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Original Article

Growth outcomes in preterm neonates receiving human milk fortifiers versus donor milk in a tertiary care hospital: A hospital-based prospective comparative study.

Dr. Shaik Mabbul[1*], Dr. Maddula Ashok[1], Dr. Sri Harsha Thatikonda[2]
[1]Assistant Professor, Department of Pediatrics, Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India.
[2]Assistant Professor, Department of Pediatrics, Dr. Pinnamaneni Siddhartha Institute of Medical Sciences and Research Foundation, Chinna Avutapalli, Vijayawada, Andhra Pradesh, India.

Abstract

Background

Preterm neonates have increased nutritional needs and are at risk of extrauterine growth restriction during neonatal intensive care. Human milk is preferred for enteral feeding; however, unfortified human milk and donor milk alone do not always provide adequate protein, energy, minerals, and micronutrients for optimal postnatal growth.

Objectives: To compare growth outcomes, feeding tolerance, and selected clinical outcomes among preterm neonates receiving human milk with fortifier supplementation versus donor milk in a tertiary care hospital.

Methods

This hospital-based prospective comparative study included 100 preterm neonates admitted to the neonatal intensive care unit and selected by consecutive sampling. Fifty neonates received human milk with fortifier supplementation, and 50 received donor milk as per routine unit feeding protocols. Baseline characteristics, anthropometric growth, feeding tolerance, neonatal morbidities, hospital stay, and discharge nutritional status were compared.

Results

Baseline characteristics were comparable between the human milk fortifier and donor milk groups, including gestational age (31.4 ± 1.8 versus 31.2 ± 1.9 weeks; p=0.59), birth weight (1328 ± 226 versus 1346 ± 238 g; p=0.70), male sex (56.0% versus 52.0%; p=0.69), and small-for-gestational-age status (18.0% versus 22.0%; p=0.62). Neonates receiving human milk fortifier showed earlier regain of birth weight (9.4 ± 2.7 versus 11.6 ± 3.3 days; p<0.001), higher daily weight gain (17.9 ± 3.8 versus 14.5 ± 3.6 g/kg/day; p<0.001), greater length gain (0.93 ± 0.22 versus 0.76 ± 0.20 cm/week; p<0.001), greater head circumference gain (0.78 ± 0.18 versus 0.64 ± 0.17 cm/week; p<0.001), and higher discharge weight (1835 ± 246 versus 1698 ± 235 g; p=0.005). Feed intolerance, necrotizing enterocolitis, late-onset sepsis, hospital stay, and mortality were not significantly different.

Conclusion

Human milk fortifier supplementation was associated with better short-term growth without increasing major complications.

Recommendations

Structured fortification protocols should be adopted with regular anthropometric monitoring and individualized feeding review.

Keywords: Donor milk; growth outcome; human milk fortifier; neonate; preterm; tertiary care hospital
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Corresponding author: Dr. Shaik Mabbul*
Email: **shaik.mabbul78614@gmail.com**
Assistant Professor, Department of Pediatrics, Konaseema Institute of Medical Sciences and Research Foundation, Amalapuram, Andhra Pradesh, India.

Introduction

Preterm birth interrupts the final trimester phase of rapid fetal nutrient accretion. It exposes the neonate to a postnatal environment in which energy expenditure, illness burden, feeding immaturity, and variable enteral intake influence growth. During neonatal intensive care, inadequate protein and energy intake rapidly translates into poor weight gain, impaired linear growth, and suboptimal head circumference growth. Postnatal growth failure remains frequent among very low birth weight and preterm infants, even in organized neonatal networks, and it is associated with clinical morbidities, prolonged hospitalization, and later

neurodevelopmental concerns [9,10]. Therefore, nutritional management in preterm neonates is not limited to survival support but is a central component of developmental care.

Human milk is the preferred enteral feed for preterm infants because it offers immunological, gastrointestinal, metabolic, and developmental advantages. However, the nutrient density of unfortified human milk is insufficient for many preterm neonates when delivered at usual fluid volumes. Human milk alone often provides lower protein, calcium, phosphorus, and selected micronutrient intakes than those required to approximate intrauterine growth. Multinutrient fortification has therefore become an important strategy to improve nutrient delivery while preserving the biological benefits of human milk [1,14]. Evidence from systematic reviews and clinical trials supports improved nutrient accretion and short-term growth with fortification, although the ideal timing, composition, and individualized adjustment remain areas of active research [1,3,12].

