

# Clinical Efficacy of The Postbiotic Drug Biodonatum In Children with Pneumonia and Reduced Sensitivity to Antibiotic Therapy

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**Abstract:** Community-acquired pneumonia remains one of the leading causes of morbidity and mortality in the pediatric population worldwide, with antimicrobial resistance constituting a mounting threat to successful clinical management. The emergence and rapid dissemination of antibiotic-resistant bacterial strains have substantially reduced the therapeutic arsenal available to clinicians treating childhood pneumonia, necessitating the investigation of adjunctive treatment strategies capable of enhancing clinical recovery and restoring microbial equilibrium. This study aimed to evaluate the clinical efficacy, safety profile, and microbiome-modulating effects of the postbiotic preparation Biodonatum when administered as an adjunct to standard antibiotic therapy in children diagnosed with community-acquired pneumonia and demonstrating reduced sensitivity to first-line antibiotic agents. A prospective, randomized, controlled clinical trial was conducted at the Department of Pediatric Infectious Diseases, Tashkent State Medical University, enrolling 90 children aged 3 to 14 years with confirmed pneumonia and documented reduced antibiotic susceptibility. Participants were randomized into two equal groups: the intervention group (n = 45) received standard antibiotic therapy supplemented with Biodonatum, while the control group (n = 45) received standard antibiotic therapy alone. Clinical, laboratory, and microbiological parameters were assessed at baseline and on days 7 and 14 of treatment.

**Keywords:** Postbiotics; Biodonatum; pediatric pneumonia; antibiotic resistance; microbiome; clinical efficacy; adjunct therapy.

**Introduction:** Community-acquired pneumonia (CAP) in children represents one of the most clinically significant and epidemiologically pressing infectious diseases in contemporary pediatric medicine. According to the World Health Organization, pneumonia accounts for approximately 14% of all deaths in children under five years of age globally, rendering it the single largest infectious cause of childhood mortality [1]. Despite remarkable advances in diagnostic imaging, microbiological identification techniques, and the development of broad-spectrum antimicrobial agents, the burden of pediatric pneumonia remains disproportionately high in low-

and middle-income countries, including the Central Asian region, where access to advanced microbiological diagnostics may be limited and antibiotic stewardship programs are still in early stages of implementation [2]. The pathophysiology of CAP in children is inherently complex, reflecting an intricate interplay between the virulence characteristics of the causative pathogen, the maturational state of the child's immune system, environmental exposures, and the baseline composition of the respiratory and intestinal microbiome. While *Streptococcus pneumoniae* historically dominated as the leading etiological agent of bacterial pneumonia in the pediatric age group,

contemporary epidemiological surveys indicate a shifting microbiological landscape characterized by increasing contributions from *Haemophilus influenzae*, *Moraxella catarrhalis*, *Mycoplasma pneumoniae*, and atypical organisms [3]. This etiological diversity imposes substantial challenges upon clinicians endeavoring to select empirical antibiotic regimens with adequate spectrum coverage prior to the availability of microbiological culture and sensitivity results.

Perhaps the most formidable obstacle confronting modern management of pediatric pneumonia is the global crisis of antimicrobial resistance, which the World Health Organization has characterized as one of the ten greatest threats to global public health [4]. In Uzbekistan, as in many transitional economies, irrational antibiotic prescribing practices, self-medication, and suboptimal infection control measures have collectively accelerated the selection pressure favoring resistant bacterial strains. Clinical observations from pediatric respiratory wards in Tashkent have documented a worrying proportion of CAP cases in which causative organisms demonstrate reduced susceptibility or frank resistance to beta-lactam antibiotics, macrolides, and in some instances, fluoroquinolones, thereby prolonging hospitalization, increasing the risk of complications, and elevating healthcare costs [5].

In this challenging clinical context, the concept of microbiome modulation as a therapeutic adjunct to conventional antibiotic therapy has attracted considerable scientific attention over the past decade. The human gut microbiome, comprising trillions of microbial cells representing thousands of distinct species, performs indispensable functions in metabolic homeostasis, immune education, and resistance to pathogen colonization [6]. Antibiotic administration, while essential for bacterial clearance in pneumonia, inevitably disrupts this finely balanced microbial ecosystem, a phenomenon referred to as dysbiosis, which may paradoxically impair immune responsiveness, compromise the gut epithelial barrier, and facilitate secondary infections by opportunistic pathogens including *Clostridioides difficile* [7]. Restoration of microbiome integrity is therefore a clinically meaningful objective in the adjunctive management of antibiotic-treated infectious diseases.

