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329 *EFFECT OF AN EXTENSIVELY HYDROLYZED PROTEIN HUMAN MILK FORTIFIER ON THE GROWTH OF PRETERM INFANTS*

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Background: Multicomponent human milk fortifiers (HMF) are required to supplement the nutritional base of human milk for the best growth of preterm infants. More extremely low birth weight infants are surviving than in the past. These vulnerable infants increase the clinical need for human milk fortifiers with higher protein and reduced or absent microbial content (commercial sterility).

Objectives: The objectives of this study were to demonstrate that a newly formulated concentrated liquid versus standard powdered HMF would support growth and tolerance when added to human milk.

Methods: This was an unblinded randomized controlled multicenter study conducted on preterm infants receiving human milk supplemented with two randomly assigned human milk fortifiers (HMF), either a newly formulated HMF containing liquid extensively hydrolyzed bovine protein (LE-HMF) or a conventional powdered intact bovine protein HMF (Similac Human Milk Fortifier, PI-HMF) as control. The study population consisted of preterm infants ≤ 33 weeks gestational age with birth weights ranging from 700 to 1500 g who were enterally fed human milk. Infants were studied from the first day of human milk fortification when subject reached an intake of at least 100 mL/kg/day of human milk until day 29 after fortification began or hospital discharge, whichever came first. Anthropometric indices, feeding tolerance, serum biochemistries, enteral intake, and morbidity data were assessed.

Results: A total of 147 preterm infants were enrolled at 14 NICUs. There were 129 infants in a total intent-to-treat (ITT) population, with 75 of these infants in a strict evaluable (SEV) group with complete data to the end of the study. There was no statistical difference for the primary outcome of weight gain (g/kg/day) between the groups in the ITT or SEV analyses. Weight gain reported in the ITT analysis was 17.5 and 18.2 g/kg/day for the PI-HMF and LE-HMF, respectively. In the SEV subset of infants, the weight over the course of the study in the experimental group (LE-HMF) exceeded the control group (LE-HMF > PI-HMF, p=0.036) and those infants receiving LE-HMF reached 1800 g ~ 1 week sooner than the infants fed PI-HMF (19 versus 26 days, respectively; p = 0.049). In the ITT analyses no differences were seen with the secondary outcomes, length and head circumference (HC) gains (cm/week) but in the SEV subset of infants the length over the course of the study in the LE-HMF exceeded the PI-HMF (p= 0.029). The protein intake from fortified human milk was significantly higher in the LE-HMF group as compared to the PI-HMF group (3.9 vs. 3.3 g/kg/day; p< .0001). Both fortifiers were well tolerated with no significant differences in overall morbidity.

Conclusion: The improved growth, excellent tolerance and low incidence of morbidity outcomes point to the safety and suitability of this experimental HMF for preterm infants. Growth with this fortifier closely matches the recent recommendations for a weight gain of at least 18 g/kg/day.