Donor human milk is an important alternative when a mother's own milk is unavailable or insufficient. It is particularly valuable in neonatal units because it preserves many protective properties of human milk and is associated with a reduced risk of necrotizing enterocolitis compared with formula-based feeding in very preterm or very low birth weight infants [2,7,8]. At the same time, donor milk is commonly pasteurized and can have lower protein and energy content than the individual requirements of rapidly growing preterm neonates. This creates a clinical balance between safety and growth, especially in settings where fortification practices, milk banking access, and monitoring capacity differ across hospitals [2,11].

Human milk fortifier supplementation attempts to close this nutrient gap by adding protein, energy, electrolytes, minerals, and vitamins to human milk. Studies evaluating fortified human milk, human milk-derived fortifiers, bovine-derived fortifiers, and individualized fortification methods have reported variable effects on growth, feeding tolerance, necrotizing enterocolitis, and sepsis [3-6,12,13]. Indian and resource-limited settings need locally generated evidence because neonatal characteristics, breastfeeding support, donor milk availability, and discharge policies differ from those in high-income settings. Hence, comparative hospital-based studies are useful for guiding pragmatic feeding practices in tertiary neonatal units.

The present study was conducted with the objective of comparing growth outcomes among preterm neonates receiving human milk fortifier supplementation versus donor milk in a tertiary care hospital. The secondary objectives were to compare time to regain birth weight, length gain, head circumference gain, discharge weight, feeding tolerance, necrotizing enterocolitis, late-onset sepsis, duration of hospital stay, and nutritional status at discharge between the two feeding groups.

Methodology

Study design and setting

This hospital-based prospective comparative study was conducted in the Department of Pediatrics and the neonatal intensive care unit of Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India, from August 2025 to January 2026. The institute is located at NH216, Chaitanya Health City, Amalapuram, in Dr. B.R. Ambedkar Konaseema district. The attached KIMS Hospital is an ultra-modern multispecialty teaching hospital with 1100 beds, outpatient and inpatient services, neonatal and pediatric care, intensive care facilities, high-technology laboratories, diagnostic imaging, blood bank, emergency care, ambulance services, surgical specialties, dialysis, pharmacy, and rehabilitation services. The hospital serves patients from Amalapuram and the surrounding Konaseema region, including 17 mandals and more than 250 villages/hamlets, and functions as a referral centre for maternal, neonatal, pediatric, medical, surgical, and emergency services.

Participants and selection method

Preterm neonates admitted to the neonatal unit during the study period were screened consecutively. A consecutive sampling method was used because all clinically eligible neonates available during the defined study period were considered until the required sample size was achieved. Participants were allocated according to the enteral feeding strategy actually received as part of routine neonatal care: human milk with fortifier supplementation or donor human milk.

Eligibility criteria

Inclusion criteria were preterm neonates born before 37 completed weeks of gestation, admission to the neonatal unit during the study period, clinical eligibility to receive enteral feeding, receipt of either human milk with fortifier supplementation or donor human milk according to unit protocol, parental or guardian consent, and availability of serial anthropometric records until discharge or death. Exclusion criteria were major congenital anomalies, major gastrointestinal malformations, chromosomal syndromes, suspected inborn errors of metabolism, need for gastrointestinal surgery, transfer out before meaningful growth assessment, absence of parental consent, or incomplete primary growth outcome records.

Study size

The sample size was calculated for comparison of mean daily weight gain between two independent feeding groups using the formula $n = 2\sigma^2(Z\alpha/2 + Z\beta)^2/d^2$, where $Z\alpha/2 = 1.96$ at 5% level of significance, $Z\beta = 0.84$ for 80% power, $\sigma = 5$ g/kg/day as the expected standard deviation of daily weight gain, and $d = 3$ g/kg/day as the minimum clinically meaningful difference between groups. The calculated sample size per group was $n = 2 \times 25 \times (1.96 + 0.84)^2 / 9 =$

43.6, rounded to 44 neonates per group. After allowing approximately 10% for incomplete records or attrition, the final sample size was rounded to 50 neonates per group, giving a total sample size of 100 neonates.

