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Review Article

Extubation in Kangaroo Mother Care. Clinical Trial - a

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ABSTRACT

Rationale: The prognosis for premature children is associated, in part, with a successful early extubation. Furthermore, it is know that the Kangaroo Mother Method (KME) decreases the stress of the children.

Objective: To test the feasibility and safety of kangaroo extubation versus the conventional incubator extubation method.

Material and Methods: Pilot clinical trial. Newborns ≤ 1500 grams and/or ≤ 32 weeks of gestation who required mechanical ventilation during the first 7 days of life and their first extubation was in the first 6 weeks of age were included. The children were randomized to the kangaroo extubation group (KME) or Incubator Extubation (IE). Data was collected on Oxygen Saturation (SatO2), Heart Rate (HR) and Fraction of Inspired Oxygen (FiO2) as well as the need for reintubation.

Results: The study protocol ended with 5 children in the KME group and 5 in the IE group. After 10 minutes, the HR in the KME group was 143 (± 35) bpm and in the IE group it was 153 (± 8) bpm (p = 0.6), SatO2 was 94% (± 2) in the KME group and 94% (± 6) in the IE group (p = 0.8), and FiO2 was 0.48 (± 0.25) and 0.36 (± 0.14) (p = 0.037). There was no need for reintubation in either of the two groups.

Conclusions: With this small study it is shown that kangaroo extubation is feasible and it provides us with information for the design of a study with a larger number of cases.

Keywords: Newborn; Kangaroo; Extubation; Parental involvement

INTRODUCTION

A significant portion of premature newborns require admission to neonatal units immediately after birth. In conventional intensive care units, these children are kept in incubators and are separated from their mothers for a considerable time. Today professionals have alternatives to facilitate keeping the children close to their parents. Among all the possible actions to decrease the impact of the separation, the kangaroo method is the one of the best studied and one of the most beneficial reported for both the mother and the newborn [1,2].

A non-negligible number of premature infants under 32 weeks of gestational age require mechanical ventilation. It has been reported that the prognosis of these premature children is, among other aspects, correlated with successful early extubation [3]. There are several studies about the benefits provided by Kangaroo Mother Care [4,5]. Several works [6,7] have indicated the benefits provided by kangaroo care in intubated children, including: better thermoregulation, vital sign stability, and less need for FiO2 to maintain adequate saturation ranges. Furthermore, a slight instability in transferring to the kangaroo position has been mentioned, likely due to the lack of established protocols for this practice [8]. Only one study has referenced the correlation between kangaroo care and post-extubation hemodynamic stability [9].

In our unit, since kangaroo care has been shown to be a method that relieves pain and reduces stress [10]. We planned to perform extubation in kangaroo care to try to make the procedure more comfortable for the child. Thus, it was decided to set up a preliminary study with the design of a clinical trial, with the aim of testing the feasibility of kangaroo extubation versus the conventional method of extubation in an incubator.

PATIENTS AND METHOD

Randomized clinical trial conducted in November and December 2014 in a 3C neonatal unit that cares for an annual mean of 140 newborns under 1500 g or under 32 weeks.

The inclusion criteria were: newborns ≤ 1500 g and/or < 32 weeks of gestation, mechanical ventilation during the first 7 days of life and first extubation during the first 6 weeks of age, and availability of the parents for the extubation.

All the parents of the children included in the study signed the informed consent form. The study protocol had been approved the Ethics Committee and during the study the principals of the Declaration of Helsinki were followed.

Study procedure: The children who met the inclusion criteria were randomized during the first days of their life, while they were on mechanical ventilation, to the intervention group, Kangaroo Care Extubation (KME), or to the control group, conventional extubation in an incubator (IE).

The research team reviewed and updated the department protocols on extubation and drafted a specific protocol for kangaroo extubation. Demo videos were created for both kangaroo and incubator extubation. Training meetings were held with the nurses. The neonatologists were informed about the study and their collaboration was requested.

Common extubation procedure for the two groups

1. Locate and inform the parents about the decision to extubation their child. If they are not in the unit, they will be required to come so that they are present during the extubation procedure independently of whether their child is in the kangaroo extubation group or the control group.

2. Once the decision has been made to extubation, in the first procedure required by the child administer the corresponding dose of caffeine citrate and hook the child up to the CPAP or BIPAP cap, adjusting it to the child's head circumference. Thread the interface straps through the holes in the cap without tightening them and place the front part for the child's face above the eyes. All this is done sometime before the extubation so that the child has time to recover from the stress of being handled. This is also the right time to auscultator the child and aspirate any secretions. This handling requires two people to be present, in order to not disrupt the patient too much. Once this phase is completed, place the child comfortably inside his/her cot.

3. Prepare the necessary material to be able to quickly perform a reintubation in case it is needed.

Incubator extubation

Sometime after the above handling and when the child has recovered from it, the extubation procedure itself will be initiated.

- All the staff responsible for the child's care should be present.
- If the child has continuous feeding, stop the enteral feeding.
- Prepare the respiratory support device planned for the child after the Endotracheal tube is withdrawn.
- The father or mother will be able to assist the nurse by holding their child while the CPAP or BIPAP cannulas are adjusted into the child's nostrils.
- If everything is correct and the child is calm, remove the adhesive tape holding the Endotracheal tube in place and extract the tube.
- Check that the flow is transmitted correctly, that the child's breathing seems effective, and that the oxygen saturation is maintained.
- Leave the child comfortably placed inside his/her cot. The parents will be able to continue comforting their child. Reconnect the enteral nutrition.

Kangaroo extubation.

