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ORIGINAL ARTICLE

Development and safety evaluation of a new device for cup-feeding

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Abstract

Purpose Cup-feeding is an alternative method for newborn feeding. Although there are cups in use for this purpose, there are still some concerns about their adequacy. The objective was to develop a cup considering the physiology of the oromotor function and the stages of sucking development.

Methods To develop this cup, it was considered the newborn mouth's anatomy (term and preterm), their oromotor functions, and the maturation levels of the oromotor functions, the milk flow velocity, and the newborn's ability to deal with the milk volumes reaching their mouth. Also this device had to be safe to be used in nurseries and neonatal units, so it needed to be adequate for the transportation of human milk from the human milk bank to the unit. It contains a metering nipple, a flow reducer, a scale to inform the milk volume being offered, and a cover. A safety study in 22 term and 22 preterm newborns was performed.

Results The diameter of the metering nipple was adequate to both term and preterm newborns, without risks to the integrity of their lips and tongue. The flow reducer allowed a better control of the milk volume, contributing for the organization of the swallowing, with less spillage of milk. There were no discomfort during the proceedings.

Conclusion This cup showed that it is a good and safe feeding device for term and preterm newborns in the transition to breastfeeding. This cup is safe to be used in Neonatal Intensive Care Units or Nurseries.

Keywords Breastfeeding · Cup-feeding · Preterm newborn · Complementary feeding

Abbreviations

NB	Newborns
WHO	World Health Organization
NICU	Neonatal Intensive Care Unit
IFF/FIOCRUZ	Instituto Nacional de Saúde da Mulher da Criança e do Adolescente Fernandes Figueira-Oswaldo Cruz Foundation
CONEP	Brazilian Ethics Committee
FiO2	Fraction of inspired oxygen
APGAR	Scale to evaluate the vitality of the newborn at birth

Introduction

There are increasing pieces of evidence of the importance of human milk for the child development. Various studies have demonstrated the benefits of breastfeeding along the first months of life, regarding cerebral development, influencing the cerebral connectivity, white matter and cerebral cortex development, language, behavior, and even the intestinal microbioma (Whitehouse et al. 2011; Heikkila et al. 2011; Kafouri et al. 2013; Deoni et al. 2013; Ramos et al. 2013; Gregory et al. 2016; Blesa et al. 2019). Nevertheless, although human milk is considered the ideal food to nourish the newborns (NB), inclusive those born preterm, it is still very difficult to maintain breastfeeding after hospital discharge in this group of infants, mainly those born with a very low gestational age (Vieira et al. 2015; Meio et al. 2018; Boquien 2018; Bonnet et al. 2019).

Alternative methods of feeding apart from the mothers' breast have been used, and the more frequent are bottle-feeding and cup-feeding. Bottle-feeding is the most used method of milk supplementation, but there are pieces of evidence that it interferes with breastfeeding maintenance;

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cup-feeding is an alternative method, increasing breastfeeding at discharge from hospital (Yilmaz et al. 2014; McKinney et al. 2016).

A successful and safe oral feeding in infants requires an appropriate maturation of the coordination of sucking with swallowing and respiration (Fucile et al. 2002; Lau 2007, 2016; Amaizu et al. 2007). The components of sucking, swallowing, and respiration and their coordinated activities mature in different time and levels, so that the functional maturation level is more dependent of the gestational age at birth than of the postnatal age, at the moment of evaluation (Fucile et al. 2002; Lau 2007, 2016; Amaizu et al. 2007). Difficulties in oral feeding is very frequent in preterms due to the still incomplete development of the central nervous system, of the cardiorespiratory system, and of the perioral musculature, affecting their ability to get feeding independence (Fucile et al. 2002; Lau 2007, 2016; Amaizu et al. 2007). Difficulties in oral feeding encompass the disorganization of the sucking pattern, the incoordination of sucking, swallowing and respiration, and the aversion or hypersensibility to the touch on the mouth area (Rocha et al. 2002).

The healthcare policy of the Baby-friendly Hospital Initiative, advised by WHO, introduced in the neonatal units the use of the cup-feeding, as an alternative method of feeding opposed to the use of bottles, to promote breastfeeding (WHO and UNICEF 2009). However, the majority of the cups used in the neonatal units was not designed for this function, so not considering the still immature oromotor abilities of preterm NB. Currently, there are cups that had been produced for this purpose, but they are still inadequate for the preterm NB, mainly in relation to the diameter of the rim of the cup. Cups with an inadequate rim diameter propitiate errors in the administration of the milk, either by increasing the spillage and waste of milk or by offering a risk of overloading the NB mouth with milk, putting the NB at risk for milk aspiration (McKinney et al. 2016). Even cups which have a smaller and more adequate diameter, being more appropriate for term NB, do not have a system for controlling the flow velocity of the milk which is being offered to the NB.

