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What Did the Neonatal Integrative Developmental Care Model and Routine Developmental Care Affect on Stress of Premature Babies?

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Abstract

BACKGROUND: Neonatal integrative developmental care model (NIDCM) is a holistic model of premature baby care referring to seven basic neuroprotective developmental cares (DCs) by involving the family.

AIM: This study aimed to assess the effect of the application of NIDCM on the stress response of premature babies.

METHODS: The research design used was quasi-experimental with a non-equivalent control group pre- and post-test. The study was conducted in the neonatal care room of Dr. Wahidin Sudirohusodo Makassar Hospital from January 2020 to April 2021. The sample was 76 subjects consisting of 38 premature babies (19 controls and 19 interventions) and 38 mothers (19 controls and 19 interventions). The collected samples were taken to the Medical Research Laboratory of Universitas Hasanuddin (HUMRC) for testing. Furthermore, baby stress was assessed from salivary cortisol levels by enzyme linked immunosorbent assay. In addition, the effect of initial cortisol, final cortisol, and birth weight on changes in salivary cortisol in premature babies was determined using the Chi-square test.

RESULTS: Neither NIDCM intervention nor routine DC has been shown to descriptive statistically decrease the stress response of premature babies in the neonatal care room, some of which are even increased. However, specifically in premature babies with a birth weight of <1800 g, NIDCM showed a better effect in lowering cortisol after treatment than regular DC.

CONCLUSIONS: The application of NIDCM intervention reduces the stressor felt by the babies in the neonatal care room, besides the condition of babies with a birth weight of fewer than 1800 g needs special attention with the NIDCM intervention.

Introduction

Premature babies are a group of babies who are at high risk of experiencing morbidity and mortality. This occurs, among others, due to respiratory disorders, and susceptibility to infection because the body's defense system is immature which is further exacerbated by an environment that does not support baby care during hospitalization [1]. Statistical data show that Indonesia ranks fifth as the country with the most cases of preterm birth. The total population of Indonesia is around 225 million people the annual percentage of preterm birth reaches 675,700 cases from around 4.5 million baby births per year [2]. In South Sulawesi, the percentage of low birth weight (LBW) in 2010 was 1.73% of live births then it increased to 2.35% in 2011. Furthermore, in 2012, it increased to 3.12% but in 2013, it decreased to 2.94%. However, in 2014, it increased to 3.02%, and in 2015, it increased again to 8.13% of live births [3].

Premature babies who were admitted to the neonatal care unit of Dr. Wahidin Sudirohusodo Hospital in 2017 were as many as 229 babies with a death rate of 21.8%. Meanwhile, in 2018, there were 195 LBW admitted and treated in the neonatal care room with a death rate of 13.3% [4]. Premature babies who experience stress have an impact on behavioral changes (facial expressions, body movements, and crying habits), metabolism changes (fat, protein, and glucose), physiological changes (oxygen saturation, pulse rate, respiration, and temperature), and hormonal changes with increasing levels of cortisol and catecholamines. These changes can cause hypoxemia, apnea, increased pulse rate, and decreased oxygen saturation [5], [6].

Babies who suffer from critical illness are physiologically stressed due to that illness, therapeutic procedures performed, or environmental exposures. In this case, the baby's body naturally tries to maintain homeostasis against stress. Stress in babies can be seen from behavioral changes including physiological responses and hormonal responses. Activation of the hypothalamic pituitary adrenal (HPA) axis is an important component of a patient's adaptation to stressful situations in maintaining body homeostasis. The final response of the HPA axis to stress is characterized by the release of cortisol from the adrenal cortex [7].

Strategies in managing the intensive baby care environment are needed to minimize stress resulting from excessive environmental stimuli. One strategy that can be developed is developmental care (DC)-care that can facilitate baby development through adequate environmental management that will increase the baby physiological stability and reduce baby stress [8]. DC includes the adjustment of babies' care and ability that involve their family. This aims to improve the baby's developmental potential through managing the intensive baby care environment. DC is applied by observing babies' behavioral responses, increasing their physiological stability, improving their sleep patterns, promoting their growth and development, and reducing environmental and harmful stimuli to them [9].

