

Premature newborn positionings and physiologic parameters – a randomized clinical study

Posicionamentos de recém-nascidos prematuros e parâmetros fisiológicos – um estudo clínico randomizado

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Abstract

Introduction: Multiple studies have shown the effects of prone (PP), supine (SP) and kangaroo (KP) positions on clinical and physiological outcomes in preterm newborns, but none compared these three types of positioning between them. **Objective:** To investigate the influence of these positionings on heart rate, respiratory rate, peripheral oxygen saturation (SpO_2) and alertness status in clinically stable preterm newborns (NBs) admitted to a neonatal intensive care unit. **Methods:** In a randomized clinical trial, clinically stable NBs with gestational ages from 30 to 37 weeks who were breathing spontaneously were allocated in three positioning groups: PP, SP and KP. Heart rate, breathing frequency, SpO_2 and alertness status were evaluated immediately before and after 30 minutes of positioning. **Results:** In all, 66 NBs were assessed (corrected age: 35.48 ± 1.94 weeks; weight: 1840.14 ± 361.09 g), (PP: n = 22; SP: n = 23; KP: n = 21). NBs in the PP group showed a significant improvement in peripheral SpO_2 (97.18 ± 2.16 vs 95.47 ± 2.93 vs 95.57 ± 2.95, p = 0.03) compared with the SP and KP groups. **Conclusion:** In clinically stable preterm NBs, the PP was associated with better peripheral oxygen saturation than the SP or KP. In addition, there was a reduction in heart rate within prone position group and in the KP group there was an increase in the number of NBs in the deep sleep classification.

Keywords: Patient positioning. Physical therapy. Preterm infant. Respiratory care units. Respiratory therapy.

Resumo

Introdução: *Vários estudos têm demonstrado os efeitos das posições prona (PP), supina (SP) e canguru (KP) sobre os resultados clínicos e fisiológicos em recém-nascidos prematuros, mas nenhum comparou esses três tipos de posicionamento.* ***Objetivo:*** *Investigar a influência desses posicionamentos na frequência cardíaca, frequência respiratória, saturação periférica de oxigênio (SpO_2) e estado de alerta em recém-nascidos pré-termo (RN) clinicamente estáveis internados em uma unidade de terapia intensiva neonatal.* ***Métodos:*** *Em um ensaio clínico randomizado, RN clinicamente estáveis com idade gestacional de 30 a 37 semanas e respirando espontaneamente foram alocados em três grupos de posicionamento: PP, SP e KP. Frequência cardíaca e respiratória, SpO_2 e estado de alerta foram avaliados imediatamente antes e após 30 minutos de posicionamento.* ***Resultados:*** *Ao todo, foram avaliados 66 RNs (idade corrigida: 35,48 ± 1,94 semanas; peso: 1840,14 ± 361,09 g), (PP: n = 22; SP: n = 23; KP: n = 21). Os RNs do grupo PP apresentaram melhora significativa na SpO_2 periférica (97,18 ± 2,16 vs 95,47 ± 2,93 vs 95,57 ± 2,95, p = 0,03) em comparação aos grupos SP e KP.* ***Conclusão:*** *Em RN prematuros clinicamente estáveis, o PP foi associado à melhor saturação periférica de oxigênio do que o SP ou KP. Além disso, houve redução da frequência cardíaca no grupo de posição prona e no grupo KP houve aumento do número de RNs na classificação sono profundo.*

Palavras-chave: *Posicionamento do paciente. Fisioterapia. Recém-nascido prematuro. Unidades de cuidados respiratórios. Terapia respiratória.*

Introduction

Every year, 15 million preterm births are recorded around the world (approximately 1 in every 10 births).[1] Brazil has the tenth highest rate of preterm births (279,300 births per year). This situation is a cause for considerable concern as preterm newborns (NBs) are more likely to develop respiratory complications and experience impaired motor and cognitive development than full-term babies.[2]

The conventional approach used with preterm NBs requires a specialized team and specific logistical support, implying greater costs. Mortality among this population is high in low-income regions, and half of babies born at less than 32 weeks of gestation die as a result of inadequate care. Simple, low-cost interventions that improve the quality of care provided represent major advances and can prevent serious, long-term outcomes in these low-income regions.

