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Improvement of digestive symptoms with a partially hydrolyzed serum, reduced lactose and *Lactobacillus reuteri* DSM 17938 - based functional infant formula in infants younger than 5 months old with infantile colic, in outpatient pediatric centers of Bogota, Colombia

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Aims and study: Infantile colic is a functional digestive disorder in first months of life, exhibited by 30% to 40% of infants. There are no specific biological markers for this entity, because of which it is diagnosed according to Rome IV criteria. As part of its management, probiotics have been studied, specifically *Lactobacillus reuteri* DSM 17938, as well as certain modifications of infant formula. The aim of this study was to evaluate clinical response to a functional infant formula with partially hydrolyzed serum protein, diminished lactose levels and the addition of de *Lactobacillus reuteri* DSM 17938 in infants under 5 months of age. Prospective descriptive non-interventional study.

Methodology: Patients from 0 to 5 months of age with a diagnosis of infantile colic according to ROME IV criteria were included, from March to June, 2018, recruited from 17 private medical offices in Bogota. Infants with organic illness and/or pharmacological treatment were excluded. Patients required management with a comfort infant formula and physician prescribed NAN® COMFORT. To evaluate the impact of infant formula, a survey to caregivers carried out at first evaluation and at 15 days after beginning the infant formula. Survey was filled out by physician at consultation. Variables such as sex, age, anthropometric measurements and digestive symptoms were included. Stata was used for the statistical analysis. The nominal and ordinal categorical variables were summarized with absolute and relative frequency distributions. The relation between the variables was established by means of the Student T, Fischer exact, and chi squared tests.

Results: Sample was made up of 51 infants, with a slight predominance of males (51.8%) and average age was 3.6 months. Average duration of symptoms previous to consultation was one month. The most frequent symptoms were excessive gas (83.9%), crying (78.6%) and pushing (67.9%). 41.1% of infants cried less than 30 minutes per day, 41.1% of the infants cried between 30 min and 2 hours per day and 17.9% cried more than 3 hours per day. The symptoms improved, for the most part, in first week of implementation of infant formula (94%). At 2 weeks, statistically significant differences were observed in: crying (p=0.006), fussiness (p=0.029), pushing (p=0.003), excessive gas (p=0.029), vomiting (p=0.003), hiccups (p=0.030), daily number of regurgitations (p=0.000), daily number of vomiting episodes (p=0.003). There was no significant difference in early satiety (p=0.320), in food rejection (p=0.577) or perianal erythema (p=0,081). Daily crying time was reduced; only 2.6% of the infants continued crying more than 3 hours a day. To the contrary, at the time of control visit (15 days), the majority of infants (84.6%) exhibited a crying time of 30 minutes a day. During the study, average gain was 476 gr in weight, 1.8 cm in height and 2.3 cm in cephalic perimeter. 98% of infants had adequate tolerance of infant formula.

Conclusions: An infant formula with some modifications in its nutritional composition (partially hydrolyzed serum protein and reduced lactose) with addition of *Lactobacillus reuteri* DSM 17938, was shown to be useful in alleviating symptoms of infantile colic in infants. Studies with a larger sample size and geographical variability should be carried out.

Digestive symptom	At time of first consultation	After 2 weeks of using functional infant formula (NAN® COMFORT)	p
Excessive Gas	83.9%	15.9%	0.029
Crying	78.6%	5.4%	0.006
Crying time 30 minutes/day	41.1%	84.6%	0.035
Crying Time greater than 3 hours/day	17.9%	2.6%	0.026
Pushing	67.9%	2.1%	0.003
Fussiness	62.3%	2.3%	0.029
Regurgitation	42.9%	8.9%	0.000
Hiccups	42.9%	2.9%	0.030
Vomiting	33.9%	9.9%	0.030

[Digestive symptoms in infants under 5 months of age with a diagnosis of infantile colic, at the time of the first consultation and after the use of a]

Disclosure of Interest: Daza W is Medical Director of Nestlé Nutrition Colombia

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