Savino *et al*., "Minor" feeding problems during the first months of life: effect of a partially hydrolysed milk formula containing fructo- and galactooligosaccharides. Acta Pædiatr 2003; Suppl 441: 86–90.

Abstract

Background: Colic, regurgitation and constipation are common feeding problems in formula-fed infants that might benefit from dietary treatment. A formula containing fructo- and galacto-oligosaccharides, partially hydrolysed proteins, low levels of lactose and palmitic acid in the β position and higher density has been tested to reduce the occurrence of these symptoms. The aim of this prospective study was to describe the effects of such a formula in infants with minor gastrointestinal disorders. *Methods:* An observational prospective trial involving practising Italian paediatricians was performed. Formula fed-infants up to 90 d of age with minor gastrointestinal problems such as infantile colics and/or regurgitation and/or constipation were enrolled in the study from January 2001 to May 2001. The study was completed within 14 d of treatment. On days 1, 7 and 14 the infants were visited by the paediatricians. Parents were given a structured diary to record daily episodes of colic, regurgitation and type and number of stools. *Results:* Of the 932 infants enrolled, 604 completed the study. Of the 214 infants with colic, 169 (79%) demonstrated a reduction in frequency of colic from 4.1 $\pm$ 2.0 per day at the beginning of the study to 2.0 $\pm$ 1.8 at the end of the study (I.C. 95%: 1.72–2.39; $p < 0.005$). A reduction in the number of episodes of colic of 1.8 per day at the beginning of the study (I.C. 95%: 1.49–2.11; $p < 0.05$) was recorded between day 1 and day 7, and of 0.26 (I.C. 95%: 0.15–0.37; $p < 0.05$) between day 7 and day 14. Of the 201 infants with regurgitation problems, 141 (70%) demonstrated a reduction of frequency of the symptoms from 4.2 $\pm$ 2.0 per day at the beginning of the study to 2.1 $\pm$ 2.2 at the end of the study (I.C. 95%: 1.75–2.35; $p < 0.005$). A reduction of 1.87 in the number of regurgitation episodes was reported between day 1 and day 7 (I.C. 95%: 1.57–2.16; $p < 0.05$) and of 0.18 (I.C. 95%: 0.06–0.31; $p < 0.05$) between day 7 and day 14. Of the 232 infants with constipation, 147 (63%) demonstrated an increase in the daily number of stools of 0.42 (I.C. 95%: 0.5–0.3; $p < 0.005$). An increase in stool frequency of 0.41 (I.C. 95%: 0.51–0.23; $p < 0.05$) was reported between day 1 and day 7, and of 0.04 (I.C. 95%: 0.22–0.14; p = ns) between day 7 and day 14. Parents' evaluation of the formula was 7.9 $\pm$ 1.8 (score 0–10); 550 parents (91%) gave a positive judgement (score >6). The evaluation by the paediatricians of the improvement in symptoms after the treatment was 8.2 $\pm$ 1.5; 574 (95%) a positive effect (score >6). *Conclusion:* This study shows that the majority of infants followed by paediatricians for minor gastrointestinal symptoms improve within 2 wk of feeding with this new formula. Further double blind, controlled studies are needed to confirm whether the amelioration of symptoms observed in this trial is in fact due to the new formula.