Various studies of the effects of different positionings for NBs and their clinical and physiological impacts have been undertaken. According to most of these studies, the prone position (PP) has beneficial effects on oxygenation,[3,4] neural development, hemodynamic control and respiratory pattern, and a lower risk of gastroesophageal reflux compared with the supine position (SP).[3,5,6] The PP appeared to improve arterial oxygen saturation in NBs with respiratory distress syndrome,[3] while SP was associated with less restorative sleep.[7] Other researchers, however, failed to find worse values of ventilatory parameters when SP was used in this population.[8,9] Furthermore, the excessive handling of preterm NBs associated with some positions can have adverse physiological effects.[10] The kangaroo position (KP) resulted in improved development of preterm NBs and promoted bonding between mother and NB.[11,12] The KP is also associated with important physiological benefits, including restful sleep, improved thermoregulation, and reduced agitation and crying.[13]

Although several studies provide important evidence of the efficacy of the different positionings considered here, there are, to the authors' knowledge, no studies comparing the effects of the PP, SP and KP nor a consensus on the length of time for which these positions should be used.

In this study we hypothesize the PP will improve peripheral oxygen saturation (SpO_2), heart rate (HR), respiratory rate (RR) and restful sleep more than the SP or KP. We assessed and quantified the influence of the three different types of positioning (PP, SP and KP) on SpO_2, HR, RR and alertness status in preterm NBs in a neonatal intensive care unit (ICU).

Methods

We carried out a randomized clinical trial in the neonatal ICU at the Hospital de Clínicas, Universidade Federal do Paraná, Curitiba (UFPR), Brazil, following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).[14] The study, which followed the CONSORT guidelines,[15] was approved by the institution's Research Ethics Committee (CAAE no.

96014418.9.0000.0096; approval no. 2.880.386/2018) and registered with the Brazilian Registry of Clinical Trials (RBR 3w3sry). The data were collected between September 2018 and December 2019. Participants' parents or legal guardians were informed of the study aims, the procedures involved and the possible risks and benefits, and after a voluntary informed-consent form was signed, the data collection began.

Participants

The study sample consisted of preterm NBs with gestational ages of 30 to 37 weeks in the neonatal ICU at the Hospital de Clínicas, UFPR; weighing from 1000 to 3000 g; who were breathing spontaneously and hemodynamically stable; recently breastfed; with no respiratory distress, congenital cardiac diseases or respiratory complications; with no active hemorrhage; and with SpO_2 level of 89% or more. Each NB's mother was required to be present during the data collection (so that the NB could be assigned to the KP group if necessary). NBs were excluded if they were receiving mechanical ventilation, oxygen (catheter, mask or hood) or palliative care or had undergone abdominal-thoracic surgery, because of which they could not be handled or placed in a particular position.

All the NBs that could potentially be included in the study were recruited by the researchers and, after their parents or legal guardians had signed a voluntary informed-consent form, were included in the study. The following data were recorded: sex, gestational age, corrected age and weight at the time of observation, 5-minute Apgar score, length of stay in the ICU and medications administered. The clinical outcome variables SpO_2, HR, RR, and organization of alertness status were recorded before positioning and 30 minutes after positioning. Assessments were performed in the morning, at least one hour after the NBs have been breastfed. SpO_2 and HR were measured simultaneously with a Dixtal DX 2022 multiparameter monitor. RR was measured by an assessor for one minute with a Vollo 500-memory stopwatch.

Alertness status assessment at the time of observation was performed based on the Brazelton criteria,[16,17] adapted by Guimarães et al.,[18] which comprises four behavioral states: deep sleep; light sleep/sleepy; quiet alert state; agitated/crying state. Assessments were performed in the morning, at least one hour after the NBs have been breastfed. At the beginning of the observation period all the NBs had been monitored and had been resting in the traditional position (lateral decubitus) for at least 30 minutes.[19] The data from the assessments before and after each intervention were collected by the same assessor, who had previously been trained.

After the initial assessment, the NBs were randomly allocated to one of three groups (PP, SP, KP) and were left in this position for 30 minutes, when they were immediately assessed again. The NBs in the PP group were placed in the prone position with a cushion providing anterior support for their trunk, their head turned to the side and aligned with their torso and the limbs flexed.[20] In the SP group, the NBs were placed in the supine position with their heads kept in the center position, their hips and knees kept flexed with a cushion and a U-shaped cushion placed around them for stability.[20] Finally, in the KP group, each dry, naked NB was placed on his/her stomach on the mother's bare chest and covered with a warm blanket.[21]

Randomization and allocation concealment

The NBs were allocated randomly to one of three groups using a simple randomization procedure (computer-generated random numbers). The allocation was done with non-transparent, sequentially numbered, sealed envelopes, which were only opened when the random allocation was performed. This procedure was carried out by an independent physical therapist who was not involved in the recruitment, assessment or study interventions.

