L'EFFETTO BARRIERA DELLA FLORA INTESTINALE…….

……*correlati clinici in età pediatrica*

Giacomo Biasucci

Dipartimento Ospedaliero Materno - Infantile
U.O. di Pediatria e Neonatologia
Ospedale "Guglielmo da Saliceto"
Piacenza

Probiotici – nuova definizione

Preparazioni di cellule microbiche o componenti di cellule microbiche che hanno effetto benefico sulla salute ed il benessere dell′ospite (e.g. lattobacilli, bifidobatteri)

Salminen 1999

Eur J Nutr (2006) 45 [Supplement 1]:I/1–I/18
DOI 10.1007/s00394-006-1101-1

ORIGINAL CONTRIBUTION

W. Allan Walker
Olivier Goulet
Lorenzo Morelli
Jean-Michel Antoine

Progress in the science of probiotics: from cellular microbiology and applied immunology to clinical nutrition

Journal of Pediatric Gastroenterology and Nutrition
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Medical Position Paper

Probiotic Bacteria in Dietetic Products for Infants: A Commentary by the ESPGHAN Committee on Nutrition

ESPGHAN Committee on Nutrition: *Carlo Agostoni, †Irene Axelsson, ‡Christian Braegger, §Olivier Goulet, ||Berthold Koletzko, #Kim F. Michaelsen, **Jacques Rigo, ††Raanan Shamir, ‡‡Hania Szajewska, §§Dominique Turck, and |||Lawrence T. Weaver

Flora batterica fecale

LM	*formula*
Bifidobatteri	Bacteroidi
Lattobacilli	Bifidobatteri
	Stafilococchi
	E. coli
	Clostridi

Possibili cause: differente qualità e quantità proteica, oligosaccaridi, fattori immuno-modulatori cellulari e umorali

Satokari RM, Vaughan EE, Favier CF, et al. Diversity of *Bifidobacterium* and *Lactobacillus* spp. in breast-fed and formula-fed infants as assessed by 16S rDNA sequence differences. *Microb Ecol Health Dis* 2002;14:97–105.

Harmsen HJ, Wildeboer-Veloo AC, Raangs GC, et al. Analysis of intestinal flora development in breast-fed and formula-fed infants by using molecular identification and detection methods. *J Pediatr Gastroenterol Nutr* 2000;30:61–7.

Rubaltelli FF, Biadaioli R, Pecile P, et al. Intestinal flora in breast- and bottle-fed infants. *J Perinat Med* 1998;26:186–91.

Heine W, Mohr C, Wutzke KD. Host–microflora correlations in infant nutrition. *Prog Food Nutr Sci* 1992;16:181–97.

Ouwehand A, Isolauri E, Salminen S. The role of the intestinal microflora for the development of the immune system in early childhood. *Eur J Nutr* 2002;41(Suppl 1):132–7.

Kunz C, Rodriguez-Palmero M, Koletzko B, et al. Nutritional and biochemical properties of human milk. Part I: General aspects, proteins, and carbohydrates. *Clin Perinatol* 1999;26:307–33.

