Journal of Neonatal Surgery
ISSN(Online): 2226-0439
Vol. 14, Issue 6s (2025)
https://www.jneonatalsurg.com

OPEN ACCESS

Impact of Probiotic Supplementation on duration of hospital stay in Preterm and Low Birth Weight Neonates In a Tertiary Care Centre: A Randomized Controlled Study

Dr. Priya Ambawata[1], Dr. Ranjit Ghuliani[2], Dr. Praneta Swarup[3], Dr. Rajeev Kumar Thapar[4],Dr. Abhinav Dhankar[5]*

[1]Junior Resident, School of medical Sciences & research, Sharda Hospital, Sharda University, Gr. Noida

[2]Professor, School of medical Sciences & research, Sharda Hospital, Sharda University, Gr. Noida

[3]Assistant Professor, School of medical Sciences & research, Sharda Hospital, Sharda University, Gr. Noida

[4]HOD & Professor, School of medical Sciences & research, Sharda Hospital, Sharda University, Gr. Noida

[5]*Junior Resident, School of medical Sciences & research, Sharda Hospital, Sharda University, Gr. Noida

***Corresponding author:**

Dr. Abhinav Dhankar

Junior Resident, School of medical Sciences & research, Sharda Hospital, Sharda University, Gr. Noida

Cite this paper as: Dr. Priya Ambawata, Dr. Ranjit Ghuliani, Dr. Praneta Swarup, Dr. Rajeev Kumar Thapar, Dr. Abhinav Dhankar, (2025) Impact of Probiotic Supplementation on duration of hospital stay in Preterm and Low Birth Weight Neonates In a Tertiary Care Centre: A Randomized Controlled Study. *Journal of Neonatal Surgery*, 14 (6s), 901-907.

Received: 18/030205 **Accepted: 10/04/2025**

ABSTRACT

Background: Globally, an estimated 15 million babies are born prematurely each year, while over 20 million infants are born with low birth weight (LBW). The worldwide prevalence of preterm birth (PTB) is about 10.6%, with South Asia contributing to over one-third of these cases.[1] In India, between 2019 and 2021, around 12% of births were preterm, and 18% of newborns had low birth weight. Additionally, nearly 3 million stillbirths occur globally each year, with 98% taking place in developing countries.[2]

Aim- To assess the role of probiotics usage on length of stay in preterm and low birth weight neonates in a tertiary care centre- a randomized control study.

Materials and methods : Neonates born between 28–36 weeks of gestation or weighing less than 1800 grams, admitted to the NICU at Sharda Hospital and meeting the inclusion criteria, were enrolled after obtaining informed parental consent. Data were recorded using a structured case form. Participants were randomly assigned to two groups (A and B) using computer-generated block randomization, with allocation concealed in sealed, numbered envelopes. Blinding was maintained for both the medical team and investigators. Bacillus clausii (probiotic) and sterile water (placebo) were identically coded and dispensed, with only the designated nurse aware of group assignments. Each neonate received 2.5 mL of the assigned preparation orally every 12 hours with feeds, continued until discharge or death, and temporarily withheld during feed interruptions.

Results During the study period, a total of 112 neonates were enrolled and evenly distributed into two groups: Group A (placebo, n = 56) and Group B (probiotic, n = 56). The baseline demographic characteristics, including gestational age, gender, and birth weight, were comparable between the two groups, indicating effective randomization. A statistically significant reduction in the number of NICU stay days was observed in the probiotic group compared to the placebo group, suggesting a potential benefit of probiotic supplementation in reducing hospital stay duration among preterm and low birth weight neonates.

Conclusion : The findings of this study indicate that probiotic supplementation is associated with a significant reduction in the duration of NICU stay among preterm and low birth weight neonates. This suggests that probiotics may serve as an effective adjunct in improving clinical outcomes by shortening hospitalization in this vulnerable population.