Calculation of sample size

The outcome chosen to calculate the sample size was SpO_2. Considering the sample size of a previous study[22] and a post hoc calculation of the power of this study in 84%, using an effect size of 0,77 (Cohen d), sample size was estimated in 21 NBs in each group. After adding 15% of individuals in each group to compensate any sample losses, each group was left with 24 individuals. The sample size was calculated with G*Power 3.1®.

Statistical analysis

The data were analyzed with Statistical Package for the Social Sciences® version 22.0 for Windows.

The Shapiro-Wilk test was used to determine whether the sample was homogeneous and had a normal distribution. The results are described in terms of the mean and standard deviation and frequency. Baseline characteristics were compared with ANOVA and chi-squared test. To compare the changes between groups, the differences between preintervention and postintervention measures were calculated (Δ = post – pre) for each group and the Bonferroni post hoc test was used when the result was statistically significant. A significance level of $p < 0.05$ was used.

Results

A total of 82 NBs were recruited for the study, of whom 72 met the inclusion criteria and were well enough to be handled. Each NB was randomly allocated to a group (24 subjects in each group). The final number of NBs included in the study was 66 (PG: n = 22; SG: n = 23; KG: n = 21) (Figure 1) as six participants were excluded because they were scheduled to have routine tests such as X-ray and echocardiogram at the time of the intervention.