Studies on DC have been carried out in Indonesia; however, they are limited to each part of the seven basic DCs so that it has not been integrated into a unified concept. Thus, this is considered to be a novelty from this study by looking at the application of DC for premature babies which is integrated with the family (role) in the concept of the neonatal integrative DC model (NIDCM). This study aimed to assess the effect of the NIDCM intervention versus routine DC on premature babies' stress (changes in cortisol levels).

Materials and Methods

The research design used was quasi-experimental with a non-equivalent control group pre- and post-test. The difference was only in the sample allocation for the NIDCM intervention group and the routine DC (DC) group (Figure 1).

The study was conducted in the neonatal care room: Level IIA, IIB, and III of Dr. Wahidin Sudirohusodo Hospital, Makassar, from January 2020 to April 2021.

Sample was done using a consecutive sampling technique with inclusion criteria, namely, babies born with a gestational age of <37 weeks, babies aged 1–7 days, mothers of babies, parents' approval to have their babies included in the study sample, and signed consent form. Meanwhile, the exclusion criteria were babies with intraventricular hemorrhage, congenital abnormalities, and babies who died during the study. The study sample of 76 subjects was calculated based on the formula for the different sample sizes of the 2 mean paired groups with the minimum number of samples required was 11 pairs of mothers and their premature babies in the control group and the intervention group. To anticipate dropout, it was the multiplied by 70% of the minimum number of samples. The total sample was 76 subjects consisting of 38 premature babies (19 controls and 19 interventions) and 38 mothers (19 controls and 19 interventions). Random allocation was done during the selection the control and intervention groups. The procedure for identifying baby stress was carried out by collecting samples of salivary cortisol in babies, with the following stages: (a) Salivary cortisol samples were taken between the morning and evening before the baby was given any treatment (drinking and changing diapers) when the baby was awake. (b) Samples were taken using a Salimetrics Oral Swab (SOS) which was placed under the tongue for 1–2 min. (c) The baby is allowed to chew or suck on the swab for 30–60 s, followed by washing away any saliva that has accumulated in the mouth or on the face. (d) The SOS was put into a swab storage tube I containing NaCl and then tightly closed. (e) The SOS tube was labeled with the identity and type of examination. (f) Tubes were stored in a refrigerator at a temperature of −200°C (during the collection and before being frozen, samples should be stored at a cold temperature of 2–8°C). (g) The collected samples were taken to the Medical Research Laboratory of Universitas Hasanuddin (HUMRC) for testing.

The instrument for measuring baby stress was assessed from salivary cortisol levels as measured by enzyme-linked immunosorbent assay (ELISA). The unit used was microgram per deciliter (μg/dl). Saliva collection to measure cortisol levels was done with an initial collection span of ≥1–7 days and a final collection span of 7–10 days after the application of routine DC and NIDCM intervention.

The normality test used was the Shapiro–Wilk test because the number of samples was <30 people in each group. The data are considered normally distributed if $p > 0.05$ so the bivariate analysis is carried out using a parametric test. However, if the variable is not normally distributed or $p < 0.05$, the bivariate analysis is carried out using a non-parametric test [10].

The characteristics of the dependent variable, namely, the salivary cortisol of premature babies in this study was measured before and after the seven basic neuroprotective DCs, by involving the family at the time of first admission to the hospital and on the discharge from the hospital. Data analysis was done using Wilcoxon test for data with no normal distribution and paired sample t-test for data with normal distribution.

Bivariate analysis was done to determine the effect of initial cortisol, final cortisol, and birth weight on changes in salivary cortisol in premature babies using the Chi-square test to test the hypothesis (alpha 0.05). This study has been passed for ethical clearance, with the following criteria: Approval from parents and pediatricians who were responsible for the premature baby; no invasive procedures were received by the premature baby during the study; no invasive intervention was performed on the premature baby related to NIDCM; and cortisol levels examination of the premature baby was taken from the baby's saliva for examination in the Research Laboratory of FK-RS of Universitas Hasanuddin.