Keywords: *Probiotics, NICU, Length of stay, Pre-term, Neonates, RCT*

1. INTRODUCTION

PROBIOTICS

Probiotics are supplements or foods that contain viable microorganisms that alter the microflora of the host.[3]

The Greek meaning of the word probiotic is “for life”. Which are viable live microorganisms when administered in adequate amounts confer a health benefit on the host. Several lactococci, lactobacilli and bifid bacteria are held to be health benefiting bacteria but little is known about the probiotic mechanism of gut microbiota.[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 microbiome with beneficial microbes, particularly in hosts where this process has been disrupted.[4]

Several mechanisms of probiotic action may explain how their therapeutic use can help prevent NEC. These mechanisms include enhancement of epithelial barrier function, competitive exclusion of pathogens, and direct anti-inflammatory effects on epithelial signaling pathways[4,5,6,7]

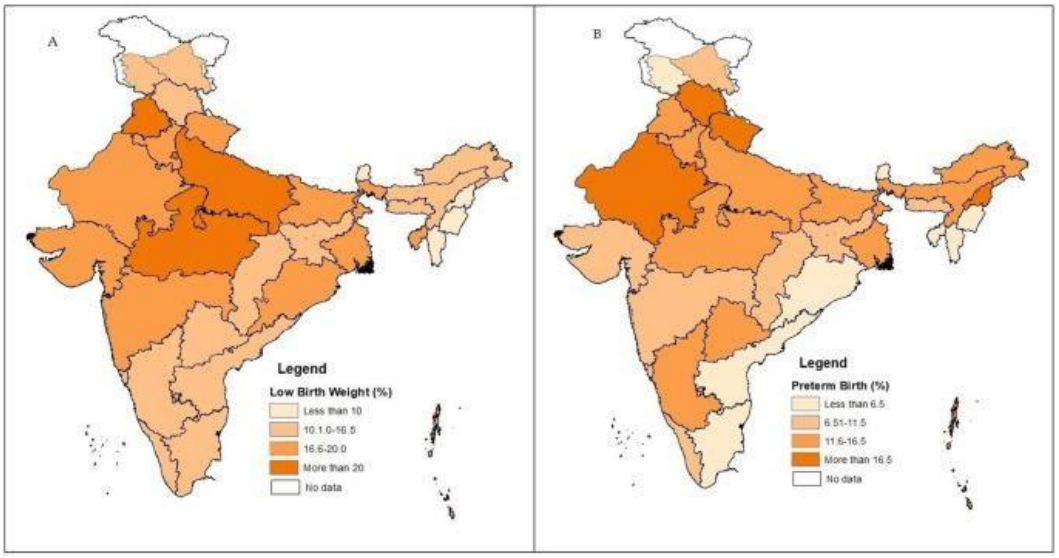


Figure 1. Spatial pattern of low birth weight (A) and preterm birth (B) in India, 2019–21. (Adapted from Jana A. Correlates of low birth weight and preterm birth in India. PLoS One. 2023)

There is limited data from India examining the impact of probiotic use on the duration of hospitalization in neonates. Recently, the Indian Academy of Pediatrics (IAP) acknowledged the scientific rationale for probiotic use in clinical practice. In light of this, a double-blinded, block randomized controlled trial was conducted to address the existing knowledge gap and evaluate the effect of probiotics on reducing the length of NICU stay in preterm and low birth weight neonates.

2. MATERIALS AND METHOD

This double-blinded, block randomized controlled study was conducted over a period of 18 months, from May 2023 to November 2024, in the Neonatal Intensive Care Unit (NICU) of Sharda Hospital, Greater Noida, Uttar Pradesh. The study population included neonates born between 28 to 36 weeks of gestation or with a birth weight of less than 1800 grams, who were on orogastric tube (OG) or katori/spoon (K/S) feeds and admitted to the NICU. A total of 112 eligible neonates were enrolled in the study. The research was initiated following approval from the institutional ethics committee, ensuring adherence to ethical guidelines throughout the study period.

