Effects of probiotics *Lactobacillus casei var. rhamnosus* on the incidence of necrotizing enterocolitis in preterm infants in Nepal: A randomized, double-blind, placebo controlled trial

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**Background & Aim:** Although recent reports suggest that the use of probiotics may enhance intestinal functions in premature infants, the mechanisms are unclear and open questions remain regarding the safety and its efficacy. The objective of this study is to evaluate the efficacy of probiotics on prevention of necrotizing enterocolitis in preterm infants.

**Methods:** We conducted a randomized, double blind, placebo controlled (1:1) study of 72 hospitalized preterm infants from March 2013 to August 2015 at Neonatal Intensive Care Unit of Dhulikhel Hospital, Kathmandu University Hospital. They were randomly allocated to receive probiotics (*Lactobacillus rhamnosus* 35) at a dose of 0.8 mg in infants >1500 gms and 0.4 mg in infants <1500 gms in 2 ml of expressed breast milk two times daily or the same amount of expressed breast milk as placebo (without probiotics). Data analysis was performed in SPSS using the chi-square test, independent T-test and Fisher’s exact test and a p value<0.05 was considered as significant. Ethical clearance was obtained from the Institutional Review Committee of Kathmandu University School of Medical Science and also from Nepal Health Research Council.

**Result:** 72 patients were studied. The probiotics group (n=37) and placebo group (n=35) showed similar clinical characteristics. Although necrotizing enterocolitis (16.2% vs. 28.6%) was found less frequent in the probiotics group compared to the control group, this difference was not significant (p=0.16). Among the risk factors for necrotizing enterocolitis, pregnancy risk factors and perinatal risk factors were not significant. However neonatal risk factors were more frequent in the probiotic group (59.3%, n=32) than in the placebo group (40.7%, n=22), the difference was significant (p=0.02).

**Conclusion:** Probiotics administration might not be sufficient to decrease the risk for necrotizing enterocolitis especially in low birth weight infants. NEC is multifactorial and depends on multiple risk factors as well.

**Biography**

Srijana Dangol Singh is currently working as an Associate Professor at Kathmandu University Hospital, Nepal.

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