

## Bifidogenicity of galacto-oligosaccharides in diarrhea management of acute malnourished infants and young children

M. Nasir<sup>1</sup>, H. U. Rehman<sup>1</sup>, N. Aziz<sup>2</sup> and M. A. Jabbar<sup>1</sup>

<sup>1</sup>Department of Food & Nutrition, University of Veterinary & Animal Sciences, Lahore, Punjab, Pakistan and <sup>2</sup>Department of Social & Community Pediatrics, Mayo Hospital, Lahore

*Bifidobacteria* and *Lactobacilli* colonized by galacto-oligosaccharides modulate the gut environment by civilizing the abnormalities of both the intestinal flora and the colonic micro-flora.<sup>(1)</sup> Maintenance of the gut environment is a key factor in determining outcome in the care of critically malnourished patients.<sup>(2)</sup> Diarrhea is the leading cause of infant and child death in Pakistan. About 4 billion episodes of diarrhea/year cause 1.5 million deaths mostly in children of less than five years.<sup>(3)</sup> Appropriately, the development of nutraceutical therapy for infantile diarrhea has become a major priority of the Pakistan Ministry of Health and of international funding agencies. Paradoxically, however, there is virtually no published anthropological literature on diarrhea-related pathologies and nutraceutical remedies for infants and young children who make up 24% of the nation's population. The study reported on here focuses on these matters to through application of prebiotics.

The objective was to assess the clinical and nutritional efficacy of prebiotics enriched functional foods for the treatment of acute diarrhea in severe acute malnourished infants and young children.

In a prospective, placebo-controlled, double-blind, randomized trial, severe acute malnourished infants were fed a control formula (F-75 an F-100) or Oligomate 55N/55NP enriched study formula (fortified F-75 an F-100 @ 1 g/100 kcal) respective to patient's weight to 6–59 months infants and young children. Safety, tolerance, and immunological effect against diarrhea was assessed based on weight gain during the treatment period (primary outcome) as well as recumbent length, abdominal distention, digestive tolerance, stool consistency and adverse events (secondary outcomes).

Forty infants and young children were enrolled. During the treatment period, difference in mean weight gain between control and study formula groups in both the intention-to-treat and per protocol populations were within the predefined equivalence boundaries of 3.9 g/d, indicating frequent weight gain in study formula fed infants. In prebiotic and control groups nutritional cure was similar (57.5% [23 of 40] and 50.0% [22 of 40];  $P = 0.40$ ). Between the groups secondary outcomes were also similar and in the prebiotic group ( $P = 0.06$ ) subgroup analyses showed possible trends towards reduced outpatient mortality. Numbers of days in hospitalized stay were minimized in case of prebiotic fed study formula. Incidences of crying, regurgitation and vomiting were similar across all groups, indicating that GOS was well tolerated by and safe in infants and young children. Secondary outcomes did not show significant differences between groups during the treatment period. Infant formulas containing prebiotics resulted in increased rate of weight gain compared with those fed a control formula. The episodes of diarrhea were also significantly less in patients fed on fortified formula compared to control formula.

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