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Original Research Article

Role of probiotics in preterm infants: a randomized controlled trial

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ABSTRACT

Background: Probiotics are live microorganisms that, when administered in adequate amounts, confer a health benefit on the host. Probiotics are proposed to aid in the quicker colonisation of the preterm gut by various mechanisms thereby providing innumerable health benefits to the preterm infants. Hence we conducted a study to analyse the role of probiotics in preterm babies. Our primary aim was to compare the weight gain pattern among preterm infants: those receiving probiotic and those who did not receive the probiotic.
Methods: Preterm/VLBW babies were selected, randomized and placed into two groups. One group was given the chosen probiotic and the other was kept as control. The weight gain pattern and the duration of hospital stay among the two groups was compared at the end of one month of age.
Results: The average weight gain in the probiotic group was higher than the control group which was statistically significant. (mean difference: 0.230 + 0.11 95% CI: -0.796 to -0.251 p value <0.000).
Conclusions: Our study was yet another evidence proving the utility of probiotics in the field of neonatalogy.

Keywords: Probiotics, Preterm, VLBW

INTRODUCTION

Very low-birth-weight infants-VLBW (birth weight <1500 g), preterm babies less than 34 weeks are more prone for extra uterine growth restriction owing to their immaturity and poor nutrition. Evidence shows that the caloric and protein deficits leads to significant morbidity and mortality, slower growth velocity along with the complications of prematurity. Therefore, the optimization of nutrition in the early postnatal life of a preterm neonate is a priority. Probiotic therapy is based on the concept of normal gut microbiota and dysbiosis.[1] WHO, defines probiotics as "live microorganisms that, when administered in adequate amounts, confer a health benefit on the host".[2] Probiotics are known to have various potentially beneficial effects on gut function and maturity. Oral introduction of probiotics has been shown to reinforce various lines of gut defence-immune exclusion, immune elimination, and immune regulation. Hence we decided to implore the beneficial effects of oral administration of probiotics in the preterm/very low birth infants focusing mainly on the effects on enteral nutrition and growth and the days in hospital.

The gastrointestinal tract of the foetus is sterile but becomes rapidly colonized in the early days of life. The predominant sources of microbes for the initial colonisation of the GIT following birth are the maternal micro biota, especially during vaginal delivery and the infant's diet (breast versus formula feeding).

Others factors that influence the composition of the enteric micro biota of infants are the environment during birth, gestational age, hygiene measures, and antibiotic treatment. As the preterm babies require supportive care like nil per oral, antibiotics to prevent infection (antibiotics pose a threat to the gut micro flora) the gut maturation is altered. Since the maturation of the gut

microbiota coincides with early life development, failure to develop a health compatible microbiota composition, may result in pathology and disease in later life. Hence this early life should represent a preferred stage of life for probiotics interventions. Probiotics act upon the infant gut by, processing enteral antigens and balancing the gut microbiota, regulating energy balance, competitively excluding pathogens (inhibiting adhesion, competing for nutrients and receptors, producing antimicrobial molecules), inducing mucin production, strengthening the gut barrier (regenerating epithelial cells, reinforcing tight junctions, restraining permeability), augmenting antigen-specific sIgA production, modulating the cytokine response of epithelial cells, controlling inflammatory responses (reducing proinflammatory cytokine production, promoting tolerogenic DCs and T cells, activating natural killer cells). modulating the differentiation of CD4+ naïve T cells.[3] In preterm infants, probiotic supplementation can allow acquisition of normal commensal flora in a host where this process has been delayed or support the transition to an intestinal micro biome with beneficial microbes, particularly in hosts where this process has been disrupted.

The aim of this study was to compare the weight gain pattern of preterm/VLBW infants who were supplemented with probiotics against the controls, during the hospital stay and up to one month after discharge. Other objective was to determine the duration of hospital stay among the two groups.

METHODS

Randomized controlled trial. Random numbers were generated from the computer and the babies were randomly placed into two groups A and B. Group (A) was taken as the control, who received only preterm care whereas Group (B) was supplemented with probiotics along with routine preterm care Figure 1.

The choice of probiotic was made after a thorough research of the literature. And we chose a locally available probiotic which contained multiple strains of organisms. Based on the literature review, dose was determined as half sachet (containing not less than 1 million CFU) twice daily. Expressed breast milk was used as the diluent for the probiotics. It was administered through palladai twice daily. Weight gain was monitored in both the groups for a period of one month. Figure 2, 4. The average duration of hospital stay between the two groups was also noted Figure 3.