The oromotor development and the pattern of sucking of the preterm NB, dependent of the gestational corrected age, are different from what occurs with the term NB, and the establishment of an effective sucking depends on the level of the oromotor development. The safe and effective feeding of the preterm NB is related to a sucking with rhythm and coordinated with the respiration and the swallowing (WHO and UNICEF 2009). Thereof, it arose a demand of developing a device—a cup—which best adjusted itself with the physiological and anatomic needs of the preterm NB and which, at the same time, could enable the oromotor maturation of these NB, bearing in mind the opportunity of a future breastfeeding.

Therefore, with these conceptual considerations in mind, it was developed a model of device to administrate the complementary feeding to risk NB admitted in the neonatal intensive care unit (NICU), which encompassed the adaptive needs of preterm NB, or term NB with temporary difficulties of being breastfed, and their oromotor abilities, preparing these NB to be breastfed. A prototype was manufactured in polypropylene, and it was performed a study to evaluate the safety of this device.

Methods: development of the cup and methodology of the study of safety

The study was performed at the Neonatology Department of the Instituto Nacional de Saúde da Mulher da Criança e do Adolescente Fernandes Figueira-Oswaldo Cruz Foundation (IFF/FIOCRUZ).

Development of the device

To design this cup, the inventor considered the anatomy of the newborn mouth, both term and preterm, the newborn oromotor functions, and, mainly for the preterm newborns, the levels of maturation of the oromotor functions and the appearance of their reflexes, the ability of the newborn to deal with the volumes of milk reaching the mouth and the flow velocity of the milk. Also, this device had to be safe to be used in Nurseries and Neonatal Units, so they needed to be adequate for the transportation of the milk from the milk bank to the unit. To enable the diameter of the cup to fit the newborn mouth, a small metering nipple was designed, allowing a better adjustment with the newborn mouth, limiting the volume of the milk offered, and thus permitting the newborn to sip the milk; it also has a flow reducer, with ondulations, which controls the velocity of the milk reaching the metering nipple and so the newborn's mouth. The reasoning for the design of the flow reducer was that, if one puts obstacles in the milk passage, the milk flow velocity would be reduced because of energy dissipation, consequently diminishing the outflow, and a smaller milk volume would reach the newborn's mouth. The cup has a scale in one size informing the diet volume offered and, a cover, to prevent the contact with the surrounding air.

Evaluation of the prototype

The first part of this study was a manual evaluation of the manufactured prototype by the inventor (Mallet, NR); it consisted of checking if the prototype was in agreement with the design and respecting the idealized purposes, and making all the necessary adjustments, until reaching the final prototype.

In this stage, the quality of the material used, the size of the metering nipple reaching the NB mouth, and the adjustments which had to be done were evaluated. After this, with the final prototype, the study to evaluate the safety of the device was realized. The feeding cup, after all the adjustments, is shown in Fig. 1.

Safety study

This study was approved by the Ethics Committee of the IFF/FIOCRUZ and by the Brazilian Ethics Committee—CONEP—with the number CAAE 30893914.6.0000.5269. This study was performed in two phases: phase 1—evaluation in term NB and phase 2—evaluation in preterm NB. All NB were included after their parents agreed with their participation in the study and signed the informed consent form.

Sample size

The calculation of the sample size was based in the probability of the need of use a cup to feed healthy term NB in the nursery and preterm NB who had been in the NICU, and were being prepared for hospital discharge. In this group of infants, the probability of needing a cup for an alternative feeding, according to the Baby-friendly Hospital Initiative protocol, is 5% for healthy term NB and 70% for preterm NB. So for the phase 1, with a confidence of 80%, the calculated sample size was 20 NB to be evaluated using the cup. For the phase 2, with a confidence of 97%, the calculated sample size was 25 NB, considering an error of 20%.