Variables

The independent variable was the type of feeding strategy, categorized as human milk with fortifier supplementation or donor human milk. The primary dependent variable was mean daily weight gain expressed as g/kg/day. Secondary dependent variables were time to regain birth weight, weekly length gain, weekly head circumference gain, discharge weight, time to reach full enteral feeds, feed intolerance, necrotizing enterocolitis, late-onset sepsis, duration of hospital stay, extrauterine growth restriction at discharge, discharge on exclusive human milk feeding, need for formula supplementation, and death before discharge. Baseline covariates included gestational age, birth weight, sex, mode of delivery, and small-for-gestational-age status.

Data sources and measurement

Data were obtained from neonatal case records, NICU admission registers, feeding charts, nursing monitoring sheets, anthropometric charts, laboratory records, and discharge summaries using a structured data extraction form. Gestational age was recorded from obstetric dating and neonatal assessment. Birth weight and serial body weight were measured in grams using calibrated neonatal weighing scales. Length was measured using an infantometer, and head circumference was measured using a non-stretchable measuring tape. Feed intolerance was recorded when feeds were withheld or modified because of recurrent vomiting, abdominal distension, significant gastric residuals, or clinical concern documented by the treating team. Necrotizing enterocolitis, late-onset sepsis, small-for-gestational-age status, and extrauterine growth restriction were identified from clinical records using standard neonatal definitions and discharge documentation.

Quantitative variables

Continuous quantitative variables such as gestational age, birth weight, daily weight gain, length gain, head circumference gain, discharge weight, time to full enteral feeds, and duration of hospital stay were analysed as mean and standard deviation because they were measured on continuous scales. Clinically meaningful categories were created only when needed for interpretation or neonatal risk stratification, such as sex, mode of delivery, small-for-gestational-age status, feeding group, presence of feed intolerance, necrotizing enterocolitis, late-onset sepsis, extrauterine growth restriction, formula supplementation, and mortality.

Bias

Selection bias was reduced by using consecutive enrolment of eligible neonates during the defined study period. Measurement bias was minimized by using routine NICU anthropometric protocols, calibrated weighing scales, standard measuring equipment, and predefined operational definitions for feeding intolerance and clinical outcomes. Information bias was limited by extracting data from structured hospital records and cross-checking growth variables with nursing and discharge charts. Confounding was addressed by comparing baseline characteristics between groups and by interpreting growth outcomes in relation to gestational age, birth weight, and small-for-gestational-age status. Attrition-related bias was reduced by including all neonates with available growth outcomes up to discharge or death.

Feeding protocol

Feeding decisions were made according to unit policy, clinical stability, availability of the mother's own milk, donor milk access, and the treating neonatologist's assessment. In the human milk fortifier group, the fortifier was added after enteral feeds were established according to the neonatal unit protocol. Donor milk was used when the mother's own milk was unavailable or inadequate. Feed advancement, monitoring for intolerance, and temporary withholding or modification of feeds were performed using standard neonatal care principles. Fortification was intended to improve protein, mineral, and energy intake while retaining the protective advantages of human milk [1,14].

Statistical analysis

Data were entered in a spreadsheet and analysed using standard statistical methods. Continuous variables were summarized as mean ± standard deviation and compared between the two independent groups using the independent samples t-test. Categorical variables were summarized as frequency and percentage. The chi-square test was used to compare categorical variables when expected cell counts were adequate, and Fisher's exact test was used when expected counts were less than five. A two-sided p-value <0.05 was considered statistically significant.

Ethical considerations

The study was conducted after approval from the Institutional Ethics Committee of Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India. Written informed consent was obtained from parents or legal guardians before enrolment. Participant confidentiality was maintained by using study codes and restricting access to identifiable information. No additional invasive procedure was performed solely for research purposes, and all neonates received routine neonatal care according to institutional protocols.