This study was conducted on both inborn and outborn neonates admitted to the Neonatal Intensive Care Unit (NICU) of Sharda Hospital. Eligible participants included preterm neonates with a gestational age between 28 and 36 weeks or a birth weight of less than 1800 grams, who were receiving feeds via orogastric tube (OG) or katori/spoon (K/S) method. Neonates who were shifted to the mother's side or were nil per oral (NPO) due to critical illness were excluded from the study.

Following parental consent—obtained after clearly explaining the study's objectives, methodology, and potential benefits—neonates who met the inclusion criteria were enrolled. Gestational age was assessed using the Dubowitz scoring method, as detailed in the annexures, and nude birth weight was measured using a calibrated electronic pan balance with a sensitivity of 10 grams. All relevant demographic and clinical data were recorded in a predesigned case record form.

Participants were randomized using a double-blinded block randomization method. A computer-generated sequence was used to create randomization blocks, with each block consisting of four participants. This ensured equal distribution into two groups—Group A (placebo, n = 56) and Group B (probiotic, n = 56)—maintaining a 1:1 allocation ratio across 14 blocks. Allocation concealment was ensured using sequentially numbered, opaque, sealed, and stapled envelopes, inaccessible to the investigators responsible for participant enrollment and assessment.

The intervention involved administration of Bacillus clausii as the probiotic, with each 5 mL respule containing 2 billion spores. The placebo consisted of 5 mL sterile water, packaged identically. Blinding was maintained throughout the study; all probiotic and placebo containers were coded, with labels concealed and packed separately under designations Group A and Group B. Only the NICU in-charge nurse, responsible for administering the intervention, had access to the allocation details.

The primary parameters observed during the study included gestational age, birth weight, and duration of NICU stay.

Results

During our study period, a total of 112 neonates were enrolled in the study with equal distribution of neonates in both the groups i.e. Group A- placebo (n=56) and Group B- Probiotic (n=56).

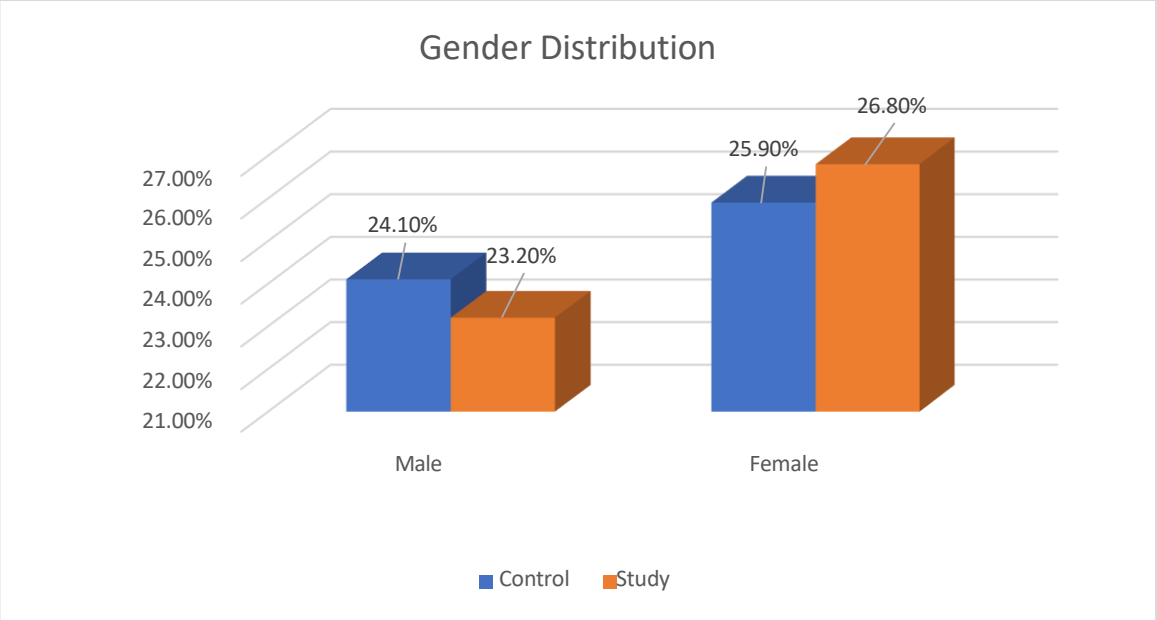
3. DEMOGRAPHIC CHARACTERISTICS-

GENDER

The study population included 48 males (45.28%) and 58 females (54.71%) neonates.