Probiotics, defined as live microorganisms conferring health benefits upon the host when administered in adequate quantities, have been studied extensively as microbiome-protective adjuncts to antibiotic therapy [8]. However, the therapeutic landscape has recently been enriched by the emergence of postbiotics, a conceptually innovative category of bioactive

compounds defined by the International Scientific Association for Probiotics and Prebiotics as preparations of inanimate microorganisms and/or their components that confer a health benefit on the host [9]. Unlike probiotics, postbiotics do not require viable organisms and therefore circumvent the risks associated with live bacterial administration in immunocompromised patients, offer superior stability during storage and transport, and provide more precisely characterized and reproducible bioactive profiles. Postbiotic preparations may encompass cell wall fragments, lipoteichoic acids, exopolysaccharides, peptidoglycans, bacteriocins, short-chain fatty acids, and heat-killed bacterial cells, each of which may exert distinct immunomodulatory, antimicrobial, or barrier-protective effects [10].

## LITERATURE REVIEW

The relationship between the intestinal microbiome and respiratory immunity has been the subject of intensive investigation since the conceptualization of the gut-lung axis by Marsland and colleagues, who demonstrated through murine models that gut microbial signals profoundly shape the phenotype and functional capacity of pulmonary immune cells [1]. Subsequent human studies corroborated these experimental observations by revealing that children with recurrent respiratory infections exhibit characteristic patterns of gut microbial dysbiosis, including reduced abundance of short-chain fatty acid-producing Firmicutes and depletion of immunoregulatory *Bifidobacterium* species, compared to healthy control children [2]. These findings provided a compelling mechanistic foundation for the hypothesis that microbiome-targeted interventions might augment respiratory immune defenses and improve outcomes in childhood pneumonia.

A systematic review and meta-analysis by Hao and colleagues, encompassing fourteen randomized controlled trials and involving more than 3,400 participants, established that probiotic supplementation during antibiotic therapy for respiratory tract infections significantly reduced the duration of illness, the incidence of antibiotic-associated diarrhea, and the frequency of secondary respiratory infections compared to placebo [3]. Notably, strains belonging to the *Lactobacillus* and *Bifidobacterium* genera demonstrated the most consistent beneficial effects across trials, suggesting that the immunomodulatory properties of these organisms and their metabolites are of primary therapeutic relevance. Subsequent mechanistic studies revealed that *Lactobacillus rhamnosus* GG, one of the most extensively characterized probiotic strains, exerts its protective effects through upregulation of toll-like

receptor signaling pathways, enhancement of mucosal IgA secretion, and suppression of tumor necrosis factor-alpha and interleukin-6 production by intestinal macrophages [4].

The concept of postbiotics emerged as a refinement of the probiotic framework, driven partly by recognition that the bioactive compounds secreted or released by beneficial bacteria, rather than the organisms themselves, may be sufficient to recapitulate the immunological benefits of their living counterparts without the attendant risks of viable microorganism administration [5]. Aguilar-Toala and colleagues proposed a mechanistic classification of postbiotic compounds encompassing cell-free supernatants, bacterial cell wall components including peptidoglycans and lipoteichoic acids, exopolysaccharides, and metabolic end-products such as short-chain fatty acids and bacteriocins, each of which has been shown to engage discrete pattern recognition receptors on innate immune cells and thereby modulate inflammatory gene expression programs [6]. Heat-inactivated bacterial preparations, in particular, have been shown to retain their toll-like receptor-stimulating capacity while offering enhanced safety profiles relative to live organisms, making them particularly suitable for administration to young children receiving concurrent antibiotic therapy.

With respect to antimicrobial resistance in pediatric respiratory pathogens, surveillance data from Central Asian countries including Kazakhstan and Kyrgyzstan document penicillin resistance rates in *Streptococcus pneumoniae* isolates ranging from 18% to 34%, with macrolide resistance rates exceeding 25% in some urban pediatric populations [7]. Although comparable population-based surveillance data for Uzbekistan remain limited, clinical microbiological reports from Tashkent City Children's Hospital indicate that a substantial proportion of pneumonia-associated bacterial isolates demonstrate reduced susceptibility to amoxicillin-clavulanate and azithromycin, the two most commonly prescribed first-line agents for pediatric CAP in the region [8]. These patterns underscore the urgent need for therapeutic strategies capable of augmenting antibiotic efficacy or providing complementary antibacterial and immunomodulatory support in the context of resistant infections.

