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Effects of pre-feeding oral stimulation on oral feeding in preterm infants: A randomized clinical trial

Manon Bache [a,*], Emmanuelle Pizon [b], Julien Jacobs [c], Michel Vaillant [d], Aline Lecomte [e]

[a] Neonatal Intensive Care Unit, Centre Hospitalier de Luxembourg, 4 rue Ernest Barblé, 1210 Luxembourg
[b] Service d'Évaluation et de Rééducation Fonctionnelle, Centre Hospitalier de Luxembourg, 4 rue Ernest Barblé, 1210 Luxembourg
[c] CRP-Santé, Administration and Center for Health Studies, 1A-B, rue Thomas Edison, L-1445 Strassen, Luxembourg
[d] CRP-Santé, Competences Center for Methodology and Statistics, 1A-B, rue Thomas Edison, L-1445 Strassen, Luxembourg
[e] Centre de Recherche Public de la Santé, CRP-Santé, Administration and Center for Health Studies, 1A-B, rue Thomas Edison, L-1445 Strassen, Luxembourg

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ABSTRACT

Objective: To evaluate the effect of early oral stimulation before the introduction of oral feeding, over the duration of concomitant tube feeding ("transition period"), the length of hospital stay and the breastfeeding rates upon discharge in preterm infants.
Study design: Preterm infants born between 26 and 33 weeks gestational age ($n = 86$), were randomized into an intervention and control group. Infants in the intervention group received an oral stimulation program consisting in stimulation of the oral structures for 15 min at least for 10 days, before introduction of oral feeding. Oral feeding was introduced at 34 weeks GA in both groups.
Results: Breastfeeding rates upon discharge were significantly higher in the intervention than in the control group (70% versus 45.6%, $p = 0.02$). There was no statistical difference between the two groups in terms of the length of the transition period or the length of the hospital stay.
The need for prolonged CPAP support (HR = 0.937, $p = 0.030$) and small size for gestational age at birth (HR = 0.338, $p = 0.016$) were shown to be risk factors for a prolonged transition period.
Conclusion: A pre-feeding oral stimulation program improves breastfeeding rates in preterm infants. The study results suggest that oral stimulation, as used in our specific population, does not shorten the transition period to full oral feeding neither the length of hospital stay.

1. Introduction

Oral feeding problems in preterm infants are of growing concern for society: cases of breast-feeding failures often result in delayed hospital discharge, maternal stress and long-term health problems. Sucking and swallowing are present in early foetal life but the coordination of sucking and swallowing and breathing and swallowing is thought not to occur before 32 and 33–34 weeks gestational age (GA) respectively. Even if the coordination of suck–swallow–breathe is not necessary to begin oral feeding, effective and safe oral feeding requires the adequate coordination of sucking, swallowing and respiration so as to avoid aspiration, apnea, bradycardia and oxygen desaturations., [1,10,11,13,20]. At present, in the absence of specific contraindications, oral feeding is commonly introduced at around 33 to 34 weeks GA. Usually, there exists a transition period of combined gavage and oral feeding which lasts days or weeks.

Accelerated maturation of the sucking reflex and earlier readiness for bottle-feeding are reported when preterm neonates are presented with non-nutritive sucking (NNS) opportunities during gavage feeding [4]. Recent evidence points to the fact that the sensory consequences associated with the production of NNS have beneficial effects on oral feeding performance and on the development of specific sucking skills [3,6,15,17,18].

Recent studies have suggested that an oral stimulation program combined with NNS applied to preterm infants for at least 10 days in the period of full gavage feeding can facilitate their oral feeding progress, improve breastfeeding rates among preterm infants and decrease the length of hospital stay, while no particular negative outcomes have been reported in the said studies [2,7–9,16,17,19].

In the present situation of our neonatal intensive care unit (NICU), as in the large majority of NICUs, preterm infants never receive oral stimulation before the introduction of oral feeding. Difficulties in the transition from tube to independent oral feeding are frequently observed, even for infants born after 32 weeks GA.

The objective of this study was to evaluate the effect of an oral stimulation program on the length of the transition period in preterm

* Corresponding author.
E-mail address: bache.manon@chl.lu (M. Bache).

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infants (primary outcome), on the length of hospital stays and on breastfeeding rates upon discharge (secondary outcomes).

2. Methods

In a prospective randomized controlled clinical trial, the effect of pre-feeding oral stimulation on the achievement of full oral nutrition within 15 days from offering oral feeding was investigated.

For an expected full-oral-feeding success rate of 95% in the intervention group versus 70% in controls, the minimal sample size needed to allow the detection of a difference between the two groups was 37 patients in each group, with a power of 80% and an alpha level of 5%.

A total of 101 preterm infants from the neonatal intensive care unit of the Children's Hospital of the Centre Hospitalier de Luxembourg, Luxembourg, were included, from July 2011 to November 2012. Infants were declared eligible for enrolment if they were born between 26 and 33 weeks GA, as determined by clinical examination and first-trimester ultrasound.

Infants were excluded from the study if they presented congenital malformations, severe asphyxia, presence of third- or fourth-degree intracranial haemorrhage, severe periventricular leukomalacia, chronic lung disease, if they suffered from a hospital infection, a necrotising enterocolitis, if they were transferred to another hospital before discharge or died during hospitalisation.