Table 9. Demographic characteristics of the study population based on Gender

GROUPS	Male	Female	Total	χ^2 value	df	P value
Control Group (A)	27	29	56	0.0358	1	0.850
	24.1%	25.9%	50.0%			
Study Group (B)	26	30	56			
	23.2%	26.8%	50.0%			
Total	53	59	112			
	47.3%	52.7%	100.0%			



GESTATIONAL AGE (Weeks)

Gestational Age was comparable in both the groups.

Table 10. Demographic characteristics based on gestational age

Gestational Age	Control Group (n=56)	Study Group (n=56)
Mean	33.6	33.8
Median	34.0	34.0
Standard deviation	2.09	2.07
Minimum	29.3	28.3
Maximum	38.3	39.4

Independent Samples T-Test				
		Statistic	**df**	
Gestational Age(weeks)	Student's t	-0.652	109	

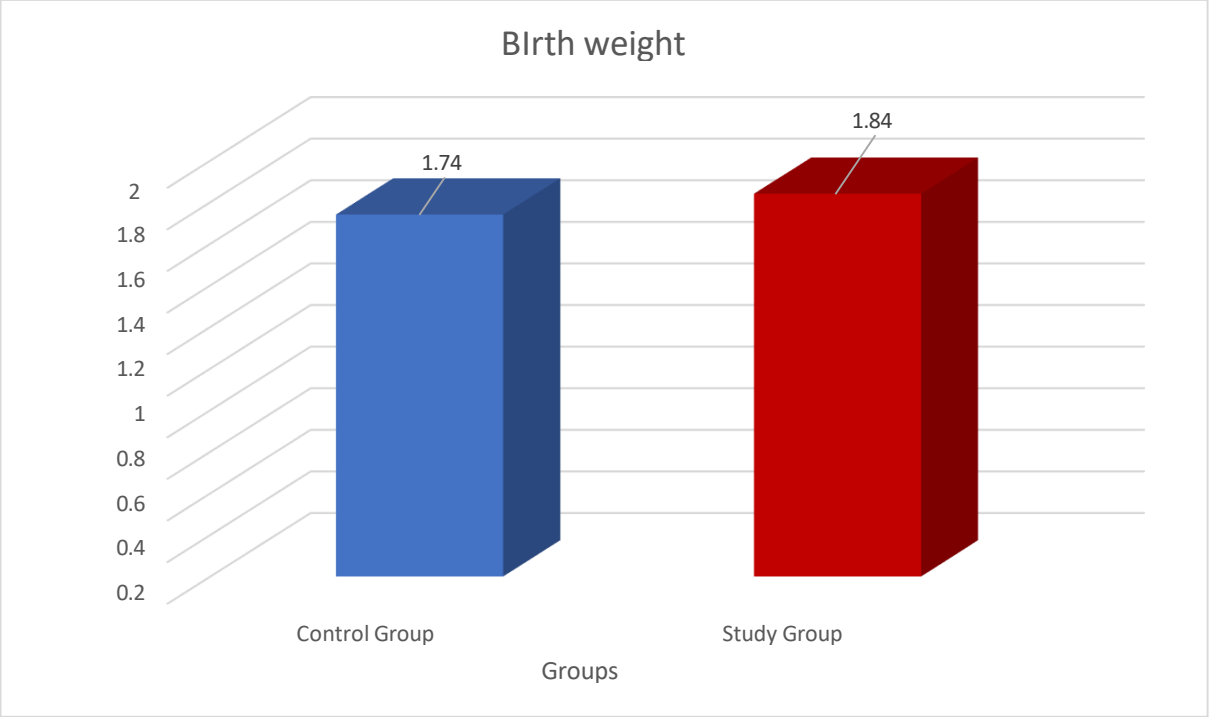
4. BIRTH WEIGHT

Birth weight was comparable in both the groups.