## METHODOLOGY

This study was designed as a prospective, randomized, open-label, controlled clinical trial conducted at the Department of Pediatric Infectious Diseases and Clinical Pharmacology, Tashkent State Medical University Clinical Hospital, Tashkent, Uzbekistan, between January 2023 and December 2024. The study

protocol received ethical approval from the Institutional Review Board of Tashkent State Medical University (Protocol No. 14/2022), and written informed consent was obtained from the parents or legal guardians of all participating children prior to enrollment, in full compliance with the Declaration of Helsinki and applicable national regulatory requirements governing clinical research involving pediatric subjects.

Children aged 3 to 14 years admitted to the pediatric respiratory ward with a confirmed diagnosis of community-acquired pneumonia were screened for eligibility. Pneumonia diagnosis was established based on internationally recognized clinical and radiological criteria, including the presence of fever exceeding 38.0 degrees Celsius, respiratory rate elevated beyond age-specific thresholds, physical examination findings consistent with lung consolidation, and radiologically confirmed pulmonary infiltrates on chest radiography interpreted by a board-certified pediatric radiologist. Reduced antibiotic sensitivity was defined as a minimum inhibitory concentration exceeding established EUCAST clinical breakpoints for the relevant antibiotic-pathogen combination, as determined by standardized disk diffusion and broth microdilution methods performed in the certified hospital microbiology laboratory.

Participants were randomized in a 1:1 ratio using computer-generated random allocation sequences sealed in opaque envelopes. The intervention group (n = 45) received standard antibiotic therapy selected on the basis of local empirical guidelines and subsequently adjusted where possible upon availability of microbiological sensitivity results, with the addition of Bionatum administered orally at a dose of one sachet dissolved in 50 milliliters of water twice daily for fourteen consecutive days. The control group (n = 45) received identical standard antibiotic therapy without any postbiotic supplementation. Clinical assessments were performed by trained pediatricians at enrollment (baseline), on day 7, and on day 14 of treatment, recording body temperature, respiratory rate, oxygen saturation, the presence and severity of cough, and general wellbeing scores. Laboratory investigations including complete blood count, C-reactive protein quantification by nephelometry, and erythrocyte sedimentation rate were performed at each time point. Stool samples were collected for microbiological culture at baseline and on day 14 to evaluate the prevalence of antibiotic-associated dysbiosis. Statistical analyses were performed using SPSS version 26.0, with categorical variables compared using the chi-squared test and continuous variables analyzed by Student's t-test or the Mann-Whitney U test, as appropriate; a two-

tailed p-value of less than 0.05 was considered statistically significant.

**RESULTS AND ANALYSIS**

A total of 90 children meeting the eligibility criteria were enrolled and randomized across the two study groups. The baseline demographic and clinical characteristics of participants were well balanced between the intervention and control groups, ensuring comparability for subsequent outcome analyses. The mean age of participants in the intervention group was 6.8 years (standard deviation ± 2.4 years), and the mean age in the control group was 7.1 years (± 2.6 years), a difference that was not statistically significant (p = 0.52). Boys constituted 53.3% of the intervention group and 51.1% of the control group. The mean duration of illness prior to hospital admission was 3.2 days in both groups (p = 0.87). Bacteriological analysis of respiratory specimens at baseline identified *Streptococcus pneumoniae* as the predominant pathogen in 38.9% of cases, followed by *Haemophilus influenzae* in 22.2%, *Moraxella catarrhalis* in 15.6%, and mixed bacterial flora in the remaining 23.3%. The distribution of causative organisms was comparable between the two groups (p = 0.79). All isolates demonstrated reduced susceptibility to at least one first-line antibiotic, with penicillin-class resistance being most prevalent (62.2% of isolates), followed by macrolide resistance (34.4%).

The primary clinical outcome measures demonstrated consistently superior results in the Bionatum-supplemented intervention group compared to the control group across all assessed time points. Normalization of body temperature, defined as sustained reduction below 37.5 degrees Celsius for at least 24 consecutive hours, occurred significantly earlier in the intervention group, with a mean time to defervescence of 3.4 days compared to 5.1 days in the control group (p < 0.001). Resolution of productive cough, quantified using a validated pediatric symptom severity scale, was documented in 84.4% of intervention group participants by day 7, compared to 57.8% of control group participants at the same assessment point (p = 0.006). Similarly, normalization of respiratory rate to age-appropriate values was

achieved by day 7 in 88.9% of the intervention cohort versus 66.7% of the control cohort (p = 0.011). Oxygen saturation measurements, assessed by pulse oximetry, recovered to values exceeding 96% by day 7 in 91.1% of intervention participants compared to 73.3% of controls (p = 0.024).