Results

The results of the univariate analysis are shown in Table 1, which among the 34 respondents, most are female by 27 people (79.4%) and only 7 respondents (20.6%) are male. Most of the respondents, 25 people (73.5%), used hypertension medication, with each respondent's lifestyle was 17 people (50%) having a good lifestyle, and most of the respondents experiencing moderate stress by 27 (79.4%) and mild stress was experienced by 7 people (20.6%).

Table 1: Characteristics of research subjects

Characteristics	Control (n = 19)	Intervention (n = 19)	p-value*
Mother			
Age, median (min-max)	32 (15–39)	27 (18–40)	0.518
Parity			
Primipara	10 (52.6%)	6 (31.6%)	0.333
Multipara	9 (47.4%)	13 (68.4%)	
Education			
Low	10 (52.6%)	1 (5.3%)	0.148
Moderate	2 (10.5%)	10 (52.6%)	
High	7 (36.8%)	8 (42.1%)	
Experience of having a premature baby			
Yes	1 (5.3%)	2 (10.5%)	0.560
No	18 (94.7%)	17 (89.5%)	
Type of birth			
SC/using tools	10 (52.6%)	13 (68.4%)	0.333
Normal vaginal	9 (47.4%)	6 (31.6%)	
Baby			
Gender			
Male	12 (63.2%)	9 (47.5%)	0.524
Female	7 (36.8%)	10 (52.6%)	
Gestational age, median (min-max)	34 (27–36)	33 (28–36)	0.837
Birth weight, median (min-max)	1650 (1100–2450)	1900 (1190–2490)	0.936

*Test homogeneity of variance

Neonatal integrative DC mode refers to the seven basic neuroprotective DCs by involving the family, namely, (1) healing environment, (2) cooperating with the family, (3) positioning and handling, (4) maintaining sleep, (5) minimizing stress and pain, (6) protecting the skin, and (7) optimizing the nutrition. However, of the seven basic DCs, only five interventions can be carried out optimally. The two basic neuroprotective development cares that have not been maximally applied are (1) healing environment which includes noise and (2) cooperating with the family.

To analyze the effect of the NIDCM on baby stress, the changes in the baby's salivary cortisol levels were assessed in the time span between admissions to the neonatal care room to a maximum of 10 days in the neonatal care room.

There were several ways of collecting saliva samples that did not match the specified time span, so some data must be removed (not analyzed), namely, two people from the intervention group and six people from the control group. Thus, the data that can be processed were only 30 samples, 17 from the intervention group and 13 samples from the control group.

Based on the results of data analysis in Table 2, it can be seen in the NIDCM group that the changes in the median in cortisol levels decreased by 0.70 μg/dL – from 13.4 μg/dL to 12.7 μg/dL with the value of the Wilcoxon test of p = 0.906 while in the routine DC group, it decreased by 5.60 μg/dL – from 18.8 μg/dL to 13.2 μg/dL with the value of the Wilcoxon test is p = 0.345. This means that there was no significant change (decrease) (p > 0.05) in salivary cortisol levels in both groups, both in the NIDCM group and in the routine DC group. This happened because some premature babies in each group experienced a decrease and some experienced an increase. This was revealed after separation was made between those who experienced an increase and those who experienced a decrease, then analyzed by Chi-square test between the two groups, as shown in Table 3.

