Abstract and Key words

Title: A randomized controlled trial comparing the effect of fortification of human milk with an infant formula powder with unfortified human milk on the growth of very low birth weight babies

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Aim: To study the effects of human milk fortification with an infant formula on the growth (weight gain pattern, linear growth and head growth) and biochemical parameters of preterm VLBW babies.

Material and Methods:

Design: Prospective, randomized controlled trial.

Setting: Level III neonatal unit of a tertiary care hospital in south India

Subjects: Preterm infants weighing <1500 grams and <34 weeks of gestation born between November 2013 to December 2014 were enrolled. Sample size was calculated to be 138 (69 each arm) to achieve a power of 90% with Alpha error of 5% for a 2 tailed test.

Babies were randomized, stratified according to birth weight (<1250 gm and 1250 to < 1500 g.) into two groups. One group received fortified human milk while the other
exclusive human milk. Fortification was done with a commercially available infant milk powder added to expressed breast milk and continued till the baby reached 1.8 Kg. Primary outcome was rate of weight gain/kg/day. Secondary outcome measures were linear growth, head circumference increase, biochemical parameters to assess the adequacy or excess of protein supplementation and Co-morbidities like feed intolerance, sepsis and NEC.

Results: Total 163 babies were randomised during the study period, out of which 148 babies (73 in the standard arm and 75 in the fortification arm) completed the trial. Base line demographic data among the two groups were comparable. Weight gain/kg/day (16.06 ± 2.9 g/kg/day vs 18.03 ± 2.9 g/kg/day; p<0.001) and linear growth (length gain in cm /week 0.96±0.23 cm vs 1.04±0.21cm; p=0.016) was significantly higher in the fortification arm as compared to the control arm. The head growth (head circumference gain in cm/week) and length of hospital stay improved in the fortification arm, though not statistically significant. Biochemical parameters, rates of sepsis, feeding intolerance and NEC were not different between the two groups.

Conclusion: Fortification with Infant milk powder can be a useful alternative for human milk fortification for feeding preterm VLBW babies in low resource settings

Key words: Human milk fortification; Infant milk powder; newborn