 3.2	1.8 ± 1.7	0.07	0.19	<0.0001
Pain score	3.3 ± 3.9	5.8 ± 5.1	5.1 ± 4.7	1.6 ± 2.7	0.56	0.23	<0.0001

Abbreviations: HR, heart rate (beats per minute); O_2 Sat, oxygen saturation (%).
†Period effect
‡Period treatment interaction
§Treatment effect
Distress with a score of 0 to 5
Pain with a score of 0 to 8
Data are presented as mean ± s.d.

account the characteristics of a randomized, crossover study, consisting of a series of three Student's *t*-Tests for two samples, according to Altman, 1994.[12] First, we tested the influence of the study period on the results (period effect); second, we tested the influence of the first intervention on a second intervention (carryover effect) and finally, if we did not find the influence of the study period or of the carryover effect, we tested the intervention effect. Data were analyzed with SPSS software, version 12.

Ethics

This study was approved by the Institutional Research Ethics Committee, and written informed consent was obtained from all parents of the studied patients.

Results

During the study period, 94 babies were identified with birth weight ⩽2000 g and gestational age ⩽35 weeks. However, 20 of them met our exclusion criteria (14 with evidence of intrauterine infection, 4 with serious malformations and 2 arrived in our NICU >24 h after birth) and 23 were not included for other causes (11 died before inclusion, 4 were transferred, for 6 the informed consent was not available, for 1 the parents refused to consent and 1 was injured at birth). Excluding the babies who died, birth weight and gestational age did not differ between the babies included and not included (birth weight $P = 0.688$ and gestational age $P = 0.482$).

Of the 51 remaining eligible babies, there were four loses, three due to worsening clinical condition and one because of a room change, which made it impossible to carry out the evaluations in both groups as established earlier. Therefore, only complete evaluations were considered, with a total of 47 babies and 94 evaluations. The 47 babies evaluated presented a mean of 1467 ± 340 g of weight at birth, a gestational age of 32 ± 2 weeks and 10 days of life when the evaluation began. There was no difference between the groups in relation to weight and days of life during the evaluations (Table 1). After randomization, 30 babies were allocated to group 1 (first evaluated in the nest) and 17 babies were allocated to group 2 in an inverse sequence. Each evaluator observed an average of 5 ± 2 babies. The evaluation was performed daily in 87% of the cases.

The distress and pain scores associated with diaper change was significantly less during the nested condition compared with the non-nested ($P<0.0001$). The heart rate was significantly higher when nested ($P = 0.012$) and without change in oxygen saturation (Table 2).

Discussion

Diaper change seems a distressing procedure for preterm infants and the results of this study point to a favorable effect of the

nesting intervention. The lower Facial Pain Score by Neonatal Facial Coding System and Distress Score observed in the nested condition may be attributable to self-regulation when nested, due to postural stability, reduction of energy expenditure and easy movement of their limbs to the midline.[13] The observed difference in mean heart rate frequency needs more investigation as both groups presented physiological levels expected for this age.

One randomized, crossover study[5] investigated the behavioral reaction of preterm infants during diaper change. Physiological responses (heart rate and oxygen saturation) and behavioral reactions (Preterm Infant Pain Profile and Echelle Doleur et Inconfort) were observed with or without Newborn Individualized Developmental Care and Assessment Program. Despite an apparent similar study design, as the design details are not presented, comparison between that trial and our trial is difficult. As for the physiological parameters, the study referred the reduction of bradycardia and hypoxia in the Newborn Individualized Developmental Care and Assessment Program group. We observed no episodes of bradycardia and hypoxia in either condition, but during nesting we observed faster heart rate. However, as for the pain assessment scales, the results using the Preterm Infant Pain Profile and Echelle Doleur et Inconfort scales[5] are similar to those found in the present study using the Neonatal Facial Coding System scale. Sizun *et al*.[5] and our current results are both consistent with the theoretical basis of developmental care interventions in preterm newborn infants.

Another prospective trial[14] compared crying responses, neurobehavioral activity and physiologic changes during retinopathy of prematurity screening in 38 preterm babies at 31 weeks of post-menstrual age (19 nested and 19 non-nested). During the eye examination all babies displayed increased neurobehavioral activity and crying, but the distress was significantly less for the nested group ($P<0.01$). Similarly, the analysis in our study showed reduction of Distress and Pain Scores when the babies were nested during diaper change.

This trial had at least two limitations; there could be no blinding because the infants when in the intervention group had nesting that was evident to the evaluator. An additional limitation of the study is the short-term nature of the outcomes.

The results of this trial indicate that diaper changes cause significant distress in preterm infants despite this not being considered as stressful. It will be important to investigate whether the improvements found in this short-term experience will be maintained over a more extended period.

We conclude that nesting in a postural support promotes physiological and behavioral stability in premature infants.

Conflict of interest

The authors declare no conflict of interest.

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