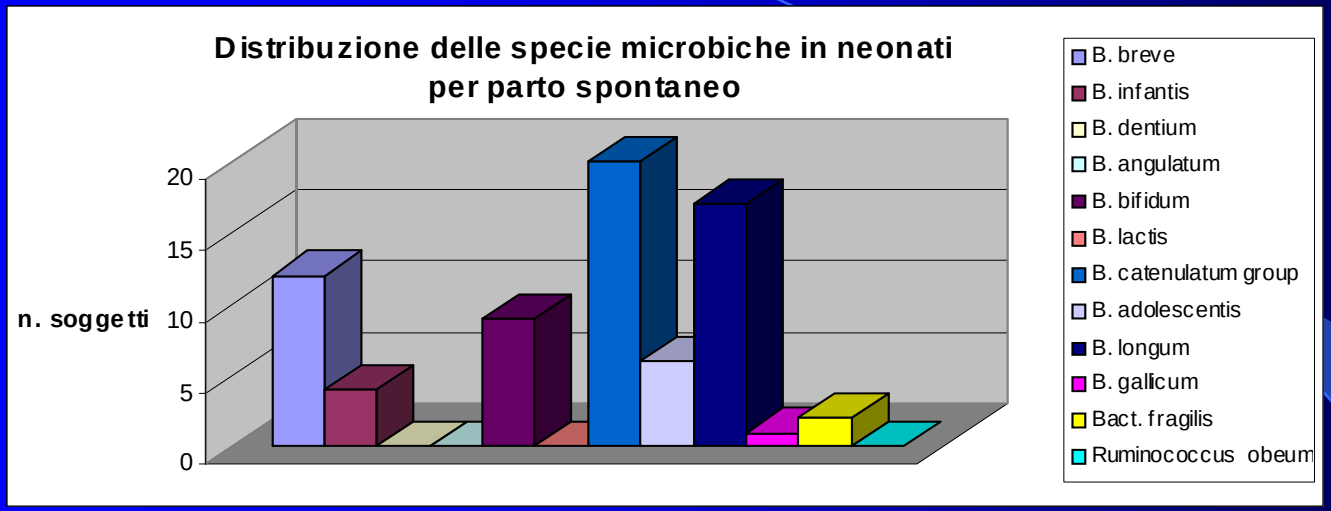
Molecular characterization of intestinal microbiota in infants born by caesarean delivery

Biasucci G[1], Benenati B[1], Morelli L[2], Bessi E[3], Boehm G[4,5]

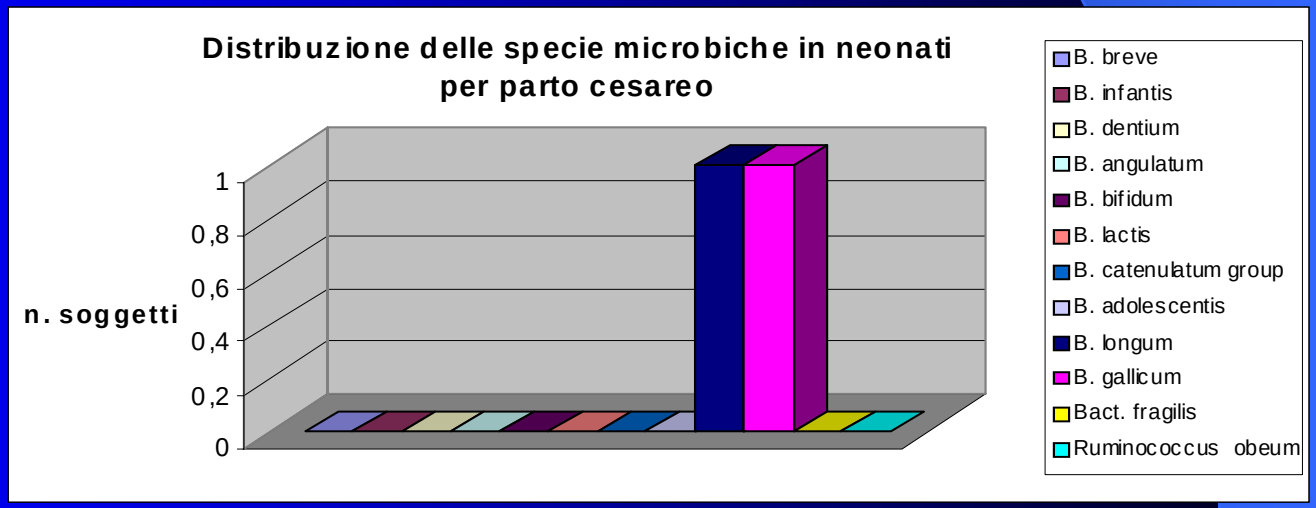
[1] Department of Paediatrics and Neonatology, “Guglielmo da Saliceto Hospital”, Picenza, Italy; [2]Institute of Microbiology, Sacred Heart Catholic University, Piacenza, Italy, [3] AAT- Advanced Analytical Technologies Srl, Piacenza, Italy, [4] Numico Research, Friedrichsdorf, Germany, [5] Sophia’s Hospital, Erasmus University Rotterdam, The Netherlands

