

14 CLINICAL STUDIES

14.5 Pediatric Malnutrition

A preliminary randomized, controlled study was conducted to assess the acceptability, safety, and digestibility of dietary plasma proteins in young children. Masked study diets were provided sequentially to each of 10 young, Peruvian children (9 – 25 months) recovering from severe protein-energy malnutrition, during 3 randomly ordered, 7-day dietary periods. The control diet was prepared from rice, milk, vegetable oil, and sugar; the 2 study diets included bovine-derived plasma proteins to replace either 25% or 50% of the milk protein of the control diet. All children consumed the entire amounts offered of each of the diets. The mean number of daily bowel movements, mean apparent absorption and retention of nitrogen, and mean apparent absorption of carbohydrate were similar for each diet. Fractional absorption of dietary lipid and of total energy increased significantly in relation to the amount of bovine-derived plasma proteins in the diet. Although the simultaneous replacement of milk fat in the control diet was replaced by vegetable oil in the plasma protein-containing diet, the difference in digestibility of these sources are both excellent (> 90%). Therefore, the increase in fractional absorption is likely due to increased bovine-derived plasma protein content. Numerical improvements in nitrogen retention were also noted with increased bovine-plasma protein which means improved absorptive function was also a potential explanation for the improvement. Each diet was well-tolerated by the children in the study, and there was no evidence of any adverse effects of plasma proteins. Another randomized, controlled, community-based intervention study to evaluate the effects of bovine-derived plasma proteins and/or multiple micronutrients on children's growth, morbidity, and micronutrient status was performed. A total of 259 children who were initially 6 to 7 months of age received 1 of 4 maize-based dietary products daily for 8 months: plasma proteins, whey protein concentrate (control group), whey protein concentrate plus multiple micronutrients, or plasma proteins plus multiple micronutrients. Two hundred and twenty-five (225; 86.9%) children completed ≥ 60 days of observation, 184 (71.0%) completed ≥ 180 days of observation, and 132 (51.0%) finished the full 8 months of observation. All diets were well-tolerated. There were no significant differences in the number of dropouts by treatment group at any time point. There were no significant differences in growth or rates of morbidity by treatment group for those children who completed 8 months of observation. Children who received multiple micronutrients had lower rates of anemia. Those who received whey protein concentrate plus multiple micronutrients showed less of a decline in serum ferritin than those who did not, but there were no differences in other biochemical indicators of micronutrient status by treatment group. Administration of multiple micronutrients reduced anemia and iron deficiency in this population, but the multiple micronutrients content and source of protein in the product did not affect other indicators of micronutrient status, growth, or morbidity.