Sometime after the above handling and when the child has recovered from it, the extubation procedure itself will be initiated.

- All the staff responsible for the child's care should be present.
- If the child has continuous feeding, stop the enteral feeding.
- Have the father or mother stand alongside the incubator. Turn on the heater, and gently turn the child so that he/she is placed transversally in the incubator in the supine position.
- With the nurse standing to the side of the parent, open the door to the incubator.
- Have the father or mother put their hands under the child's cot, one hand supporting the head and the other a little lower. Have him/her hug the child, leaning forward a little bit and supporting him/her against his/her chest while the nurse follows their movements fastening the respirator tubing and the tube.
- With the child already in kangaroo position, have the father or mother move backwards to sit in the chair. The nurse will fasten the tubing to the chair's arm and check that the tube is not angled.
- Once the child is fastened to the father or mother, withdrawn the cot. Afterwards, wait until the child is calm and comfortable, a minimum of one half hour.
- After this time, turn on the required non-invasive respiratory support device, place the cannulas in the child's nostrils and check the pressure.
- If everything is correct and the child is calm, remove the adhesive tape holding the endotracheal tube in place and extract the tube.
- Check that the flow is transmitted correctly, that the child's breathing seems effective, and that the oxygen saturation is maintained.
- Leave the child comfortably positioned in kangaroo care and reconnect the enteral tube.

When the doctor indicated the extubation, it was performed either in kangaroo care or in the incubator according to the previous randomization. The main endpoint that was considered, as an indirect measurement of the child's stress and comfort, was the change in heart rate and oxygen saturation and the need for FiO2. The reintubation rate in the first 24 hours after the extubation was also collected.

Each patient included in the study had a case report form designed specifically for the study.

Analysis plan.

The collected data was analyzed with the STATA/SE v. 10.0 programs. Percentages were used to describe the categorical variables and means ± standard deviations for the continuous variables. As for analyzing the correlations, Student's T- tests were used since the distribution of the quantitative variables was normal. The Shapiro-Wilk test was used to check the variable's normality.

RESULTS

There were 17 eligible children during the study period. Twelve parents agreed to let their child be included in the study and they were randomized. Two cases were excluded after the randomization because in the end their parents were not able to be present during the extubation procedure. In the end, there were 10 included cases which comprised our study population. Five of the children were extubated in kangaroo care and five in the incubator. There were no statistically significant differences in the gestational age and weight in both groups (KME), mean GA 29.1 + 1.8 weeks and mean weight 948.3 + 250.5 g *vs* IE, mean GA 28.3 + 1.8 weeks and mean weight 948.4 + 181.7 g).

The mean heart rate, oxygen saturation, and need for FiO2 endpoints in the two groups are shown in (Table 1).

None of the children included in the study needed reintubation in the following 24 hours. There were also no adverse events in either of the two groups.

DISCUSSION

This first preliminary study shows how extubation in kangaroo care is feasible and well-tolerated by the children. Our results show how the heart rate and oxygen saturation were similar in both groups despite the fact that the saturation in the incubator group

Table 1: Heart rate, Oxygen saturation, and FiO2 pre- and post-extubation in Kangaroo care and in the incubator.

	KME	IE	
HR prior	148 (± 12)	144 (± 12)	*P* = 0.6
HR at 10 min.	143 (± 35)	153 (± 8)	*P* = 0.6
HR at one hour	147 (± 38)	152 (± 13)	*P* = 0.8
FiO2 prior	0.33 (± 0.11)	0.33 (± 0.16)	*P* = 0.9
FiO2 at 10 min.	0.48 (± 0.25)	0.36 (± 0.14)	*P* = 0.37
FiO2 at one hour	0.47 (± 0.29)	0.34 (± 0.15)	*P* = 0.4
SatO2 prior	92% (± 1%)	97% (± 3%)	*P* = 0.024
SatO2 at 10 min.	94% (± 2%)	94% (± 6%)	*P* = 0.8
SatO2 at one hour	93% (± 3%)	95% (± 5%)	*P* = 0.4

HR: Heart Rate.
SatO2: Oxygen Saturation.
FiO2: Fraction of Inspired Oxygen.

was significantly higher before the extubation. There were also no differences in the need for FiO2. The data obtained in this preliminary work will be used to design a multi-center study on extubation in kangaroo care in children under 1500 g or under 32 weeks of GE using a sample size with enough power to establish the possible benefits of this type of extubation and its safety.

Extubation is a stressful procedure for the child, the parents, and for the professionals who are involved in the procedure. Given the benefits of kangaroo care for both the child (11) and the parents (12), it can be thought that with KME perhaps the child will feel more comfortable and the stress can be decreased.

From the author's point of view, one of the most interesting aspects of this study is that it has enabled the creation of a protocol for extubation in both kangaroo care as well as in an incubator and the nursing professionals were specifically trained. This aspect may be one of the study's strengths since it will facilitate designing the new study.

There was no need to perform a reintubation while the child was in kangaroo care in any of the cases included in the study. This has occurred in a case prior to the study start. The time to transfer the child to the incubator for reintubation was minimal and the child was reintubated without any problems. Considering the new study that will be conducted, an emergency reintubation procedure protocol will be created for when the child is in kangaroo care.

There are many limitations to our study since, as mentioned, the sample size is very small but it was only intended to establish the feasibility of extubation in kangaroo care. As stated by Dr. Uwe Ewald, the parents' chest is the new care space for premature children, therefore we have the new challenge of exploring the possibility of performing the procedures required by the premature children in kangaroo care and thus being able to determine the possible benefits.

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