2006, submitted for publication

Neonati da parto spontaneo



Neonati da parto cesareo



Come può, la flora intestinale, avere un ruolo nell'effetto protettivo del LM (meno gastroenteriti ed infezioni) ?:

Bifidobatteri e lattobacilli:

produzione di:

ac.acetico, lattico, acidi organici

riduzione pH

competizione per:

nutrienti e

siti adesione epiteliale

Inibizione della crescita di batteri potenzialmente patogeni

Howie PW. Protective effect of breastfeeding against infection in the first and second six months of life. *Adv Exp Med Biol* 2002; 503:141–7.
Howie PW, Forsyth JS, Ogston SA, Protective effect of breast feeding against infection. Br Med J 1990;300:11–16.

Kelleher SL, Casas I, Carbajal N, et al. Supplementation of infant formula with the probiotic *Lactobacillus reuteri* and zinc: impact on enteric infection and nutrition in infant rhesus monkeys. *J Pediatr Gastroenterol Nutr* 2002;35:162–8.
Sudo N, Sawamura S, Tanaka K, et al. The requirement of intestinal bacterial flora for the development of an IgE production system fully susceptible to oral tolerance induction. *J Immunol* 1997; 159:1739–45.

Revisione sistematica al 2003 di studi relativi a formule addizionate con probiotici:

Fonti:

EMBASE, MEDLINE, COCHRANE

Risultati:

6 RCT finalizzati alla valutazione di efficacia clinica su end point rilevanti

4 basati su formule di partenza e di proseguimento

2 basati su formule ipoallergeniche

Author	Study	Allocation concealment	Age (mo)	Patients/ Setting	Intervention	Main results	Jadad score
Infant and follow-on formulas							
Saavedra et al.[25]	RCT	Adequate	5–24	Chronic medical care hospital (USA)	FOF with *Bifidobacterium* bifidum (1.9×10^9 CFU/g) and *Streptococcus thermophilus* (0.14×10^7 CFU/g of powder) (n = 29) or control formula (n = 26), mean duration 81 days	Reduced number of patients with diarrhea (RR 0.2 [0.06–0.8]; NNT 5 (3–20)	5
Phuapradit et al.[26]	RCT*	Unclear	6–36	Orphanage (Thailand)	FOF with *Bifidobacterium* lactis Bb12 (10^8/g of powder, n = 62) or with Bb12 + *Streptococcus thermophilus* (ST) (dose not reported, n = 56) or cow's milk formula (n = 57) for 8 mo	Episodes of observed diarrhea; control 25%, Bb 65%, Bb + ST 52% (significance not reported)	1

*No details on randomization given.

RCT = randomized controlled trial; IF = infant formula; FOF = follow-on formula; CFU = colony forming units; RR = relataive risk; NNT = number needed to treat; SCORAD = score of atopic dermatitis.

Langhendries et al.[27]	RCT*	Unclear	0–2	Home (Belgium)	IF + *Streptococcus thermophilus* and *Lactobacillus helveticus* (*Bifidobacterium bifidum*) 10^6/g of powder, (n = 20) or control (n = 20) or breast-fed infants (n = 14; not randomized)	Colonization with bifidobacteria at 1 month, similar in Bb formula (12/20) *v* breast-fed (8/14), but significantly higher ($P < 0.05$) than in the group fed standard infant formula(4/20) Mean bacterial count of bifidobacteria similar in all colonized infants. Fecal pH significantly lower in the breast-fed infants than in the nonacidified bottle-fed infants.	3
Nopchinda et al.[28]	RCT*	Unclear	6–36	Orphanage (Thailand)	FOF (?) with *Bifidobacterium bifidum* Bb12 (3×10^7 CFU/g of powder, n = 51) or with Bb12 + *Streptococcus thermophilus* (ST) (3×10^7 CFU/g of powder n = 54) or cow's milk formula (FOF) (no details given) (n = 43) for 6 mo	Nutritional status (mean Z score of: weight; change of weight; height; height change; weight/height during 6 mo of intervention) Significant differences between groups at entry; no data on the amount of formula consumed and on the duration of intervention in each group. At 6 mo, data of 84/184 (57%) subjects enrolled (Bb12 71%; Bb12 + ST 43%, FOF 58%)	2

*No details on randomization given.