Results

Participant flow

During the study period, 124 preterm neonates were screened for eligibility. Twenty-four neonates were

excluded before final analysis because they did not fulfil eligibility criteria (n=13), were transferred or referred before completion of growth assessment (n=6), had incomplete serial anthropometric records (n=3), or parental/guardian consent was not provided (n=2). Thus, 100 preterm neonates were included in the final analysis: 50 neonates in the human milk fortifier group and 50 neonates in the donor milk group. The baseline maternal and neonatal characteristics were comparable between the two groups. The mean gestational age was 31.4 ± 1.8 weeks in the human milk fortifier group and 31.2 ± 1.9 weeks in the donor milk group (p=0.59). The mean birth weight was 1328 ± 226 g and 1346 ± 238 g, respectively (p=0.70). There was no statistically significant difference between the two groups with respect to sex distribution, mode of delivery, or small-for-gestational-age status (Table 1).

Table 1. Baseline characteristics of the study participants

Variable	Human milk fortifier group (n=50)	Donor milk group (n=50)	p-value
Gestational age, weeks	31.4 ± 1.8	31.2 ± 1.9	0.59
Birth weight, g	1328 ± 226	1346 ± 238	0.70
Male sex	28 (56.0%)	26 (52.0%)	0.69
Caesarean delivery	29 (58.0%)	27 (54.0%)	0.69
Small for gestational age	9 (18.0%)	11 (22.0%)	0.62

Neonates receiving human milk fortifier showed better postnatal growth compared with those receiving donor milk. The mean daily weight gain was significantly higher in the human milk fortifier group than in the donor milk group (17.9 ± 3.8 g/kg/day versus 14.5 ± 3.6 g/kg/day; p<0.001). Similarly, length gain and head circumference gain were significantly greater among neonates receiving human milk fortifier. The time required to regain birth weight was shorter in the human milk fortifier group. Discharge weight was also significantly higher among neonates receiving fortified human milk (Table 2).

Table 2. Growth outcomes among preterm neonates

Growth outcome	Human milk fortifier group (n=50)	Donor milk group (n=50)	p-value
Time to regain birth weight, days	9.4 ± 2.7	11.6 ± 3.3	<0.001
Weight gain, g/kg/day	17.9 ± 3.8	14.5 ± 3.6	<0.001
Length gain, cm/week	0.93 ± 0.22	0.76 ± 0.20	<0.001
Head circumference gain, cm/week	0.78 ± 0.18	0.64 ± 0.17	<0.001
Discharge weight, g	1835 ± 246	1698 ± 235	0.005

The mean time to reach full enteral feeds was slightly lower in the human milk fortifier group, although the difference was not statistically significant. Feed intolerance was observed in 5 neonates in the human milk fortifier group and 7 neonates in the donor milk group. Necrotizing enterocolitis was uncommon in both groups. The incidence of late-onset sepsis was comparable between the groups. The mean duration of hospital stay was lower in the human milk fortifier group; however, the difference did not reach statistical significance (Table 3).

Table 3. Feeding tolerance and clinical outcomes

Outcome	Human milk fortifier group (n=50)	Donor milk group (n=50)	p-value
Time to full enteral feeds, days	8.8 ± 2.6	9.7 ± 3.0	0.11
Feed intolerance	5 (10.0%)	7 (14.0%)	0.54
Necrotizing enterocolitis	2 (4.0%)	1 (2.0%)	0.56
Late-onset sepsis	6 (12.0%)	8 (16.0%)	0.56
Duration of hospital stay, days	24.6 ± 8.1	27.8 ± 8.7	0.06

At the time of discharge, extrauterine growth restriction was observed in 11 neonates in the human milk fortifier group and 20 neonates in the donor milk group. Although the proportion was lower in the human milk fortifier group, the difference was borderline statistically significant. Discharge on exclusive human milk feeding was more frequent in the fortifier group, while formula supplementation was required more often in the donor milk group, but these differences were not statistically significant. Mortality before discharge was low and comparable between the two groups (Table 4).

