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Effect of *Bifidobacterium* Triple Viable Bacteria Tablets on Neonatal Necrotizing Enterocolitis and Its Impact on Serum Factors of the Patients

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Abstract: *Objective*: To analyze the efficacy of Bifidobacterium triple viable bacteria tablets on neonatal necrotizing enterocolitis (NEC) and its impact on serum factors of the patients. *Methods*: From January 2021 to May 2025, 88 neonates with NEC admitted to our hospital were selected as study subjects. During the study, these 88 patients were evenly divided into two groups, namely the observation group and the control group, with 44 patients in each group based on the random number table method. In terms of treatment, the control group was treated with meropenem, while the observation group received additional treatment with *Bifidobacterium* triple viable bacteria powder based on the treatment plan of the control group. The clinical efficacy and differences in serum inflammatory factor levels between the two groups were compared. *Results*: The efficacy of the observation group (90.91%) was better than that of the control group (72.73%) ($P < 0.05$). After treatment, the levels of C-reactive protein (CRP) and procalcitonin (PCT) in both groups decreased compared to those before treatment, and the values of the above indicators in the observation group were lower than those in the control group ($P < 0.05$). *Conclusion*: Based on conventional treatment for NEC neonates, the use of Bifidobacterium triple viable bacteria tablets has significant efficacy and can effectively reduce serum inflammatory factor levels.

Keywords: *Bifidobacterium* triple viable bacteria tablets; Necrotizing enterocolitis; Neonates; Serum factors

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1. Introduction

Neonatal necrotizing enterocolitis (NEC) is a common and severe intestinal inflammatory disease among newborns and low birth weight infants. It is characterized by rapid onset and progression, not only causing a series of digestive symptoms such as abdominal distension, diarrhea, and bloody stools, but also potentially leading to shock, apnea, and even death in severe cases. This poses a significant threat to the health and life of the affected infants, while also presenting considerable challenges for clinical treatment [1, 2]. Currently, clinical treatment for NEC primarily involves antibiotics, gastrointestinal decompression, fasting, and parenteral nutrition. Among

these, meropenem, as a broad-spectrum antibiotic, plays a certain role in reducing intestinal mucosal lesions and inflammatory stimulation, as well as relieving clinical symptoms [3]. However, conventional treatment regimens often have issues such as slow onset and limited therapeutic effect, making it difficult to effectively reduce the mortality rate of NEC and improve the prognosis of the patients. Therefore, finding more efficient and safe treatment methods has become an important direction for clinical research. As a microecological preparation, *Bifidobacterium* triple viable powder mainly consists of *Bifidobacterium longum, Lactobacillus acidophilus*, and *Enterococcus faecalis*. These beneficial bacteria can colonize and proliferate in the intestine, regulate intestinal flora imbalance, enhance intestinal barrier function, inhibit the growth of harmful bacteria, and also have immunomodulatory effects that can reduce intestinal inflammatory responses. It has achieved good results in the treatment of various digestive diseases [4, 5]. In view of this, this study intends to explore the efficacy of combined use of *Bifidobacterium* triple viable powder with meropenem in the treatment of newborns with necrotizing enterocolitis, as well as its impact on serum inflammatory factor levels in these patients. The aim is to provide a better treatment regimen and theoretical basis for clinical treatment of NEC.

2. Materials and methods

2.1. General information

A total of 88 NEC patients admitted to the hospital were included in the study and randomly divided into two groups using random sampling, with 44 patients in each group. The general information of the two groups was comparable ($P > 0.05$), as shown in **Table 1**.

Table 1. Comparison of baseline data [($\bar{x} \pm s$), cases (%)]

Group	n	Gender		Gestational age (weeks)	Birth weight (kg)
		Male	Female		
Study	44	22	22	32.43 ± 0.84	2.37 ± 0.42
Control	44	20	24	32.27 ± 0.63	2.41 ± 0.38
t/χ^2		0.182		1.011	0.468
p-value		0.669		0.315	0.641

2.2. Inclusion and exclusion criteria

2.2.1. Inclusion criteria

(1) Meet the diagnostic criteria for NEC in reference, and the diagnosis is further confirmed through X-ray imaging [6].

(2) The patient presents clinical manifestations such as abdominal distension, frequent vomiting, increased frequency of defecation, and changes in stool characteristics (diarrhea).

(3) The patient's family members sign the informed consent form.

2.2.2. Exclusion criteria

(1) Patients with intestinal perforation or severe symptoms requiring surgical treatment.