RCT = randomized controlled trial; IF = infant formula; FOF = follow-on formula; CFU = colony forming units; RR = relataive risk; NNT = number needed to treat; SCORAD = score of atopic dermatitis.

Author	Study	Allocation concealment	Age (mo)	Patients/ Setting	Intervention	Main results	Jadad score
Foods for special medical purposes							
Isolauri et al.[30]	RCT*	Unclear	Mean age 4.6 (age range not given)	Infants with atopic eczema during breast feeding (Finland)	Extensively hydrolyzed whey formula (H) (n = 9) Extensively hydrolyzed whey formula + *Bifidobacterium* lactis Bb-12 (HBb12) (1×10^9 CFU/g) (n = 9); Extensively hydrolyzed whey formula + *Lactobacillus* GG (HLGG) (3×10^8 CFU/g) (n = 9) Duration of intervention not reported (2 mo?)	After 2 mo: SCORAD significantly decreased in both groups treated with probiotic supplemented hydrolysates (HBb12 before treatment: 12 (5.5–18); after treatment: 0 (0–3.8); HLLG before treatment: 14.5 (6–25.3); after treatment: 1 (0.1–8.7); no significant difference in HS group; before treatment: 10 (6.5–26.5); after treatment: 13.4 (4.5–18.2). SCORAD significantly improved in 9/9 in HS-Bb-12 group after 2 mo *v* 9/9 in HS/LGG group *v* 4/9 in HS group; RR: 2.2 (95% CI: 1.5–5). After 6 mo: no difference in SCORAD.	2
Majamaa and Isolauri[29]	RCT*	Unclear	2.5–15.7	Infants with atopic eczema and cow's milk allergy (Finland)	Extensively hydrolyzed whey formula (n = 14) or extensively hydrolyzed whey formula + *Lactobacillus* GG (5×10^8 CFU/g) (n = 13) for 1 mo; follow-up for 2 mo	SCORAD after 1 mo significantly [from 26 (17–38) to 15 (7–28)], but no change in controls (from 21 (14–31) to 19 (13–31)]. After 2 mo: no significant difference between the study groups.	2

*No details on randomization given.

RCT = randomized controlled trial; IF = infant formula; FOF = follow-on formula; CFU = colony forming units; RR = relataive risk; NNT = number needed to treat; SCORAD = score of atopic dermatitis.

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Probiotics in the Treatment and Prevention of Acute Infectious Diarrhea in Infants and Children: A Systematic Review of Published Randomized, Double-Blind, Placebo-Controlled Trials

*Hania Szajewska, and †Jacek Z. Mrukowicz

**Department of Pediatric Gastroenterology and Nutrition, The Medical University of Warsaw, Warsaw, Poland; and †Medycyna Praktyczna, Cracow, Poland*

Methods: A systematic review of published, randomized, double-blind, placebo-controlled trials on probiotics in the treatment or prevention of acute diarrhea defined as >3 loose or watery stools per 24 hours in infants and children.

Conclusions: There is evidence of a clinically significant benefit of probiotics in the treatment of acute infectious diarrhea in infants and children, particularly in rotaviral gastroenteritis. *Lactobacillus GG* showed the most consistent effect, although other probiotic strains may also be effective. Further research is needed. Clinical and statistical heterogeneity of the prophylactic interventions preclude drawing firm conclusions about the efficacy of probiotics in preventing acute gastroenteritis. *JPGN 33:S17–S25, 2001.* **Key Words:** Probiotics—

REVIEW ARTICLE

Lactobacillus Therapy for Acute Infectious Diarrhea in Children: A Meta-analysis

Cornelius W. Van Niel, MD*‡; Chris Feudtner, MD, PhD, MPH‡§; Michelle M. Garrison, MPH§; and Dimitri A. Christakis, MD, MPH‡§

Results. Summary point estimates indicate a reduction in diarrhea duration of 0.7 days (95% confidence interval: 0.3–1.2 days) and a reduction in diarrhea frequency of 1.6 stools on day 2 of treatment (95% confidence interval: 0.7–2.6 fewer stools) in the participants who received *Lactobacillus* compared with those who received placebo. Details of treatment protocols varied among the studies. A preplanned subanalysis suggests a dose-effect relationship.