Laboratory biomarkers of systemic inflammation demonstrated a markedly more rapid and complete trajectory of normalization in the intervention group relative to the control group. Mean C-reactive protein values at baseline were comparable between groups (intervention: 48.3 mg/L ± 18.7; control: 46.9 mg/L ± 17.4; p = 0.68). By day 7, mean CRP had declined to 12.4 mg/L in the intervention group compared to 24.7 mg/L in the control group, representing a statistically significant and clinically meaningful between-group difference (p < 0.001). By day 14, CRP had normalized to below 5 mg/L in 88.9% of intervention participants compared to 64.4% of control participants (p = 0.005). Erythrocyte sedimentation rate demonstrated a parallel pattern of accelerated normalization in the intervention group, with day-7 mean values of 18.3 mm/h compared to 28.6 mm/h in the control group (p < 0.001).

Antibiotic-associated diarrhea, defined as three or more loose stools per day occurring within the first ten days of antibiotic administration, was documented in only 6 participants (13.3%) in the intervention group compared to 18 participants (40.0%) in the control group, representing a highly statistically significant reduction in incidence (relative risk = 0.33; 95% confidence interval: 0.14–0.77; p = 0.006). No serious adverse events were recorded in either group, and Bionatum was well tolerated by all participants in the intervention cohort, with no instances of allergic reactions, abdominal discomfort exceeding mild severity, or premature discontinuation attributable to the study preparation. Microbiological analysis of stool specimens collected on day 14 revealed a significantly higher prevalence of *Lactobacillus* and *Bifidobacterium* species in the intervention group compared to the control group (p = 0.008), indicating effective preservation of beneficial microbiota populations in Bionatum-supplemented participants.

**Table 1. Comparison of Clinical Outcome Parameters Between Intervention and Control Groups**

Clinical Parameter	Intervention Group (n=45)	Control Group (n=45)	p-value	Significance
Time to defervescence (days)	3.4 ± 0.8	5.1 ± 1.2	< 0.001	***

Clinical Parameter	Intervention Group (n=45)	Control Group (n=45)	p-value	Significance
Cough resolution by Day 7 (%)	84.4%	57.8%	0.006	**
Respiratory rate normaliz. by Day 7 (%)	88.9%	66.7%	0.011	*
SpO2 > 96% by Day 7 (%)	91.1%	73.3%	0.024	*
Antibiotic-associated diarrhea	13.3%	40.0%	0.006	**
CRP normalized by Day 14 (%)	88.9%	64.4%	0.005	**

Note. \*p < 0.05; \*\*p < 0.01; \*\*\*p < 0.001. CRP = C-reactive protein; SpO2 = peripheral oxygen saturation.

**Table 2. Inflammatory Biomarker Dynamics Across Treatment Time Points (Mean ± SD)**

Biomarker	IG Baselin	CG Baselin	IG Day 7	CG Day 7	IG Day 14	CG Day 14
CRP (mg/L)	48.3 ± 18.5	46.9 ± 17.2	12.4 ± 5.2	24.7 ± 9.8	3.1 ± 1.4	8.6 ± 3.9
ESR (mm/h)	34.2 ± 9.1	33.8 ± 8.7	18.3 ± 5.6	28.6 ± 7.3	10.1 ± 3.2	19.4 ± 6.5
WBC (×10 <sup>9</sup> /L)	14.8 ± 3.2	14.5 ± 3.4	8.6 ± 1.9	11.4 ± 2.7	6.8 ± 1.1	9.1 ± 2.0
Neutrophils (%)	78.4 ± 8.3	77.9 ± 7.8	62.1 ± 6.4	71.3 ± 7.2	54.3 ± 5.1	65.7 ± 6.8

Note. IG = Intervention Group; CG = Control Group; CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; WBC = white blood cell count; SD = standard deviation. All between-group differences at Day 7 and Day 14 are statistically significant (p < 0.01).

The composite clinical recovery score, integrating all primary clinical outcome measures into a single validated index, revealed a statistically significant advantage for the intervention group at both the day-7 (mean score 7.8/10 vs. 5.4/10; p < 0.001) and day-14 (mean score 9.4/10 vs. 7.6/10; p < 0.001) assessment points, further corroborating the multidimensional clinical benefit conferred by Biodonatum supplementation across the spectrum of disease manifestations assessed in this trial. Duration of hospitalization was additionally shorter in the intervention group, with a mean length of stay of 8.3

days compared to 11.7 days in the control group (p < 0.001), a finding with significant implications for healthcare resource utilization and patient family quality of life.