RESULTS

Statistical analysis was done using the Independent T-test and the results tabulated. 49 babies who met the inclusion criteria (<1.5 kgs/ preterm <34 weeks of gestation) were taken into the study and placed into the two groups after randomization. 4 babies were excluded from the study as they were lost for follow up and started on formula feeds.

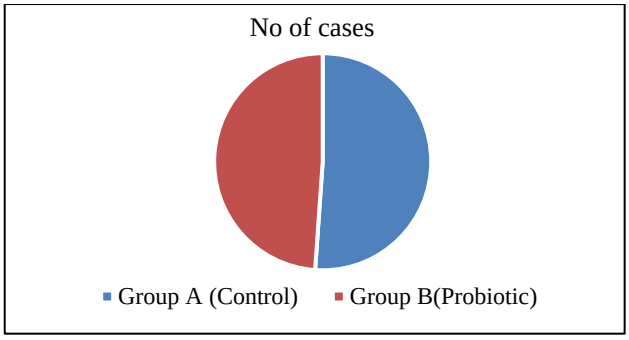

Figure 1: Distribution of cases.

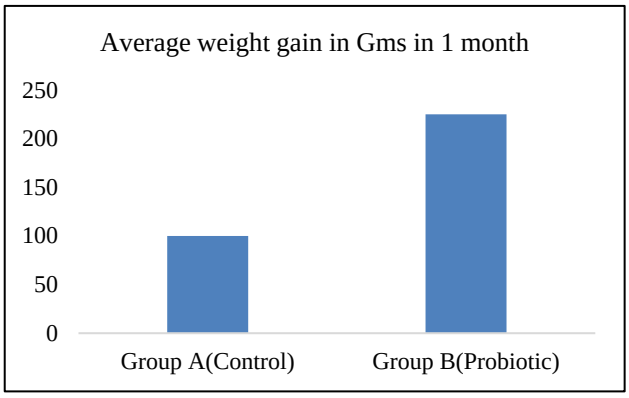

Figure 2: Average weight gain.

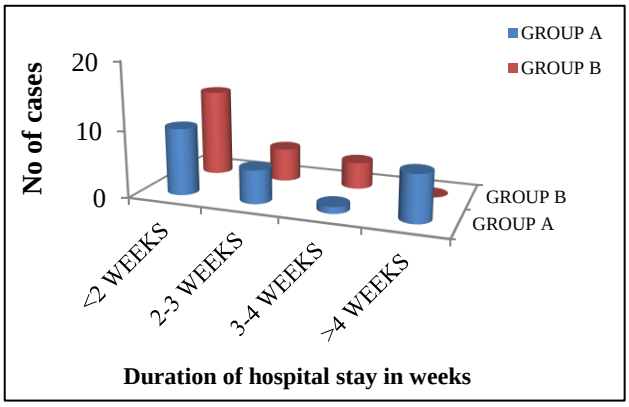

Figure 3: Number of hospitalisation days.

The average weight gain in the probiotic group was higher than the control group which was statistically significant (mean difference: 0.230±0.11 95% CI: -0.796 to -0.251 p value <0.000). The duration of hospital stay in the two groups was compared and the results were tabulated. Statistically analysis was not significant between the groups (mean difference -5.576±2.233; p value <0.016).

DISCUSSION

Probiotics restore the gut from the existing dysbiosis in the preterm babies to normal gut milieu. They also help the gut by promoting various immunological functions.

This helps the immature gastrointestinal tract in feed tolerance. They also reduce the growth of pathogenic bacteria by competing for their attachment to the intestinal villi. Researchers have found that probiotics were useful when used singly or in combinations. In our study we employed multistrain probiotic which contained lactobacillus acidophilus, bifidobacterium infants, saccharomyces boulardi etc.

Study observed the beneficial effects associated with probiotic supplementation in relation to post-natal weight gain in preterm infants. Our study showed that there was a statistically significant increase in weight gain in the probiotic supplemented preterm infants. Numerous studies were done in the past decade which showed significant increase in the weight gain with probiotic supplementation.[4] The probiotic supplemented group showed an increase in the weight at the end of one month of usage. Even though the results of some studies done in the recent past, have proved that there is not much of a beneficial effect, the use of probiotics in preterm infants cannot be underestimated.[5,6]

Few studies have analysed the hospitalisation days and have shown a positive association- reduction in the number of hospitalised days.But, in our study there was no significant reduction in the average duration of hospital stay.[7]

CONCLUSION

This study is another proof in the growing field of evidence for the usage of probiotics in preterm infants. Even though our study was conducted in a small sample size, it could be observed that the usage of probiotics in preterm infants had beneficial effect on the growth of these infants. Yet specific guidelines must be established for the usage of the probiotics in the preterm infants.

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