Conclusion. The results of this meta-analysis suggest that *Lactobacillus* is safe and effective as a treatment for children with acute infectious diarrhea. *Pediatrics* 2002; 109:678–684; *gastroenteritis, infectious diarrhea,* Lactobacillus, *meta-analysis, rotavirus.*

ARTICLES

Probiotics in primary prevention of atopic disease: a randomised placebo-controlled trial

Marko Kalliomäki, Seppo Salminen, Heikki Arvilommi, Pentti Kero, Pertti Koskinen, Erika Isolauri

Methods In a double-blind, randomised placebo-controlled trial we gave *Lactobacillus* GG prenatally to mothers who had at least one first-degree relative (or partner) with atopic eczema, allergic rhinitis, or asthma, and postnatally for 6 months to their infants. Chronic recurring atopic eczema, which is the main sign of atopic disease in the first years of life, was the primary endpoint.

Findings Atopic eczema was diagnosed in 46 of 132 (35%) children aged 2 years. Asthma was diagnosed in six of these children and allergic rhinitis in one. The frequency of atopic eczema in the probiotic group was half that of the placebo group (15/64 [23%] *vs* 31/68 [46%]; relative risk 0·51 [95% CI 0·32–0·84]). The number needed to treat was 4·5 (95% CI 2·6–15·6).

Interpretations *Lactobacillus* GG was effective in prevention of early atopic disease in children at high risk. Thus, gut microflora might be a hitherto unexplored source of natural immunomodulators and probiotics, for prevention of atopic disease.

Lancet 2001; **357:** 1076–79

Probiotics and prevention of atopic disease: 4-year follow-up of a randomised placebo-controlled trial

Marko Kalliomäki, Seppo Salminen, Tuija Poussa, Heikki Arvilommi, Erika Isolauri

Perinatal administration of the probiotic *Lactobacillus rhamnosus* strain GG (ATCC 53103), reduces incidence of atopic eczema in at-risk children during the first 2 years of life (infancy). We have therefore assessed persistence of the potential to prevent atopic eczema at 4 years. Atopic disease was diagnosed on the basis of a questionnaire and a clinical examination. 14 of 53 children receiving lactobacillus had developed atopic eczema, compared with 25 of 54 receiving placebo (relative risk 0·57, 95% CI 0·33–0·97). Skin prick test reactivity was the same in both groups: ten of 50 children previously given lactobacillus compared with nine of 50 given placebo tested positive. Our results suggest that the preventive effect of lactobacillus GG on atopic eczema extends beyond infancy.

Lancet 2003; **361:** 1869–71

ORIGINAL ARTICLE

A mixture of prebiotic oligosaccharides reduces the incidence of atopic dermatitis during the first six months of age

G Moro, S Arslanoglu, B Stahl, J Jelinek, U Wahn, G Boehm

Arch Dis Child 2006;**000**:1–6. doi: 10.1136/adc.2006.098251

See end of article for authors' affiliations

Correspondence to: Prof. Dr. med. habil. G Boehm, Numico Research Germany, Bahnstr. 14–30, 61381 Friedrichsdorf, Germany; guenther.boehm@milupa.de

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Background: Oligosaccharides may alter postnatal immune development by influencing the constitution of gastrointestinal bacterial flora.
Aims: To investigate the effect of a prebiotic mixture of galacto- and long chain fructo-oligosaccharides on the incidence of atopic dermatitis (AD) during the first six months of life in formula fed infants at high risk of atopy.
Methods: Prospective, double-blind, randomised, placebo controlled trial; 259 infants at risk for atopy were enrolled. A total of 102 infants in the prebiotic group and 104 infants in the placebo group completed the study. If bottle feeding was started, the infant was randomly assigned to one of two hydrolysed protein formula groups (0.8 g/100 ml prebiotics or maltodextrine as placebo). All infants were examined for clinical evidence of atopic dermatitis. In a subgroup of 98 infants, faecal flora was analysed.
Results: Ten infants (9.8%; 95 CI 5.4–17.1%) in the intervention group and 24 infants (23.1%; 95 CI 16.0–32.1%) in the control group developed AD. The severity of the dermatitis was not affected by diet. Prebiotic supplements were associated with a significantly higher number of faecal bifidobacteria compared with controls but there was no significant difference in lactobacilli counts.
Conclusion: Results show for the first time a beneficial effect of prebiotics on the development of atopic dermatitis in a high risk population of infants. Although the mechanism of this effect requires further investigation, it appears likely that oligosaccharides modulate postnatal immune development by altering bowel flora and have a potential role in primary allergy prevention during infancy.