Table 11. Demographic characteristics based on birthweight

	GROUP	N	Mean	Median	SD	SE
Birth weight	Control	56	1.74	1.65	0.430	0.0574
	Study	56	1.84	1.80	0.374	0.0500

Independent Samples T-Test				
		Statistic	**df**	**p**
Birth weight	Student's t	-1.29	110	0.201

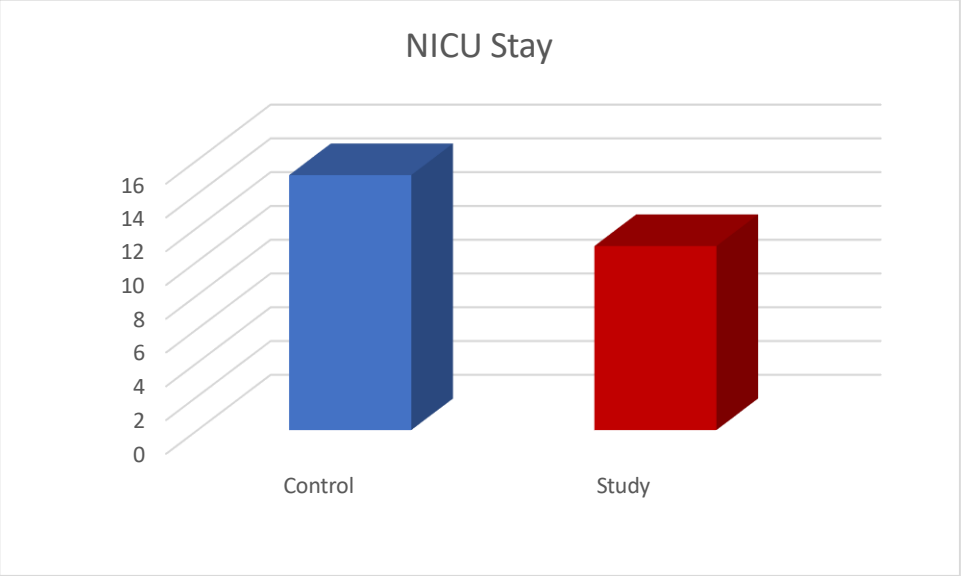


NICU STAY (Days)

The p-value for the difference in NICU stay between the Control and Study groups is 0.0131 ($p < 0.05$) which is statistically significant, suggesting that the Study group had a significantly shorter NICU stay compared to the Control group

Table 19. NICU Stay in days in control and study group

NICU Stay	Control (n=56)	Study (n=56)
Mean	15.1	10.9
Median	11.5	8.0
Standard deviation	10.2	7.11
Minimum	4	4
Maximum	50	32



5. DISCUSSION

Preterm neonates with low birth weight (LBW) are particularly vulnerable to the early colonization of their intestines by harmful bacteria. This abnormal microbial colonization can initiate inflammatory responses, which may subsequently result in serious conditions such as neonatal sepsis or necrotizing enterocolitis. Moreover, factors such as early and repeated exposure to antibiotics and extended hospital stays further disrupt the normal development of the gut microbiota. These disruptions diminish the diversity and stability of the beneficial bacterial communities in the intestines, impairing the establishment of a healthy microbiome that is crucial for immune regulation and intestinal health in neonates.

In our study, neonates in the probiotic group had a significantly shorter duration of NICU stay compared to those in the control group.

