970. Safety of *Bifidobacterium longum infantis* and *Lactobacillus reuteri* in Bangladeshi Infants

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Background. Although probiotics are being intensively studied in the US for many different pediatric endpoints, few studies have been performed in low-income countries. We sought to investigate safety of two commonly used probiotics in Bangladeshi infants.

Methods. Infants age 4 to 12 weeks were randomized to one month of a combination of *Lactobacillus reuteri* DSM 17938 and *Bifidobacterium longum infantis* on three different schedules: daily, weekly, or biweekly (every two weeks) or to non-probiotic control. Infants were followed for three months with mothers reporting daily health status. We compared gastrointestinal (GI) and lower respiratory (LR) symptom rates (days with symptoms/total follow-up days) across arms and assessed hospitalizations; tests for trend were also performed.

Results. As of April 2014, 123 infants have been randomized and had health data reported with a mean of 8.1 weeks of follow-up. Overall GI symptoms were rare; cough and congestion were the most common LR symptoms (table). Although some differences between arms were statistically different, no clear patterns in relation to dosing frequency were seen. 7 infants (3 from biweekly arm, 2 from weekly arm, and 2 from daily arm) were hospitalized for a total of 9 occasions–5 for pneumonia and 4 for diarrhea–and recovered fully; these hospitalizations were neither temporally related to probiotic use nor considered probiotic-related by the DSMB. No allergic responses or other reactions were observed after probiotic administration.

Percent of follow-up days with symptoms per arm

	Diarrhea	Watery or soft stool	Vomiting	Poor feeding	Colic	Cough	Congestion	Difficulty breathing
Daily	0.36	2.65	1.9	3.11	2.25	20.01*	18.89*	0.61
Weekly	0.18	4.11*	2.40	5.69*	2.52	25.51*	22.58*	3.87*
Biweekly	1.18	4.37*	3.19*	6.91*	5.20*	22.70*	25.71*	3.84*
Control	0.68	2.03	1.29	3.01	1.78	13.21	14.00	1.29
p for trend	0.0157	ns	ns	ns	ns	<0.0001	0.0068	ns

*Significantly different than control arm; ns: >0.05

Conclusion. Interim analysis identified no clear association between probiotic dosing frequency and GI or LR symptoms in young Bangladeshi infants. In this group, the two probiotics tested appeared to be safe but, in this early stage of the study, did not demonstrate a symptomatic clinical benefit.

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