Pediatrics International, 2004, 46,5: 509

Effects of bifidobacterium breve supplementation on intestinal flora of low birth weight infants

Yudong Li, Toshiaki Shimizu , Atsuto Hosaka , Noritsugu Kaneko , Yoshikazu Ohtsuka and Yuichiro Yamashiro

Background: Because bacterial populations develop during the first day of life, the authors examined whether the early administration of bifidobacteria has a positive effect on the health of low birth weight infants.

Methods: The effects of **oral administration of *Bifidobacterium breve (B. breve)*** supplements were studied in a **controlled trial with low birth weight infants** (average birth weight 1489 g). The infants were divided into three groups: Group A and B received a dose of 1.6×10^8 cells of *B. breve* supplement twice a day, **commencing either from several hours after birth (group A) or 24 h after birth (group B). Group C, the control group, received no supplement**.

Results: No significant differences in birth weight, treatment with antibiotics, and the starting time of breast-feeding among the three groups. A *Bifidobacterium*-predominant flora was formed at an average of 2 weeks after birth in group A and at an average of 4 weeks after birth in group B, while no *Bifidobacterium* was isolated in eight out of 10 infants in group C during the observation period of 7 weeks. In comparison between group A and B, *Bifidobacterium* was detected significantly earlier in group A, and the number of *Enterobacteriaceae* present in the infants at 2 weeks after birth was significantly lower in group A.

Conclusion: The results of the present study suggest that very early administration of *B. breve* to low birth weight infants is useful in promoting the colonization of the *Bifidobacterium* and the formation of a normal intestinal flora.

Reduced Incidence of Necrotizing Enterocolitis Associated with Enteral Administration of *Lactobacillus acidophilus* and *Bifidobacterium infantis* to Neonates in an Intensive Care Unit

Angela B. Hoyos, MD*

Int J Infect Dis 1999; 3:197–202.

Methods: Daily doses of 250 million live *L. acidophilus* and 250 million *B. infantis* were given to all 1237 newborns (both inpatients and transfer patients) admitted to the unit during 1 year, until they were discharged from the hospital. In this study, 1282 patients hospitalized during the previous year were used as controls.

Results: There were no complications attributed to the daily administration of *L. acidophilus* and *B. infantis*. The study groups were compared for place of origin, clinical, and demographic variables, and there was no statistically significant difference in those variables. In the historic control group, there were 85 NEC cases compared to 34 cases in the group that received probiotic prophylaxis ($P < 0.0002$). In the historic control group, there were 35 NEC-associated fatalities compared to 14 fatalities in the group that received probiotic prophylaxis ($P < 0.005$).

Dani C, Biadaioli R, Bertini G, et al. Probiotics feeding in prevention of urinary tract infection, bacterial sepsis and necrotizing enterocolitis in preterm infants. A prospective double-blind study. *Biol Neonate* 2002;82:103–8.

RCT su 585 pretermine

Lactobacillus GG dal primo pasto 6 x 10^9 CFU

Nessun effetto significativo su IVU, spesi, NEC

Oral Supplementation with *Lactobacillus casei* Subspecies *rhamnosus* Prevents Enteric Colonization by Candida Species in Preterm Neonates: A Randomized Study

