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Clinical Research

The Long-Term Efficacy of a Galactagogue Containing Sylimarin-Phosphatidylserine and Galega on Milk Production of Mothers of Preterm Infants

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Abstract

Aims: To investigate the efficacy of a galactagogue, containing Sylimarin-phosphatidylserine (SILITIDIL) and galega consumed in the first month after delivery by mothers of preterm infants, in maintaining milk production during the first 3–6 months after delivery.
Materials and Methods: Mothers of infants born at gestational age (GA) between 27 and 32 weeks, enrolled in our previous prospective, double-blind, randomized trial and randomly allocated to receive either the galactagogue (GG) or a placebo (PG), were asked about their milk production at 3 and 6 months after delivery.
Results: Of the 100 mothers involved in this study, 45 of GG and 44 of PG responded comprehensively to the questions asked. At the third month after delivery, exclusive human milk administration was reported by 22 mothers of GG and 12 mothers of PG ($p < 0.05$), whereas 29 mothers of GG and 18 mothers of PG were able to administer >50% of the amount of milk assumed. At the sixth month of life, only eight infants received exclusive human milk (six and two of GG and PG, respectively), and the data are not sufficient for a meaningful clinical evaluation.
Conclusions: It is assumed that a galactagogue during the first month after delivery improves human milk administration to preterm neonates after discharge and for the first 3 months of life.

Keywords: galactagogue, human milk, preterm infants

Introduction

Human milk is important for all infants, especially for those born prematurely, since birth and for the first 6 months of life.[1,2] Human milk for preterm infants is important after discharge because it reduces the risk of long-term morbidities with a combination of nutritional, anti-infective, anti-inflammatory, antioxidative, and epigenetic actions.[3–5] However, the availability of breast milk may decrease gradually after the first months after delivery and this makes the administration of formula milk necessary. In a previous study,[6] we showed the efficacy of a galactagogue containing silymarin-phosphatidylserine and galega in increasing milk production during the first month after delivery in a population of mothers of preterm infants. The aim of this study was to investigate whether the administration of such a galactagogue was able to influence the duration of mother's own human milk availability after discharge.

Materials and Methods

The study population consisted of the mothers involved in a previous randomized controlled trial registered study.[6] This study was approved by the Ethical Committee of Catholic University of Rome. In the previous study, the mothers were randomized to receive Silymarin-phosphatidylserine and galega (a daily single dose of 5 g of Piùlatte Plus® MILTE) or placebo (a daily single dose of 5 g of lactose) from the 3rd to the 28th day after delivery. The end period of the previous study was 1 month after delivery.

At discharge, the mothers were urged to continue to implement all relevant practices to maintain the production of milk suggested at the beginning of the study (following a balanced Mediterranean diet taking at least 1,500 mL/day of fluids and avoiding substances potentially dangerous for the child).

Moreover, all the mothers were informed that at 3 and 6 months postpartum, they would be contacted to obtain information about their breastfeeding pattern. At discharge, about half of the mothers in each group were able to feed directly at the breast. For infants unable to be breastfed, the mothers were recommended to pump the milk in a sterile bottle regularly every 3 hours and store it in the refrigerator.

All the mothers were contacted by telephone at 3 and 6 months after delivery. The questions asked concerned the administration of exclusive human milk, the administration of

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human milk for at least 50% of the total amount assumed, and the day of the last administration of human milk. Moreover, mothers were asked for the consumption of any product to increase milk production, early weaning, and the resumption of work.

Of the 100 mothers involved in the initial study, 48 of the galactagogue group (GG) and 46 of the placebo group (PG) had some milk production at the end of the first month after the delivery. These mothers were considered for this study. Of the 94 mothers involved in this study, 45 of GG and 44 of PG responded comprehensively to the questions.

Statistical analyses

Statistical analyses were performed with Microsoft Excel 2007 (Microsoft, Redmond, WA) and SPSS for Windows 17.0 (SPSS, Chicago, IL). Comparisons were made using the Student *t* test for normally distributed continuous variables and the Fisher's exact test for categorical variables, whereas the Mann–Whitney test was used to analyze the differences when the variables were not normally distributed. A *p*-value of 0.05 was considered statistically significant.

Results

At the end of the previous study period, 29 mothers of the GG produced an amount of milk >200 mL/day compared with 15 mothers of the PG ($p < 0.01$) (Table 1).