Table 2: Salivary cortisol levels between groups NIDCM and routine DC group

Group	Salivary cortisol levels of premature babies (μg/dL)		Change	Wilcoxon
	Pre-test	Post-test		
	Median (95% CI)	Median (95%IK)	median	
NIDCM (n = 17)	13.4 (1.53–24.94)	12.7 (2.89–33.70)	0.70	p = 0.906
Routine DC (n = 13)	18.8 (0.86–33.29)	13.2 (0.42–40.20)	5.60	p = 0.345
Mann–Whitney	p = 0.341	p = 0.711	p = 0.457	

Table 3: Comparison between NIDCM and routine DC on changes in salivary cortisol

Group	Changes in salivary cortisol in premature babies		RR (relative risk)	p-value
	Decrease, n (%)	Increase, n (%)	95% CI (confidence interval) for RR	
NIDCM	10 (58.8)	7 (41.2)	RR = 0.956 (0.532–1.717)	p = 1.000
Routine DC	8 (61.5)	5 (38.5)		
Total	18 (55.3)	12 (44.7)		

The comparison (Table 3) in the NIDCM group obtained that, 10 among 17 premature babies experienced a decrease (58.8%). Meanwhile in the routine DC group, eight among 13 premature babies (61.5%) experienced a decrease. The result of the RR calculation was 0.956 but it did not show a significant difference (p > 0.05).

The logical consequence of the above results is that the final salivary cortisol level of premature babies is one of the categories of treatment success to assess the baby's stress response, besides a decrease in the baby's salivary cortisol levels. Thus, the target for successful cortisol changes as the stress response in babies' treatment is when the salivary cortisol levels decrease and reach a low cortisol value (≤15 μg/dL). In other words, the stress response of premature babies in the neonatal care room is considered to be successful if the cortisol levels decrease and the final cortisol level is 15 μg/dL. On this basis, a reanalysis was carried out to assess the comparison of the stress response between babies treated with NIDCM intervention and routine DC. The results are presented in the following Table 4.

Table 4: Comparison of NIDCM on final salivary cortisol target

Variable	Category	Final premature baby's salivary cortisol target		RR (95%IK)	p-value
		Decrease, n (%)	Not, n (%)		
Group	NIDCM	10 (58.8)	7 (41.2)	1.529 (0.691–3.385)	p = 0.324
	Routine DC	5 (38.5)	8 (61.5)		

Table 4 shows the target achievement of cortisol levels in the NIDCM and routine DC groups did not significantly affect the final cortisol level. If a stratification was carried out based on the birth weight of premature babies, considering its great potential as a confounder (p < 0.25) in Table 3, the results are presented in the following Table 5.

Table 5: The effect of NIDCM on salivary cortisol level target by birth weight stratification

Variable	Category	Premature baby's salivary cortisol target		OR (95%IK)	P-value
		Decrease, n (%)	Not, n (%)		
BBW<1800	NIDCM	6 (100.0)	0 (0.0)	2.67 (1.109–6.524)	p = 0.028
	Routine DC	3 (37.5)	5 (62.5)		
BBW ≥ 1800	NIDCM	4 (36.4)	7 (63.6)	0.91 (0.241–3.430)	p = 0.654
	Routine DC	2 (40.0)	3 (60.0)		

R^2 = 20.0%; Hosmer and Lemeshow test, p = 0.105 and OR for the NID care model group, OR = 4.1 (0.683–24.504)

Table 5 shows that in the group of premature babies with BBW <1800 g, NIDCM had an effect (significant with p = 0.028) with OR = 2.67; this means that NIDCM is 2.7 Times greater in achieving the target of improving the stress response of premature babies compared to the routine DC group.

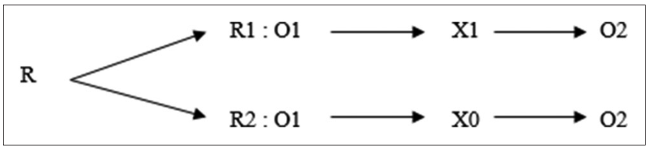

Figure 1: Research design
Description:
R: Respondents (mothers and babies) (random allocation was not done)
R1: Respondents in the NIDCM intervention group who took the pre-test and post-test
R2: Respondents in the routine DC group who took the pre-test and post-test
X1: Try out/intervention of the NIDCM group using the intervention standard
X0: Routine DC group
O2: Post-test after the NIDCM group