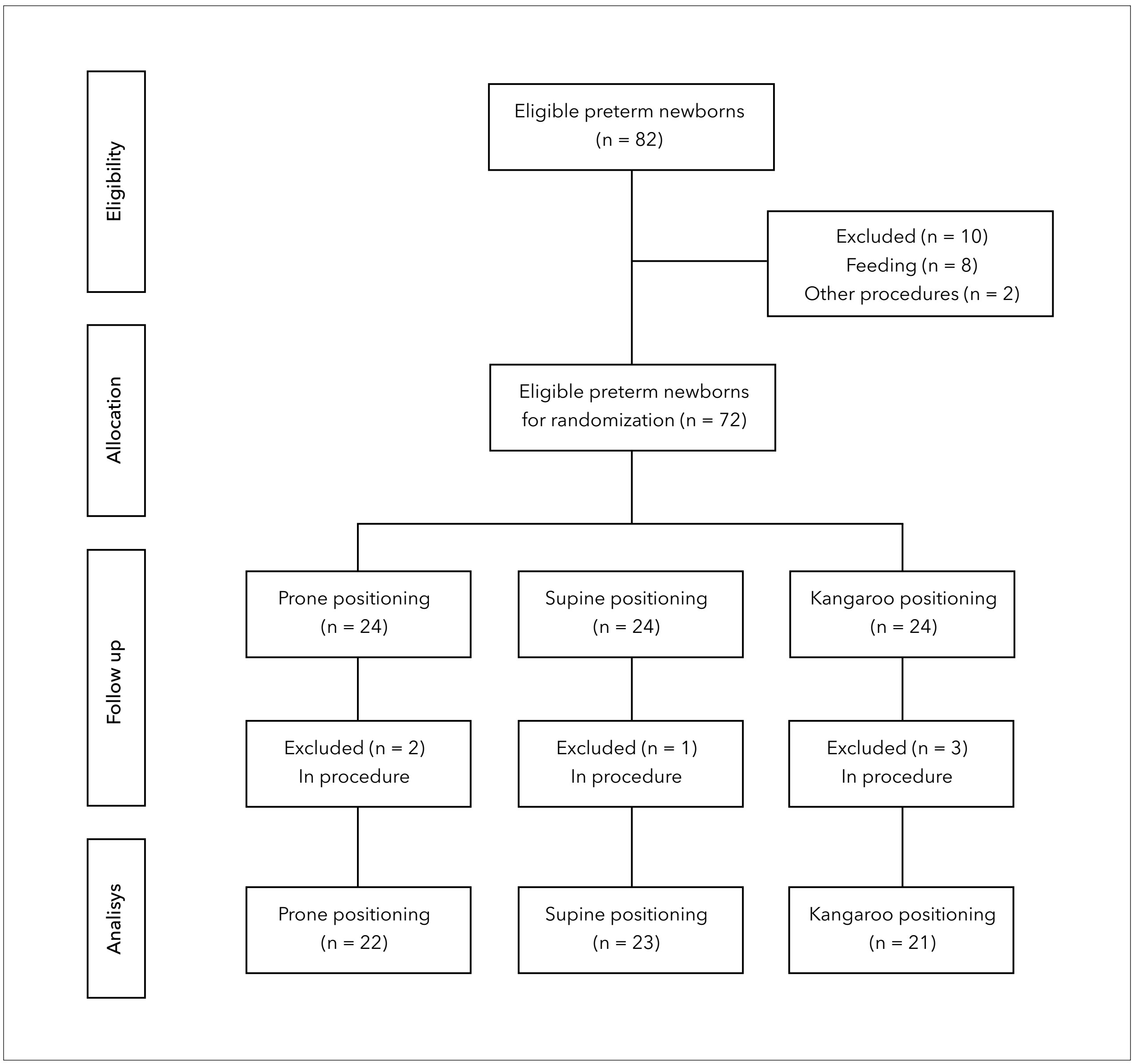

Figure 1 - Flowchart of data collection, following CONSORT recommendations.

There were no statistically significant differences in the baseline characteristics between the three groups. All individuals were in excellent health condition (as observed with the APGAR score), 59% of whom were female (Table 1). We did not observe any adverse effects of the applied interventions.

There was a statistically significant increase in SpO_2 ($p = 0.03$) in the PP group compared with the SP and KP groups. No statistically significant differences were observed between the groups in terms of HR and RR. However, there was a significant reduction of 4.54 % in HR within PP group (Table 2). Regarding the alertness status, in the KP group there was a significant increase in the number of NBs in the in the deep sleep classification as well as a reduction in the light sleep/sleepy classification at the post-intervention moment (Table 3).

Table 1 - Demographic, anthropometric and clinic characteristics of the study paricipants

Variable	**PP** (n = 22)	**SP** (n = 23)	**KP** (n = 21)	**p**
Sex M/F (n)	7/15	9/14	11/10	0.59
Gestational age (weeks)	33.35 ± 2.14	33.79 ± 1.68	33.29 ± 1.77	0.81
Corrected gestational age (weeks)	34.88 ± 1.76	34.89 ± 1.82	35.29 ± 1.32	0.85
Weight at the time of observation (kg)	1.71 ± 0.39	1.87 ± 0.36	1.95 ± 0.27	0.35
APGAR score	8.76 ± 1.25	8.16 ± 1.34	8.50 ± 0.94	0.19
Length of stay in the ICU (days)	11.58 ± 14.97	8.5 ± 9.73	11.66 ± 12.09	0.18

Note: Data described in terms of the mean ± standard deviation and absolute frequency (n); p-value refers to ANOVA and the chi squared test. PP = prone positioning; SP = supine positioning; KP = kangaroo positioning; ICU = intensive care unit.

Table 2 - Preintervention and postintervention clinical outcomes

Variable	**PP** (n = 22)		**Average % Change**	**SP** (n = 23)		**Average % Change**	**KP** (n = 21)		**Average % Change**
	Pre	**Post**		**% Change**	**Post**		**Pre**	**Post**	
SpO_2	95.76 ± 3.07	97.18 ± 2.16	1.48*,**	96.26 ± 2.23	95.47 ± 2.97	-0.82	96.00 ± 3.57	95.57 ± 2.95	-0.44
HR	140.94 ± 14.92	134.53 ± 13.01	-4.54*	139.68 ± 13.44	139.32 ± 13.34	-0.25	139.29 ± 14.75	139.43 ± 13.00	0.10
RR	51.18 ± 10.89	46.59 ± 10.38	-8.96	48.05 ± 11.75	49.26 ± 13.60	2.51	43.86 ± 11.10	39.64 ± 6.53	-9.62

Note: Data shown as mean ± standard deviation.*p< 0.05 in within-group analysis; **p = 0.03 in between-groups (ΔPP > ΔSP and ΔKP) by Bonferroni post hoc analysis. PP = prone positioning; SP = supine positioning; KP = kangaroo positioning; SPO_2 = peripheral oxygen saturation (%); HR = heart rate (beats/minute); RR = respiratory rate (breaths/minute).