P.Manzoni et al. CID, 2006;42

Group A: PT infants fed HM + probiotic x 6 wks

Group B: PT infants fed HM

P= 0.01 A vs B in frequenza di infezione

P= 0.005 in PT infants 1000-1500 g


Husni RN, Gordon SM, Washington JA, et al. *Lactobacillus* bacteremia and endocarditis: review of 45 cases. *Clin Infect Dis* 1997; 25:1048–55.
Rautio M, Jousimies-Somer H, Kauma H, et al. Liver abscess due to a *Lactobacillus rhamnosus* strain indistinguishable from *L. rhamnosus* strain GG. *Clin Infect Dis* 1999;28:1159–60.
Bayer AS, Chow AW, Betts D, et al. Lactobacillemia: report of nine cases. Important clinical and therapeutic considerations. *Am J Med* 1978;64:808–13.
Thompson C, McCarter Y, Krause PJ, et al. *Lactobacillus acidophilus* sepsis in a neonate. *J Perinatol* 2001;21:258–60.
Mackay AD, Taylor MB, Kibbler CC, et al. *Lactobacillus* endocarditis caused by a probiotic organism. *Clin Microbiol Infect* 1999;5:290–2.
Safety ???
Broughton RA, Gruber WC, Haffar AA, et al. Neonatal meningitis due to *Lactobacillus*. *Pediatr Infect Dis* 1983;2:382–4.
Oggioni MR, Pozzi G, Balensin PE, et al. Recurrent septicemia in an immunocompromised patient due to probiotic strains of *Bacillus subtilis*. *J Clin Microbiol* 1998;36:325–6.
Spinosa MR, Wallet F, Courcol RJ, et al. The trouble in tracing opportunistic pathogens: cholangitis due to *Bacillus* in a French hospital caused by a strain related to an Italian probiotic? *Microb Ecol Health Dis* 2000;12:99–101.
Hennequin C, Kauffmann-Lacroix C, Jobert A, et al. Possible role of catheters in *Saccharomyces boulardii* fungemia. *Eur J Clin Microbiol Infect Dis* 2000;19:16–20.
Nessuna segnalazione relativa a Bifidobacterium

Salminen S, von Wright A, Morelli, et al. Demonstration of safety of probiotics–a review. *Int J Food Microbiol* 1998;44:93–106.

Salminen MK, Tynkkynen S, Rautelin H, et al. *Lactobacillus* bacteremia during a rapid increase in probiotic use of *Lactobacillus rhamnosus* GG in Finland. *Clin Infect Dis* 2002;35:1155–60.

Several evaluations of the published literature have concluded that the risk of infection with probiotic lactobacilli or bifidobacteria is similar to that of infection with commensal strains, and that consumption of such products is a negligible risk to consumers, including immunocompromised hosts (65). Other side effects in which

In summary, probiotics so far used in clinical trials can be generally considered as safe. However, surveillance for possible side effects, such as infection in high-risk groups, is lacking and is needed.

Acta Pediatr. Suppl 2005,Oct, 94(449), 27-30

Dietary prebiotic oligosaccharides are detectable in the faeces of formula-fed infants.

Moro GE, Stahl B, Fanaro S, Jelinek J, Boehm G, Coppa GV.

Centre for Infant Nutrition, Macedonio Melloni Maternity Hospital, Milan, Italy.

Human milk oligosaccharides are not digested during intestinal passage and can be detected in stools. In this study it was investigated whether a prebiotic mixture of low-molecular-weight galacto-oligosaccharides (GOS) and high-molecular-weight fructo-oligosaccharides (FOS) can be detected in stool samples of formula-fed infants. The test formula was supplemented with 0.8 g/dl oligosaccharides (GOS+FOS). In the control formula, maltodextrins were used as placebo. Fecal flora was assessed at the beginning (day 1) and at the end of a 28-d feeding period (day 2). At day 2 the content of galacto- and fructo-oligosaccharides in the stool samples were measured. On study day 1, the number of bifidobacteria was not different among the groups (supplemented group: 7.7 (6.2) CFU/g; placebo group: 8.0 (6.0) CFU/g). At the end of the 28-d feeding period, the number of bifidobacteria was significantly higher in the group fed the supplemented formula when compared to placebo (supplemented group: 9.8 (0.7) CFU/g stool; placebo group: 7.1 (4.7) CFU/g stool; $p<0.001$). In all infants fed the supplemented formula, GOS and FOS could be identified in the stool samples. That was not the case in infants fed the non-supplemented formula. CONCLUSION: **The present data confirm the bifidogenicity of oligosaccharides and indicate that dietary galacto-oligosaccharides and long chain fructo-oligosaccharides remain during the whole passage in the lumen of the gastrointestinal tract, similarly to human milk oligosaccharides.**