The randomized classification of the subjects into an experimental and a control group was performed when they reached 32 weeks GA in the case of infants born within 32 weeks, and at birth in the case of infants born after 32 weeks gestational age. The process was performed using sequential numbers kept in sealed, opaque, non-translucid envelopes. Randomization was stratified based on gestational age ranges (26–27, 28–29, 30–31, 32–33) to ensure a similar gestational age distribution in the two groups.

Infants in the interventional group received pre-feeding oral stimulation whereas those in the control group received neither oral stimulation nor a pacifier before or during gavage feeding.

The intervention started on infants born within 32 gestational weeks when the patients were stable and tube-fed, receiving more than 100 ml/kg/day of milk. On infants born after 32 weeks, the intervention started immediately after clinical stability was achieved. Respiratory support, either by nasal continuous positive airway pressure (CPAP) or high-flow oxygen therapy (HFT), did not represent an exclusion criterion.

The pre-feeding oral stimulation program consisted of a 15-min stimulation program delivered by one of the eight trained nurses or one trained member from the medical staff in accordance with the stimulation program proposed by Fucile, Gisel and Lau [8]. Administrators were trained to deliver the stimulation program to the patients, by a member from the paediatric physical therapies medical staff, before the beginning of the study. A written protocol and an illustrative video of the stimulation program were available at any moment to the participant staff. Regular controls of the protocol administration were performed to assure reliability of the administrators.

The stimulation program was administered 15 to 30 min prior to tube feeding, once daily for at least 10 days. The program was stopped when the infants attained more than three oral feedings per day. The program was interrupted if the infants were medically unstable and/or had episodes of desaturation, apnoea and/or bradycardia during the intervention. Tube feeding was initiated when the preterm infants were clinically stable in terms of hemodynamics and had peristalsis according to criteria established by the caretaker staff. Enteral diet progress depended on infants' tolerance and was about 20 ml/kg/day.

The change from gavage to oral feeding was initiated at 34 weeks GA, subsequent to the beginning of the oral stimulation program in the intervention group, by breast- or bottle-feeding according to the wishes expressed by the parents. A strict protocol for oral feeding advance in the two groups was defined: on the first day (34 week GA), one oral feeding dose of five millilitres or one breastfeeding opportunity was given to the infant. If the infant ingested the 5 millilitres in less than 10 min, the dose was doubled on the next day to five millilitres twice a day (or two breastfeeding opportunities). If the infant did not ingest the prescribed volume, the same number of oral feedings was proposed until the entire quantity could be ingested orally. If an infant managed to drink three times five millilitres a day, all the feedings were proposed by bottle and/or breast to this infant on the next day. The remaining quantity of milk was administered by gavage feeding. All the nurses from the NICU, including study participant nurses, were responsible for feeding infants. Full oral feeding was defined as an oral intake of milk $\geq$150 ml/kg/day, for 3 consecutive days.

Breastfeeding in our study was defined as exclusive or partial breastfeeding. Preterm infants on a mixed breast- and bottle-feeding regime were considered as breastfed, because they received the benefits of human milk and of the strong mother-to-child relationship that develops during breastfeeding.

To define discharge criteria for patients participating in the study, we used the same criteria as for all preterm infants in our unit: weight > 2000 g, feeding autonomy for more than 3 consecutive days with appropriate weight gain and respiratory autonomy controlled by polysomnography before discharge. The member of the medical staff deciding on infants' discharge was not blinded to group assignment.

2.1. Statistical analysis

The time for transition (in days) from full gavage to full oral feeding, from the beginning of oral feeding to full oral feeding, the length of the hospital stay and the breastfeeding rate (in percents) were calculated and compared between the two groups. The Student's *t*-test and chi-square test (or Fisher's exact test as appropriate) were used, for continuous and categorical variables respectively.

The Kaplan–Meier survival technique was applied to the time of transition and the length of the hospital stay. Survival curves were compared using the Wilcoxon test.

A Cox proportional hazard model was further used to assess the influence of risk factors such as gestational age ranges, birth weight, respiratory distress syndrome and prolonged intubation periods or the need for prolonged nasal-CPAP therapy, on the relationship between the groups and the time of transition or the length of the hospital stay.

Analysis was planned in intention to treat. All tests were two-tailed and results with *p*-value below 0.05 were considered statistically significant. SAS System version 9.2 was used for statistical analyses.

The study was approved by the national research ethics committee and by the neonatal unit where it was performed. Prior free and informed consent were obtained from the parents/guardians of the newborns for their participation in the study.

3. Results

Over the whole course of the study, 116 preterm infants with gestational age between 26 and 33 weeks were admitted to the neonatal unit. 101 infants were included in the study protocol. Fifteen infants were excluded: eight presented exclusion criteria and seven had less than 10 stimulation sessions. 86 patients were finally analyzed (40 in the intervention group and 46 in the control group) (see Fig. 1).

Preterm infants in the intervention and in the control groups did not differ statistically in terms of demographic or medical characteristics (see Table 1).

The 40 infants in the intervention group received 10 or more pre-feeding stimulation sessions, with an average of 13 sessions [10–14]. The reasons for the cancelled sessions were mainly transitory medical instability or work overload in the neonatal unit. Three infants had interrupted sessions because of medical instability.

52.5% of the patients in the intervention group versus 45.6% in the control group needed CPAP support between 32 and 34 weeks GA