Table 4. Nutritional status at discharge

Discharge outcome	Human milk fortifier group (n=50)	Donor milk group (n=50)	p-value
Extrauterine growth restriction	11 (22.0%)	20 (40.0%)	0.052
Discharged on exclusive human milk feeding	39 (78.0%)	35 (70.0%)	0.36
Required formula supplementation	8 (16.0%)	12 (24.0%)	0.32
Death before discharge	1 (2.0%)	2 (4.0%)	0.56

Overall, preterm neonates receiving human milk fortifier demonstrated significantly superior growth outcomes compared with neonates receiving donor milk, particularly in terms of daily weight gain, length gain, head circumference gain, and discharge weight. Both feeding strategies were clinically safe, with no significant difference in feed intolerance, necrotizing enterocolitis, sepsis, or mortality between the two groups.

Discussion

This hospital-based prospective comparative study found that human milk fortifier supplementation was associated with significantly better short-term growth among preterm neonates than donor milk alone. The two groups were comparable at baseline for gestational age (31.4 ± 1.8 versus 31.2 ± 1.9 weeks; p=0.59), birth weight (1328 ± 226 versus 1346 ± 238 g; p=0.70), male sex (56.0% versus 52.0%; p=0.69), caesarean delivery (58.0% versus 54.0%; p=0.69), and small-for-gestational-age status (18.0% versus 22.0%; p=0.62). This baseline similarity strengthens the interpretation that the observed differences in postnatal growth were related mainly to nutritional exposure rather than major differences in starting neonatal characteristics.

The key growth finding was the higher daily weight gain in the human milk fortifier group compared with the donor milk group (17.9 ± 3.8 versus 14.5 ± 3.6 g/kg/day; p<0.001). Neonates receiving fortifier also regained birth weight earlier (9.4 ± 2.7 versus 11.6 ± 3.3 days; p<0.001), achieved greater length gain (0.93 ± 0.22 versus 0.76 ± 0.20 cm/week; p<0.001), greater head circumference gain (0.78 ± 0.18 versus 0.64 ± 0.17 cm/week; p<0.001), and higher discharge weight (1835 ± 246 versus 1698 ± 235 g; p=0.005). These findings indicate that fortification improved not only body mass gain but also linear and cranial growth, which are important markers of lean tissue accretion and brain growth in preterm neonates.

The biological explanation for these findings is that preterm neonates have high requirements for protein, energy, calcium, phosphorus, and micronutrients during the postnatal period. Unfortified milk, including donor human milk, often fails to meet these requirements at usual fluid volumes. Human milk fortifier increases nutrient density while preserving the immunological and gastrointestinal advantages of human milk. This interpretation is consistent with the Cochrane review by Brown et al., which reported improved short-term growth with multinutrient fortification of human milk in preterm infants [1], and with recommendations from the European Milk Bank Association supporting fortification when nutrient requirements exceed what human milk alone can provide [14].

Donor human milk remains valuable in neonatal care, particularly when the mother's own milk is unavailable or insufficient. Previous evidence has shown that donor milk reduces the risk of necrotizing enterocolitis compared with formula feeding in very preterm or very low-birth-weight infants [2,7,8]. However, donor milk can have lower and variable protein and energy content because of donor characteristics, storage, and pasteurization. This explains why donor milk-fed neonates in the present study showed lower growth velocity and a higher frequency of extrauterine growth restriction at discharge (40.0% versus 22.0%; p=0.052), although the latter difference remained borderline. The findings therefore support a balanced approach in which donor milk is used for safety and availability, while nutritional adequacy is monitored carefully.

Improved growth with fortification was not accompanied by a significant increase in feeding-related or infectious complications. Feed intolerance occurred in 10.0% of neonates in the fortifier group and 14.0% in the donor milk group (p=0.54), necrotizing enterocolitis in 4.0% and 2.0% (p=0.56), late-onset sepsis in 12.0% and 16.0% (p=0.56), and mortality in 2.0% and 4.0% (p=0.56), respectively. These results suggest that, within a structured feeding protocol, human milk fortification can improve growth without a measurable increase in major short-term adverse outcomes. Similar safety observations have been described

in randomized and systematic evidence, although published studies vary by fortifier type, timing of initiation, infant maturity, milk source, and illness severity [3,5,6,12,13].

The mean duration of hospital stay was numerically lower in the fortifier group than in the donor milk group (24.6 ± 8.1 versus 27.8 ± 8.7 days; p=0.06), but the difference did not reach statistical significance. This trend can be interpreted cautiously because discharge timing depends on several factors beyond growth, including cardiorespiratory stability, infection, thermoregulation, feeding maturity, and institutional discharge policies. The near-significant reduction in extrauterine growth restriction and hospital stay suggests potential clinical benefit, but larger multicentre studies with randomization and longer follow-up are required to confirm these endpoints.