Population

The NB enrolled were term and preterm NB, born in the maternity of the IFF/FIOCRUZ, who were with their mothers in the nursery, or who had been admitted in the NICU. The preterm NB included had 34 weeks corrected gestation age or less at the evaluation, and their mothers wanted to breastfeed. An equal proportion of healthy term NB who were in the Nursery, on cup-feeding with a conventional cup, were included. The exclusion criteria were malformations, genetic syndromes, congenital infections, and NB whose mothers had chosen not to breastfeed.

The objectives of this study were to evaluate the quality of the confection of the cup, in relation to the anatomy and the oromotor physiology of the NB, both term and preterm; the flow velocity of the milk reaching the NB mouth; and the adequacy of the milk volume in the NB mouth with the organization of the oromotor pattern during the feeding. Therefore, it was evaluated (I) if the metering nipple is well adjusted to the mouth of the NB; (II) the finishing of the metering nipple; (III) if the milk volume flowing through the metering nipple was adequate to organize the preterm NB swallowing; (IV) the loss of milk during the administration of the diet; (V) the physiological parameters of the NB during the administration of the diet with the cup (heart

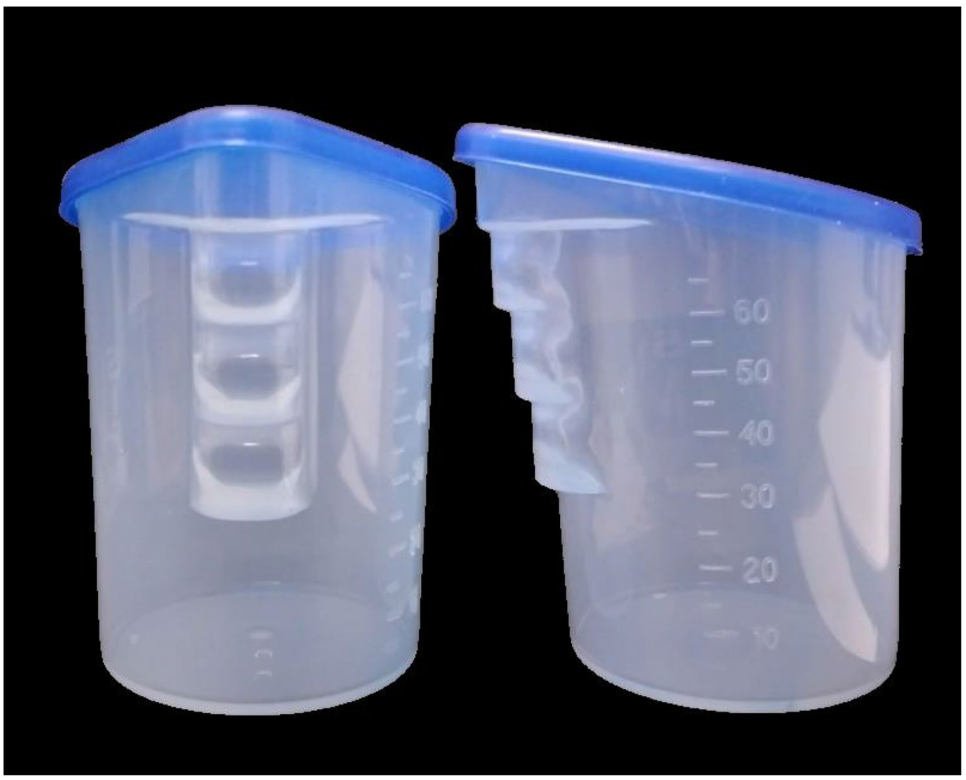

Fig. 1 Cup-feeding device

rate, respiration, oxygen saturation ($SatO_2$) and the color of the NB).

In phase 1, it was evaluated the use of the cup in healthy term NB from the nursery. The NB were monitorized, and heart rate, respiration frequency, $SatO_2$, NB color, and milk waste were registered.

In phase 2, after the establishment of the safety parameters in healthy term NB, preterm NB were evaluated. In this phase, it was evaluated: the acceptance of the cup by the NB, the possibility of choking or cyanosis, the amount of milk lost during the administration of the diet, the possibility of adverse effects, mainly in the respiratory pattern. All the NB were monitorized during the proceedings, and heart rate and $SatO_2$ were registered before, during, and after the diet administration. All NB were evaluated in alert state.

Results

During the period of March 2017 and October 2019, 44 NB were evaluated in the Department of Neonatology of IFF/FIOCRUZ, with 22 healthy term NB in phase 1 and 22 preterm NB in phase 2. These infants were examined in the nursery (22) or in the NICU (10) or intermediate unit (12). All NB were evaluated in alert state, calm, and without any sign of irritability. The characteristics of this population is described in Table 1.