**DISCUSSION**

The findings of this prospective randomized controlled trial provide robust evidence that adjunctive administration of the postbiotic preparation Biodonatum significantly enhances clinical recovery in children with community-acquired pneumonia demonstrating reduced sensitivity to antibiotic

therapy. The multidimensional beneficial effects observed across clinical, laboratory, and microbiological outcome domains are consistent with the postulated mechanisms through which postbiotic compounds may augment host immune defenses and mitigate the deleterious consequences of antibiotic-induced microbiome disruption, providing a coherent mechanistic interpretation for the observed therapeutic advantages.

The accelerated resolution of fever observed in the Bionodatum group is particularly noteworthy, as pyrexia represents not only a cardinal symptom of pneumonia but also an objective index of the intensity of systemic inflammatory responses to infection. The 1.7-day reduction in time to defervescence achieved in the intervention group relative to controls is of substantial clinical significance, as it reflects not merely symptomatic improvement but a more fundamental acceleration in the resolution of the underlying infectious and inflammatory processes driving the disease. This finding is consistent with reports from studies of postbiotic supplementation in other acute infectious conditions, in which heat-inactivated bacterial preparations were shown to modulate macrophage activation states and suppress excessive pro-inflammatory cytokine production while preserving protective antimicrobial immune responses [1]. In the context of antibiotic-resistant pneumonia, where conventional antimicrobial agents may achieve only partial bacterial clearance, the capacity of postbiotic compounds to enhance phagocytic activity and optimize the balance between pro-inflammatory and regulatory immune responses assumes heightened importance.

The dramatic reduction in the incidence of antibiotic-associated diarrhea from 40.0% in the control group to 13.3% in the intervention group represents one of the most clinically impactful findings of this investigation. Antibiotic-associated diarrhea is a well-recognized and burdensome complication of antibiotic therapy in children, arising from disruption of the gut microbiome's colonization resistance mechanisms and secondary proliferation of pathogenic or opportunistic organisms including *Clostridioides difficile* [2]. The preservation of beneficial *Lactobacillus* and *Bifidobacterium* populations documented microbiologically in the intervention group at day 14 provides a compelling mechanistic explanation for this protective effect, as these organisms are known to produce short-chain fatty acids and bacteriocins that suppress pathogen growth and reinforce intestinal epithelial barrier integrity. The postbiotic delivery of metabolically active cell fractions and fermentation products from these beneficial organisms may

therefore effectively replicate the microbiome-protective functions of living probiotic organisms without requiring viable bacterial administration.

## CONCLUSION

This randomized controlled clinical trial, conducted among ninety children with community-acquired pneumonia and documented reduced antibiotic sensitivity at Tashkent State Medical University Clinical Hospital, provides compelling evidence supporting the clinical efficacy, safety, and microbiome-protective properties of the postbiotic preparation Bionodatum when administered as an adjunct to standard antibiotic therapy. Across all primary and secondary outcome measures evaluated in this investigation, including time to defervescence, resolution of respiratory symptoms, normalization of inflammatory biomarkers, incidence of antibiotic-associated diarrhea, and preservation of beneficial gut microbiota populations, the Bionodatum-supplemented intervention group demonstrated statistically significant and clinically meaningful superiority compared to the group receiving standard antibiotic therapy alone. These findings collectively demonstrate that Bionodatum exerts a multidimensional therapeutic effect in pediatric pneumonia, encompassing immunomodulation, microbiome protection, and facilitation of inflammatory resolution, which collectively translate into substantially improved clinical outcomes in a patient population for whom conventional antibiotic therapy alone frequently proves insufficient due to the diminished efficacy resulting from pathogen antibiotic resistance.

The excellent tolerability profile of Bionodatum documented in this trial, characterized by a complete absence of serious adverse events and near-universal patient acceptance of the oral sachet formulation, further supports its suitability for routine clinical use in the pediatric population. The safety advantages of postbiotic over probiotic preparations, arising from the use of non-viable microbial components rather than live organisms, are particularly relevant in the pediatric context where the risk-benefit calculus must account for the theoretical possibility of bacteremia or sepsis associated with live microorganism administration, especially in immunocompromised individuals. Bionodatum's postbiotic composition therefore offers a favorable safety profile that complements its demonstrated clinical efficacy.

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