This finding aligns with previous research, including a study by Namrata P. et al. (2022), which reported that 88.9% (32 out of 36) of neonates in the probiotic group were discharged within two weeks, compared to 76.5% (26 out of 34) in the placebo group. The difference between the groups was statistically significant, indicating that a notably smaller proportion of neonates in the probiotic group required prolonged hospitalization (i.e., more than two weeks) compared to those in the placebo group. These consistent findings across studies support the potential role of probiotics in promoting faster recovery and reducing the length of NICU stay among neonates.[8]

Jing S. et al. in 2017 counduted a meta-analysis of 32 randomized controlled trials involving 8,998 very-low-birth-weight (VLBW) infants found that probiotic supplementation significantly reduced the length of hospital stay by an average of 3.77 days (95% CI: -5.94 to -1.60 days) compared to controls. This suggests that probiotics can play a beneficial role in shortening hospitalization in this high-risk population.[9]

6. LIMITATIONS

This study has several limitations that should be considered when interpreting the results. Firstly, the relatively small sample size may restrict the generalizability of the findings to the wider neonatal population. Secondly, as the research was conducted at a single tertiary care center, the outcomes may not be fully applicable to other healthcare settings or diverse populations. Lastly, the study did not include long-term follow-up of the enrolled neonates, which limits the ability to assess the prolonged impact of probiotic use on developmental outcomes and overall prognosis

REFERENCES

[1] Bisquera JA, Cooper TR, Berseth CL. Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. Pediatrics 2002;109(3):423–8.

[2] Dermyshi E, Wang Y, Yan C, Hong W, Qiu G, Gong X, Zhang T. The "Golden Age" of probiotics: a systematic review and meta-analysis of randomized and observational studies in preterm infants. Neonatology 2017;112(1):9–23.

[3] Pantell RH, Roberts KB, Adams WG, Dreyer BP, Kuppermann N, O'Leary ST, Okechukwu K, Woods CR.

Clinical practice guideline: evaluation and management of well-appearing febrile infants 8 to 60 days old. Pediatrics. 2021 Aug 1;148(2).

[4] Robertson C, Savva GM, Clapuci R, Jones J, Maimouni H, Brown E, Minocha A, Hall LJ, Clarke P. Incidence of necrotising enterocolitis before and after introducing routine prophylactic Lactobacillus and Bifidobacterium probiotics. Arch Dis Child Fetal Neonatal Ed 2020;105:F380–86.

[5] Repa A, Thanhaeuser M, Endress D, Weber M, Kreissl A, Binder C, Berger A, Haiden N. Probiotics (Lactobacillus acidophilus and Bifidobacterium infantis) prevent NEC in VLBW infants fed breast milk but not formula [corrected]. Pediatr Res 2015;77(2):381–8.

[6] Patel S, Chaudhari M, Kadam S, Rao S, Patole S. Standardized feeding and,probiotic supplementation for reducing necrotizing enterocolitis in preterm infants in a resource limited set up. Eur J Clin Nutr 2018;72(2):281–7.

[7] Nepean Hospital N, Australia. Friendly bacteria (probiotics) saving tiny lives Healthy Living. In: Nepean Hospital N, Australia, editor. 2013.

[8] P Namratha , Chimayi Johi , Shaileh S Patil, Viaykumar B urteli. Probiotics (Bacillus clausii) for Prevention of Late-onset Sepsis in Preterm Infants (<34 weeks):A RCT . Indian Journal of Neonatal Medicine and Research. 2022 Oct, Vol- 10(4): PO01-PO05

[9] Sun J, Marwah G, Westgarth M, Buys N, Ellwood D, Gray PH. Effects of Probiotics on Necrotizing Enterocolitis, Sepsis, Intraventricular Hemorrhage, Mortality, Length of Hospital Stay, and Weight Gain in Very Preterm Infants: A Meta-Analysis. Adv Nutr. 2017 Sep 15;8(5):749-763. doi: 10.3945/an.116.014605. PMID: 28916575; PMCID: PMC5593111..