The physiological parameters remained stable (heart rate, $SatO_2$, and changes in the color of the neonates in both groups) during the administration of the diet with the cup. The mean heart rate in preterm NB was 140.4 bpm (SD ± 20.5) before the diet, 145.3 bpm (SD ± 24) during the diet, and 141.8 bpm (SD ± 23.2) at the end of the diet. The mean SatO2 in the preterm NB during the administration of the diet were 97.5 (SD ± 2.8) before the diet, 97.3 (SD ± 2.9) during the diet, and 97.8 (SD ± 3) at the end of the diet. In the group of term NB, these values were 128.3 bpm (SD ± 20.5), 135.4 bpm (SD ± 25), and 130.1 bpm (SD ± 19.7) for the heart rate and 98.6 (SD ± 1.96), 98.3 (SD ± 1.79), and 97.8 (SD ± 2.41) for the $SatO_2$, respectively.

Concerning the evaluation of the non-nutritive sucking, all the reflexes were present in the term NB. Among the preterm NB, 50% presented an incomplete rooting reflex, and in 5 NB, it was still absent, which is expected, reflecting their immaturity. The protective reflexes were present, and regarding the adequacy of the sucking pattern, the intraoral pressure, and the frequency and rhythm of the sucking, they were present in the majority of the preterm NB: 91%, 86.4%, and 86.4%, respectively.

In relation to the rim of the cup metering nipple, it was adequate in both term and preterm NB. The milk volume reaching the NB's mouth was adequate. None of the NB showed signs of discomfort during the diet's administration, nor presented apneia, lip, or tongue trauma. To evaluate spillage of the milk during the feeding with the cup, a gauze compress, of the same size for all NB evaluated, was put under the NB's chin. This compress was weighted before and after the feeding; the weight's difference reflected the milk spillage. It was possible to evaluate 14 term NB and 10 pretem NB; in 4 term NB and 1 preterm NB, there was loss of milk caused by the movement of the NB arm; in 1 preterm NB, the weight of the gauze compress was missing. The spillage mean proportion found was 4.3% for the term NB and 2.9% for the preterm NB.

Table 1 Characteristics of the newborns enrolled in the study

	Preterm 22		Term 22	
	Mean (SD)		Mean (SD)	
Gestational age at birth (wk)	33.6 (2.58)		38.4 (2.28)	
Birthweight (g)	1928.1 (512.5)		3116.5 (459.3)	
		N (%)		*N* (%)
C-section		18 (81.8)		11 (50)
Female		17 (77.3)		10 (45.5)
	Median (IQR)		Median (IQR)	
APGAR 1 min*	8 (7–9)		9 (7–9)	
APGAR 5 min*	9 (9–9)		9 (9–9)	

*21 preterm newborns and 19 term newborns

Discussion

This cup was safe to administrate complementary diet for both preterm and term NB. All the evaluations were performed with the NB at alert state. It was not found any evidence of changes in physiological parameters, with a stable $SatO_2$ during all the proceeding. These findings are in agreement with two systematic reviews comparing the use of cup-feeding and bottle-feeding as alternative methods to feed preterm NB, in which it was reported greater stability of heart rate and the maintenance of $SatO_2$ during cup-feeding (McKinney et al. 2016; Penny et al. 2018).

The rim of this cup metering nipple was well finished, bringing no risk for the integrity of the lip and tongue of the NB, and fitted well with the NB mouth. The cup's metering nipple limits the amount of milk being offered, without causing discomfort or milk spillage from the lip commissures, as the small loss of milk between the beginning and the end of the feeding demonstrated. The idea behind the design of the metering nipple for this cup was to overcome

the disproportion between the diameter of the existent cups and the diameter of the NB mouth, mainly of the preterm ones. The better fit of the sizes—the metering nipple and the NB mouth—would favor the decrease of milk loss by the lip commissures, therefore diminishing the milk spillage, as was observed in this study. One of the limitations reported by the two systematic reviews was the waste of milk during the cup-feeding, although it did not affect the weight gain of these NB (McKinney et al. 2016; Penny et al. 2018). McKinney et al. (2019) recently published the results of a clinical trial comparing two types of cup: the Nifty cup, designed to have a better adjustment to the size of the NB mouth, avoiding the spillage of milk, and a conventional cup. The authors reported that there not differences between the cups concerning the milk spillage, but there was greater acceptability of the Nifty cups by the mothers, who felt more confidents.