(2) Patients with congenital intestinal developmental abnormalities.

(3) Patients with severe pulmonary diseases and congenital heart diseases.

2.3. Methods

Both groups of patients received the same basic treatment measures, including fasting treatment, gastrointestinal decompression, maintenance of water and electrolyte balance, and close monitoring of the patient's vital signs. After completing the above basic treatment arrangements, the control group was treated with Meropenem for Injection (produced by Ouyi Pharmaceutical Co., Ltd. of Shijiazhuang Pharmaceutical Group, approval number: National Medicine Approval Number H20103094, specification: 0.25 grams). The specific medication method was to add 1 gram of the drug to 500 milliliters of 0.9% sodium chloride injection, administered intravenously three times a day. On the basis of the control group's treatment plan, the observation group additionally used Jinshuangqi for adjuvant treatment. The specific medication was *Bifidobacterium Lactobacillus* Triple Viable Tablets (produced by Inner Mongolia Shuangqi Pharmaceutical Co., Ltd., approval number: National Medicine Approval Number S19980004, specification: 0.5 grams per tablet). The tablets were completely dissolved in warm water and then administered orally or through nasal feeding three times a day for one week of continuous treatment. During the treatment period, medical staff should closely monitor and observe changes in the patient's vital signs and other indicators.

2.4. Observation indicators

2.4.1. Clinical efficacy

(1) Significant effect: After treatment, all clinical symptoms such as abdominal distension, diarrhea, and vomiting in the child have resolved, the daily number of bowel movements and stool characteristics have returned to normal, the child can resume normal oral feeding, and abdominal X-ray examination shows no abnormalities.

(2) Effective: After treatment, the clinical symptoms of the child have improved significantly. Although there is intolerance to breast milk, the child can accept formula feeding. At the same time, the results of abdominal X-ray examination have improved compared to before treatment.

(3) Ineffective: After treatment, there is no improvement in symptoms such as abdominal distension, diarrhea, and vomiting in the child. Abdominal X-rays still show abnormalities, and the condition may even worsen, leading to severe complications such as septic shock and intestinal perforation. Total efficacy = (Significant effect + Effective) / Total number × 100%.

2.4.2. Levels of serum inflammatory factors

Collect 3 milliliters of venous blood samples from the child before and after treatment, place them in a centrifuge, set the centrifugal speed to 3000 rpm, set the centrifugal radius to 8 centimeters, and perform centrifugation for 10 minutes. After centrifugation, carefully aspirate the supernatant serum, and then use enzyme-linked immunosorbent assay (ELISA) to detect the levels of C-reactive protein (CRP) and procalcitonin (PCT) in the serum.

2.5. Statistical analysis

SPSS 26.0 was used for data analysis. Measurement data were represented by $\bar{x} \pm s$, and the comparison was conducted using the t-test. Count data were expressed as n(%) and analyzed using χ^2 test. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Clinical efficacy

The efficacy of the observation group (90.91%) was better than that of the control group (72.73%) ($P > 0.05$), as shown in **Table 2**.

Table 2. Comparison of clinical efficacy [cases (%)]

Group	*n*	Markedly Effective n (%)	Effective n (%)	Ineffective n (%)	Overall Efficacy n (%)
Study	44	24 (54.55)	16 (36.36)	4 (9.09)	40 (90.91)
Control	44	19 (43.18)	13 (29.55)	12 (27.27)	32 (72.73)
χ^2					4.889
p-value					0.027

3.2. Levels of serum inflammatory factors

After treatment, the levels of CRP and PCT in both groups decreased compared to those before treatment, and the values of the above indicators in the observation group were lower than those in the control group ($P < 0.05$), as shown in **Table 3**.

Table 3. Comparison of serum inflammatory factor levels ($\bar{x} \pm s$)

Group	*n*	CRP (mg/L)		PCT (μg/L)	
		Pre-treatment	Day 7	Pre-treatment	Day 7
Study	44	26.56 ± 5.89	10.25 ± 1.42*	4.12 ± 1.26	0.92 ± 0.15*
Control	44	25.58 ± 5.24	15.31 ± 1.05*	3.98 ± 1.14	1.85 ± 0.22*
t-value		0.825	19.005	0.547	23.168
p-value		0.412	< 0.001	0.586	< 0.001

Note: Compared with the same group before treatment, *$P < 0.05$.