Based on Figure 2, all babies with BW of <1800 g, all (100.0%) reached the salivary cortisol

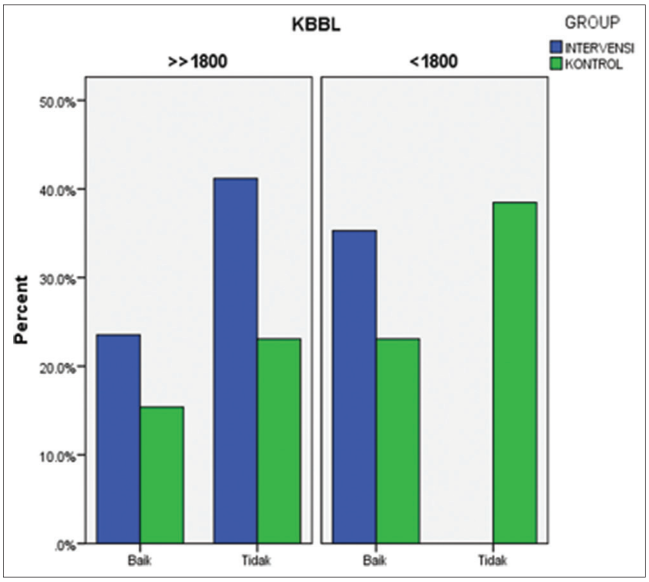

Figure 2: Bar chart of the difference in the incidence percentage of salivary cortisol level target in premature babies between the NIDCM and routine DC groups with stratification by birth weight category

level target in the NIDCM group, while in the routine DC, most of them did not reach the target. In babies with BW of 1800 g, although many of them have reached the target, there were more who did not reach the target, both in the NIDCM and routine DC groups. This means that the effect of the NIDCM intervention, although it can affect all babies treated in the neonatal care room, is only statistically significantly different from the routine DC group in the group of babies with BW of <1800 g.

Discussion

The NIDCM holistically refers to the seven basic neuroprotective DCs by involving the family – which in this study included (1) healing environment, (2) cooperating with the family, (3) positioning and handling, (4) maintaining sleep, (5) minimizing stress and pain, (6) protecting the skin, and (7) optimizing nutrition. However, of the seven basic DCs, only five interventions can be carried out optimally. Seven basic DCs that have been carried out in this study are slightly different from neuroprotective research in Europe, which covered eight neuroprotective cares consisting of (1) access to parents for 24 h, (2) parental psychological support, (3) pain management, (4) environmental influences, (5) postural support, (6) skin-to-skin support, (7) lactation and breastfeeding, and (8) sleep protection. Most were conducted through meta-analytical studies, only one was conducted through observational studies and one study was conducted on experimental animals [11].

In this study, there are two points of neuroprotective development cares that have not been maximally implemented, namely, (1) healing environment – which includes noise and (2) cooperating with the family. Regarding the healing environment (noise) – because there are several factors that must be controlled, such as the number of babies in the neonatal care room, the actions taken by the baby outside the incubator, the number of operated, the mobilization of health workers in the room, thus the bias would be very high if it was measured without controlling these factors. Premature babies are at high risk of being exposed to sensory stimuli during critical periods – especially distorted light and noise stimuli. Very LBW babies are exposed to an average noise level of 56.44 dB (A) and an average light level of 70, 56 lux – stay in NICU for 26–42 weeks postmenstrual age. Noise can have a negative impact on sleep quality and duration that alters brain development, so it is necessary to regulate sound levels not to exceed 50 dB, with a peak of < 65 dB [12].

Other studies reveal that sound frequency and intensity can be categorized as speech, equipment noise, therapeutic sound, and noise around staff activities. Noise intensity in the NICU should remain below 45 dB. Most of the noise in the NICU is caused by the noise of staff activities [13]. However, during this pandemic, noise measurements in the intervention group were only carried out at certain times in the afternoon, not during busy times such as visit times or other treatment times. Noise measurement in this study was done using a sound level meter set for the reading time for 5 s, collecting data for 5 min, and read every 5 s.