Table 3 - Alertness status

Variable n (%)	**PP** (n = 22)		**SP** (n = 23)		**KP** (n = 21)	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
Deep sleep	14 (63.6)	19 (86.4)	10 (43.4)	15 (65.2)	12 (52.2)	21 (91.2)*
Light sleep/sleepy	7 (31.8)	3 (13.6)	11 (47.8)	6 (26.1)	11 (47.8)	1 (4.4)*
Quiet alert	0 (0)	0 (0)	1 (4.4)	0 (0)	0 (0)	0 (0)
Agitated alert/crying	1 (4.6)	0 (0)	1 (4.4)	2 (8.7)	0 (0)	1 (4.4)

Note: *p < 0.05 in within-group analysis by chi-square test. PP = prone positioning; SP = supine positioning; KP = kangaroo positioning.

Discussion

In this study, we compared simultaneously the physiological effects in NBs of three different positionings and showed that individuals in the PP group had higher SpO_2 after the intervention than NBs in the other groups. After 30 minutes in the PP, the NBs had a mean increase in SpO_2 of 1.48 %, whereas in the other two groups this metric decreased. In addition, there was a significant reduction of 4.54 % in HR within PP group. There was an increase in the number of NBs in the deep sleep classification and a reduction in the light sleep/sleepy in the KP group.

Widely used in ICUs, PP improves functional residual capacity,[4] optimizes the mechanics of ventilation[23,24] and reduces ventilation-perfusion mismatches,[25] which, together, would explain the improvement in SPO_2 observed in the present study. Although the intervention time was only 30 minutes, it is enough for physiological changes to occur.[24,26,27]

There was statistically significant difference in HR within PP group with a mean reduction of six beats/minute after the intervention, whereas it remained unchanged in the SP and KP, showing that the PP may favor an important clinical outcome. There is one randomized study that PP leads to a reduction in HR[22] compared with neonatal massage. The difference in HR between the groups may have not been observed with statistical significance in this study most likely due to insufficient number of NBs for this outcome. It is already known that in NBs, PP leads to better sleep and adaptive self-regulatory reactions.[7,28]

Although our results do not prove a significant change between the three groups regarding the alertness status, in the KP group we observed a significant increase in the number of NBs in the deep sleep classification as a consequence of the reduction in the light sleep/sleepy classification. Studies show that KP influences body temperature during skin-to-skin contact, as well as pain, which generally leads to greater relaxation of the NB with consequent improvement in sleep.[29] SP exposes the NBs to greater environmental stimuli, such as lighting, involuntary movements, changes in body temperature, local noise, among others. In addition, they become susceptible to involuntary awakening.[30]

This is, to our knowledge, the only study to compare simultaneously the effects of the PP, SP and KP in NBs; nevertheless, it suffers from some limitations: 1) the sample size not provided sufficient power to detect a clinically difference in other outcomes (HR, RR and slow wave sleep); 2) since the positioning duration was 30 minutes and one-day technique, the effect of longer-term therapy should be considered; 3) NBs's acceptability and perception of treatment by the mothers was not evaluated; however, due to the very good adherence to the positions, the authors believe that NBs had a positive acceptability; 4) we did not consider the effects of environmental stimuli (noise, lighting and handling) on the NBs, although these could interfere with the results, particularly for the variable slow wave sleep;[4] 5) the exclusion of extremely premature patients (< 29 weeks) and using conventional oxygen therapy or non-invasive ventilatory support (NIV, HFNC) may contribute to a limitation of the study, since the results cannot be applied to these preterm infants.

Regardless of these limitations, this study has demonstrated the potential usefulness and cost-effectiveness of prone positioning for clinically relevant outcomes in preterm infants. This study may also provide information to develop clinical guidelines and recommendations. Large, multi-centered studies are necessary to better define what type of positioning is most beneficial for preterm infants with respiratory distress in ICU and provide evidence-based conclusions about this daily questioning of neonatal ICUs.

Conclusion

In preterm newborns, the prone position was associated with better peripheral oxygen saturation than the supine and kangaroo positions. In addition, there was a reduction in HR within prone position group and in the KP group there was an increase in the number of NBs in the deep sleep classification.

Authors´ contributions

All authors were responsible for the conceptualization, methodology and writing of the original draft. ESC, LFB, FLA, MGA were responsible for the investigation and, together with SRV, for data curation and project administration. Validation, visualization, review and editing were done by RAAP and SRV. All authors approved the final version.

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