4. Discussion

Neonatal necrotizing enterocolitis (NEC) mainly occurs in premature infants within days to weeks after birth and newborns with a birth weight below the normal standard. In severe cases, it can even cause serious complications such as intestinal perforation [7-8]. Relevant reports have pointed out that the incidence rate of NEC in neonatal intensive care units is 2%–5% [9]. Among them, the probability of very low birth weight infants developing NEC is 4.5%–8.7%, and the fatality rate is 20%–30%; while the fatality rate of ultra-low birth weight infants is between 30%–50.9%. Clinical treatment of NEC often adopts comprehensive measures, such as fasting, gastrointestinal decompression, anti-infection, maintenance of water and electrolyte balance, and nutritional support. Anti-infection is the key. As a broad-spectrum carbapenem antibiotic, meropenem has strong antibacterial activity and good tissue penetration, which can inhibit intestinal pathogens, reduce intestinal mucosal lesions and inflammatory stimulation, and relieve symptoms. It is widely used in NEC treatment. However, further research on the pathogenesis of NEC has found that delayed colonization and abnormal composition of intestinal flora in newborns can easily lead to intestinal microecological imbalance, damage the intestinal barrier, and promote

inflammatory reactions. Therefore, regulating intestinal flora and restoring intestinal microecological balance has become a new direction for the treatment of NEC [10].

The results of this study showed that the treatment effect of the observation group (90.91%) was better than that of the control group (72.73%) ($P < 0.05$). This suggests that *Bifidobacterium* triple viable bacteria tablets played a positive auxiliary role in the treatment of neonatal necrotizing enterocolitis. It can effectively regulate the intestinal flora structure of neonatal necrotizing enterocolitis, increase the number of beneficial bacteria, and improve intestinal microecological balance. Analysis of the reasons: Necrotizing enterocolitis is a common severe gastrointestinal disease in neonates. Its pathogenesis is complex and closely related to factors such as intestinal flora imbalance, impaired intestinal mucosal barrier function, and low immune function. The intestinal development of neonates is not yet mature, intestinal flora colonization is delayed and unstable, and it is susceptible to external factors and prone to flora imbalance, which in turn triggers intestinal inflammatory reactions and mucosal damage.

As a broad-spectrum antibiotic, meropenem injection can effectively inhibit or kill pathogenic bacteria and control infection, but it may also damage the normal intestinal flora, further aggravating flora imbalance. *Bifidobacterium* triple viable bacteria tablets contain various beneficial bacteria such as *Bifidobacteria* and *Lactobacilli*. After entering the intestine, these beneficial bacteria can colonize and propagate in large numbers, forming a biological barrier to inhibit the growth and reproduction of harmful bacteria and regulate the balance of intestinal flora. At the same time, beneficial bacteria can also produce substances such as short-chain fatty acids, lower the intestinal pH, improve the intestinal microenvironment, enhance the intestinal mucosal barrier function, reduce the absorption and transport of intestinal toxins, thereby reducing intestinal inflammation and promoting intestinal mucosal repair and regeneration. Additionally, *Bifidobacterium* triple viable bacteria tablets may also regulate the body's immune function, enhance the resistance of newborns, improve their tolerance to infection, and improve the treatment effect.

After treatment, the levels of CRP and PCT in both groups of children decreased compared to before treatment, and the values of these indicators in the observation group were lower than those in the control group ($P < 0.05$). CRP and PCT are commonly used inflammatory markers in clinical practice, and their levels can reflect the degree of inflammatory response in the body. During the pathogenesis of necrotizing enterocolitis, intestinal inflammatory responses stimulate the body to produce large amounts of inflammatory mediators, leading to increased levels of CRP and PCT. In the observation group, the use of Bifidobacterium triple viable tablets resulted in a more significant decrease in serum CRP and PCT levels, further confirming the anti-inflammatory effect of these tablets. The anti-inflammatory mechanism may be related to regulating intestinal flora balance. The increase in beneficial bacteria can inhibit the growth of harmful bacteria, reduce the production of endotoxins and other inflammatory mediators by harmful bacteria, and thereby reduce intestinal inflammatory responses. Additionally, Bifidobacterium triple viable tablets may also exert their anti-inflammatory effects by regulating the function of immune cells, inhibiting the activation of inflammatory signaling pathways, and reducing the release of inflammatory factors.

5. Conclusion

In summary, the use of *Bifidobacterium* triple viable tablets in addition to conventional treatment for NEC in newborns has significant efficacy and can effectively reduce serum inflammatory factor levels.

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Disclosure statement

The author declares no conflict of interest.

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