Importantly, the conception of this cup considered the need to decrease the flow velocity of the milk reaching the NB mouth. In this way, it would be avoided an excessive amount of milk inside the NB's mouth, above their capacity of organizing the coordination of the swallowing, allowing the NB self-organization, and turning the feeding more safe. This cup has, to exert this function, a flow reducer, comprised by small ripples, which place barriers or obstacles for the flow of the milk, thus allowing the decrease of its velocity until the milk reaches the mouth. There were no changes in the physiological parameters, the FiO_2, or discomfort during the feeds, in this way indicating the security of the control of the milk volume reaching the mouth. McKinney et al. (2016) in the systematic review reported that the term bottlefed NB, compared with the cup-fed NB, were capable of receiving a greater diet volume, but presented more oxygen desaturation. They hypothesized that this finding would be related with a greater flow volume in the NB's mouth with the use of the bottle, not allowing the flow volume control (McKinney et al. 2016). The presence of the flow reducer in this cup, thought exactly to exert this function, permits this control, therefore offering more security during the administration of the diet and respecting the NB capacity to receive the volume of milk that reaches the mouth.

Besides the benefits for the NB, already exposed, the design of metering nipple, with a small diameter, and the milk flow reducer, give more confidence for the health professional during the proceeding, as well as for the NB mothers, trained for the use of this cup.

In addition to these properties, this cup functions as a stimulator of the oromotor abilities and oral reflexes of the NB, mainly the anterior tongue movements, which will help in grasping the mother's breast, for future breastfeeding. The correct use of this cup implies in putting the metering nipple between the lips of the NB, leaning on the inferior lip, and in this way stimulating the anterior movements of the tongue. The nipple should not be kept inside the NB mouth, as it can block the tongue movements, but leaned on the inferior lip. With the persistence of its use, at each diet, the NB will train their oromotor abilities, specially the preterm NB, whose abilities are still immature.

Another characteristic of this cup is that it has a cover, preventing the exposure of the milk to the surrounding air. This allows for the diet, in the cases in which bank human milk are being used, to be prepared in the milk dispensary and transported to the nursery or the NICU. There, the cup with the milk can be offered to the NB who are still hospitalized, but whose mothers are being prepared to breastfeed.

Limitations and strengths of this study

Although there were no objective measurements of flow velocity of the milk reaching the newborn's mouth, the control of the milk flow is done by the person who is giving the diet. The ondulations of the flow reducer help the administrator to manage the milk flow, together with the small size of the metering nipple. We also did not perform a study to prove that there was no bacterial contamination of the milk offered; nevertheless, the cup used was sterilized and filled with the milk by the nurse at the neonatal unit taking all the proper care, as it is recommended. But the cover, avoiding the contact with ambient air, will contribute to protect the milk during transportation, as it occurs with the bottles. Another limitation is that no other cups were compared with this one; this was a safety study. However, as this is a new device, it will probably be compared with other cups in use. Although the spillage was considered small, the training of the nursing team and the continuous use in the neonatal unit will probably contribute to completely avoid it.

Conclusion

The diameter of the metering nipple was adequate to the size of both term and preterm NB, and the finishing of the nipple's rim did not offer risks to the integrity of the lips and tongue of the NB. The metering nipple with the flow reducer allowed a better control of the volume of milk being offered, contributing for the organization and coordination of the swallowing, with less milk spillage. The continuous use of this cup favors the stimulation of the oromotor abilities of the NB and the anterior movements of the tongue, which will help in the grasping of the mother's breast. For the best of our knowledge, this cup is distinguished from others cups by the size of the metering nipple and by the presence of a flow reducer to better control the milk volume reaching the NB's mouth, besides having a cover which permits to avoid contact of the milk with the surrounding air.

In conclusion, it was demonstrate that this cup was safe to be used in NICU or nurseries, as a NB feeding device for administrating complementary diet in the transition to breastfeeding.

Additional information

The cup-feeding device has patent protection in the following territories: Brazil, USA and Europe (Germany, France, Great Britain and Switzerland). Currently, it is licensed in Brazil. For additional information about this technology, please contact feedingcupdevice@iff.fiocruz.br.

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Declarations

Conflict of interest The authors declare no competing interests.

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