At the end of third month after delivery, 45 mothers of GG and 44 mothers of PG answered questions posed by phone, whereas 5 mothers (3 of GG and 2 of PG) did not give reliable data.

Exclusive human milk administration was reported by 22 mothers of GG and 12 of PG ($p < 0.05$), whereas 29 mothers of GG and 18 mothers of PG were able to administer >50% of the amount of milk consumed. The differences between groups were statistically significant ($p < 0.05$). We have no data on the quantity of milk expressed because many infants were directly breastfed.

Table 1. Data About Human Milk Availability at Discharge, Third, and Sixth Month After Delivery in Study Groups

	Group A (50)	*Group B (50)*	p
At discharge[a]			
HM >200 mL/day	29	15	<0.01
HM >150 mL/day	31	21	<0.05
HM >100 mL/day	42	31	<0.01
Some HM	48	46	n.s.
At third month			
N	45	44	
Exclusive HM	22	12	<0.05
HM >50% of total amount	29	18	<0.05
At sixth month			
N	45	44	
Exclusive HM	6	2	n.s.
HM >50% of total amount	22	12	<0.05
Weaning	45	44	n.s.
Resumption of work	35	32	n.s.
Last day of some HM	136 ± 56	116 ± 50	n.s.

[a]Data from our previous RCT.

HM, human milk; n.s., not significant; RCT, randomized controlled trial.

At the sixth month of life (180 days), only eight infants received exclusive human milk (six and two of GG and PG, respectively), whereas a significantly higher number of infants of GG received human milk for almost one meal and for >50% of the total amount of milk consumed ($p < 0.05$). Some amount of human milk was consumed for 136 (SD ±50) days in GG and for 116 (SD ±50) days in PG, being the difference not statistically different.

Only two mothers of each group reported having taken substances to stimulate lactation. Weaning started for all infants during the fourth month of life and the resumption of work was not different in the two groups.

Discussion

Our previous study demonstrated that the administration of a galactagogue containing silymarin-phosphatidylserine and galega improves milk production in mothers of preterm neonates from the first days after child birth, and increases breastfeeding during the first month.[6]

Most of the mothers answered our questions about breastfeeding at 3 and 6 months after giving birth. All the mothers stated they continued to implement all relevant practices to maintain the production of milk, as suggested at discharge.

It is noteworthy that at the third month after delivery, 48.9% of mothers of GG were able to feed their neonates exclusively with human milk versus 27.3% of mothers of PG. Moreover, a significantly higher number of GG mothers were able to give >50% of total amount as human milk as compared with PG mothers. At 6 months, the number of infants receiving exclusive human milk was very low in both groups. However, some amount of human milk was consumed by a significantly higher number of infants of GG mothers. It should be emphasized that at 6 months of age, all children had started weaning and the resumption of work was evenly distributed in mothers of the two groups.

This follow-up study showed that GG mothers continued to administer human milk for a longer period than PG mothers. Many factors can improve the duration of human milk production such as regular breast pumping, degree of removal of the milk, and maternal determination.

In our study, one of the determining factors may have been early administration of mother's own milk to the preterm infant. In fact, some authors have reported that the higher the early administration of the mother's own milk, the longer the duration of breastfeeding.[7,8] Indeed, in our previous study, the effect of galactagogue administration led the GG mothers to express a significantly greater amount of human milk to ensure their babies have exclusive breast milk feeding.[6]

The strength of our study is that all the involved mothers adhered to the study because they were motivated to maintain the administration of their own breast milk after discharge. The results confirm this in both groups. This observational study has some limitations to be outlined. First of all, data were collected through a telephone interview and we do not have quantitative data on milk production. Second, we have no data on the substances taken by some mothers to stimulate production of milk, even if the number is limited and evenly distributed between the two groups. Third, we did not investigate qualitative and quantitative data on the weaning and growth, but that was not the objective of this study.

Conclusions

Despite its limitations, our study demonstrates that the administration of a galactagogue in the first month after delivery improves human milk administration to preterm neonates also after discharge and for the first 3–6 months of life.

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The study was approved by the Ethical Committee of Catholic University of Sacred Heart, Rome. Mothers adhered to the study and they did not receive any reward for participating in the study. The project did not have specific support.

Disclosure Statement

No competing financial interests exist.

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