CONCLUSIONS

Our review of available clinical trials found only limited data on the safety and clinical effects probiotic preparations added to infant formulas, follow-up formulas, and special medical foods. There is no published evidence for any long-term clinical benefit of infant formulas supplemented with probiotic bacteria. No data are available on possible long-term effects on intestinal colonization and its effects on long-term gastrointestinal and immune functions. Acquisition of such data would be highly desirable given the suggestion that bacteria ingested during early infancy are more likely to permanently colonize the intestine than those ingested during later life (84). There are some data supporting a short-term benefit of some probiotic strains in infants and young children with infectious diarrhea.

The Committee recognizes that there is evidence that some probiotic preparations have benefits on health and well-being. Reported benefits include a reduced severity of diarrhea, potential preventive effects on diarrhea, promising results of in vitro and animal studies on digestive and immune functions, and indications from human studies on possible short-term preventative and therapeutic effects on atopic eczema. In view of the potential for benefits on child health that might be achieved by the use of some probiotic bacteria, major efforts on their thorough evaluation are justified.

The

“FURTHER STUDIES ARE NEEDED”

SYNDROME

Journal of Pediatric Gastroenterology and Nutrition
41:584–599 © November 2005 ESPGHAN Committee on Nutrition

Medical Position Paper

Global Standard for the Composition of Infant Formula: Recommendations of an ESPGHAN Coordinated International Expert Group

*Berthold Koletzko,[1] †Susan Baker, ‡Geoff Cleghorn, §Ulysses Fagundes Neto, ‖Sarath Gopalan, ¶Olle Hernell, #Quak Seng Hock, **Pipop Jirapinyo, ††Bo Lonnerdal, ‡‡Paul Pencharz, §§Hildegard Pzyrembel,[2] ‖‖Jaime Ramirez-Mayans, ¶¶Raanan Shamir, ##Dominique Turck, ***Yuichiro Yamashiro, and †††Ding Zong-Yi

Journal of Pediatric Gastroenterology and Nutrition
41:578–579 © November 2005 Lippincott Williams & Wilkins, Philadelphia

Editorial

The Composition of Infant Formula: A Worldwide Approach

*Alfredo Guarino, MD and †Stefano Guandalini, MD

In this scenario, the recommendations are inevitably "conservative" in that they are rigidly evidence-based, i.e. based purely on consolidated scientific information

Non menzione a chiare lettere dei "nutrienti funzionali"
(in particolare: prebiotici, probiotici)
ma apertura sulla inclusione in documenti futuri

EUROPEAN COMMISSION
HEALTH and CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

Scientific Committee on Food

SCF/CS/NUT/IF/65 Final
18 May 2003

Report of the Scientific Committee on Food on the Revision of Essential Requirements of Infant Formulae and Follow-on Formulae

(adopted on 4 April 2003)

The working group recommends that nutritional, physiological and therapeutic effects be demonstrated by appropriate clinical studies described in detail. Formulae with added probiotic microorganisms should be labelled with the exact name of the strain and its concentration (number of microorganisms per weight unit of formula as ready for consumption). The label should include recommendations as to the amount and duration of consumption, and on storage and preparation.

Follow-on formulae with added bacteria regarded as probiotics have been for since about three years. The Committee has no reason to object to the addition of bacteria regarded as probiotics to follow-on formulae, provided the requirements described below are fulfilled.
Only bacterial strains with identity and genetic stability demonstrated by cultural and molecular methods should be used, if they can be considered as generally safe when added to the individual food and have been shown to survive the gastrointestinal passage, have the capacity to proliferate in the gut for the duration of consumption and can modify the intestinal milieu (for example pH, short chain fatty acids). The identity of the probiotic strain should be described by molecular methods in a dossier and be available to the food control authorities. The content of viable bacteria should be such throughout shelf-life as to achieve 10^6 to 10^8 colony forming units per gram of formula prepared as ready for consumption. Processing, packaging and storage should not impair the viability of the bacteria.

Grazie per l’attenzione!