Generalizability

The findings apply to comparable tertiary neonatal units managing preterm and very low-birth-weight infants with structured enteral feeding protocols, trained nursing support, serial anthropometric monitoring, and access to human milk fortifier and donor milk. Extrapolation to peripheral centres, extremely preterm neonates, units without donor milk access, or settings with different fortification schedules should be cautious because feeding tolerance, infection burden, anthropometric practices, and discharge policies vary across health systems.

Conclusion

In this hospital-based comparative study, preterm neonates receiving human milk fortifier supplementation achieved better short-term growth than those receiving donor milk. Fortifier use was associated with higher daily weight gain, improved length and head circumference gain, faster regain of birth weight, and greater discharge weight. Feeding tolerance and major clinical outcomes, including necrotizing enterocolitis, late-onset sepsis, hospital stay, and mortality, were comparable between the two groups. These findings support the use of structured human milk fortification protocols in tertiary neonatal units to reduce postnatal growth restriction while maintaining clinical safety. Donor milk remains valuable when a mother's own milk is unavailable, but nutritional monitoring is essential.

Limitations

This was a single-centre study with a sample size of 100 neonates, limiting statistical power for uncommon outcomes such as necrotizing enterocolitis and mortality. Group allocation followed clinical feeding practice rather than randomization. Long-term neurodevelopmental outcomes, biochemical nutritional markers, breast milk composition, and post-discharge growth were not assessed. Residual confounding from illness severity and feeding interruptions remains possible.

Recommendations

Tertiary neonatal units should implement written human milk fortification protocols for eligible preterm neonates, with clear criteria for initiation, advancement, temporary withholding, and monitoring. Weight, length, and head circumference should be recorded serially and reviewed during clinical rounds. Donor milk should remain available when mother's own milk is inadequate, but nutritional adequacy must be assessed closely. Future multicentre studies with randomization, breast milk composition analysis, biochemical monitoring, and post-discharge follow-up are recommended to define optimal fortification timing, dose adjustment, safety, cost-effectiveness, and long-term neurodevelopmental impact in Indian neonatal care settings.

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Abbreviations

DHM: Donor human milk
EUGR: Extrauterine growth restriction
HMF: Human milk fortifier
NICU: Neonatal intensive care unit
NEC: Necrotizing enterocolitis
SD: Standard deviation
SGA: Small for gestational age
VLBW: Very low birth weight

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Conflict of interest

The author declares no conflict of interest.

Author contributions

SM-Concept and design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript. Statistical analysis and interpretation, revision of manuscript.

MA- Design of the study, results interpretation, review of literature, and preparing the first draft of the manuscript, revision of the manuscript.

SHT-Results interpretation, review of literature, and preparing the first draft of the manuscript, and revision of the manuscript.

Data availability

Data available on request

Author biography

Dr. Shaik Mabbul is an Assistant Professor in the Department of Pediatrics at Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India. He is involved in undergraduate and clinical teaching, pediatric patient care, and academic activities in the field of child health. His areas of professional interest include general pediatrics, neonatal care, pediatric infections, and clinical research related to childhood diseases.

Dr. Maddula Ashok is an Assistant Professor in the Department of Pediatrics at Konaseema Institute of Medical Sciences & Research Foundation, Amalapuram, Andhra Pradesh, India. He is actively engaged in pediatric clinical practice, medical education, and research-oriented academic work. His professional focus includes the diagnosis and management of common pediatric illnesses, neonatal and child health care, and evidence-based pediatric practice.

Dr. Sri Harsha Thatikonda is an Assistant Professor in the Department of Pediatrics at Dr. Pinnamaneni Siddhartha Institute of Medical Sciences and Research Foundation, Chinna Avutapalli, Vijayawada, Andhra Pradesh, India. He is involved in clinical pediatrics, teaching, and academic research. His areas of interest include pediatric medicine, neonatal care, infectious diseases in children, and improvement of clinical outcomes in pediatric practice.

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