The second neuroprotective development care that has not been maximally implemented is the point of cooperating with the family. Contact restrictions during the COVID-19 pandemic have caused parents, especially mothers, to unable maximally accompany their babies for 24 h in the neonatal care room. Thus, the application of family-centered care has not been maximally implemented. Furthermore, parental guidance on how to care for their baby has also not been maximized due to the limitations of mother's visits. The quality relationship between mother and child from an early age in premature babies will affect their further development, where mothers are expected to bond with their babies through physical closeness, skin-to-skin contact, kissing the baby, carrying toys or cloth used by the baby, talking to the baby, touching the baby, as well as feeling the baby movement [14].

The baby's stress response in this study was the baby's physical and emotional reaction when there was a change in the care environment in the neonatal care room. Saliva collection from the baby to see cortisol levels was used to evaluate stress in premature babies. Baby cortisol levels were measured by ELISA examination. Many researchers used salivary cortisol reactivity to evaluate stress in premature babies in the neonatal care room and it has been used as a valid method [15], [16], [17], [18], [19], [20].

The results of this study showed that the decrease in cortisol as an illustration of the decrease in the stress response of premature babies during hospitalization in the neonatal care room did not show a significant difference. Because cortisol changes in the NIDCM group were not different from those in the routine DC group, statistical analysis was continued to find out whether it was affected by other factors.

It was found that birth weight (BBW) is a confounder of cortisol levels. In the group of premature babies with BBW of <1800 g, the NIDCM intervention had a significant effect of 2.7 times greater in achieving the target of improving the stress response of premature babies compared to the routine DC group. In babies with BBW of <1800 g, all of them reached the target salivary cortisol levels, meanwhile, in the routine DC group, there were more who did not reach the target. In babies with BW of 1800 g, although many of them have reached the target, there were more who did not reach the target, both in the NIDCM and routine DC groups. This means that the effect of the NIDCM intervention, although it can affect all babies treated in the neonatal care room, is only statistically significantly different from the routine DC group in the group of babies with BW of <1800 g.

The results of this study are supported by the study of Peterson *et al*. [21] which revealed that the baby birth weight contributed to the magnitude of the salivary cortisol response in the first 4 months. Birth weight is also considered to be an independent predictor of the baby's stress response directly and through its effects on postnatal glucocorticoids. The salivary cortisol response to inoculation at 4 months correlates significantly with baby birth weight and mean plasma cortisol in the first 4 weeks.

The results of this study also show changes in salivary cortisol after the NIDCM intervention with a mean value of 0.70 μg/dL – which means a decrease in cortisol levels from the initial to the final. Decreased cortisol levels are caused by (1) reduced stress due to improvement with treatment of underlying disease; (2) increased maturity of the hypothalamic–pituitary–adrenal (HHA) axis with the increasing age of the baby, (3) the process of adaptation to stressful stimuli; and (4) the onset of effects related to the suppression of adrenal activity by repeated and severe stress (adrenal insufficiency) [15], [22]. Besides, there are several conditions that affect the results of cortisol so that the baby becomes stressed, namely, the sampling time that exceeds 5 min [23], cheek massage done to increase saliva [18], or aspiration of saliva with a syringe [16], [19].

The researcher assumes that the length of stay for premature babies is closely related to the care the baby undergoes while in the neonatal care room and is also determined by gestational age along with the baby's birth weight. It is very important for the maximum involvement of families, especially parents, in the care of premature babies because it is the parents who really understand the baby's needs and is more intense in providing individual care to babies – this, after all, will have an indirect effect on reducing the length of stay in the hospital for the babies.

Conclusions

NIDCM intervention in premature babies with baby birth weight of <1800 g showed a better effect in reducing baby stress (cortisol levels) after treatment than routine DC.

Ethical considerations

This study has been passed the ethical clearance from the Medical Faculty of Universitas Hasanuddin Makassar, with the certificate number of 938/UN4.6.4.5.51/PP36/2009.

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