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Article

Diagnostic Utility of Eosinophil and Platelet in Newborns With Food Protein-Induced Allergic Proctocolitis: A Retrospective Study

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Abstract

Aims/Background: Food protein-induced allergic proctocolitis (FPIAP) is a common allergic disease in the clinic. Despite being the diagnostic gold-standard method, the avoidance-provocation test has certain limitations that hinder its clinical applications. Detection of peripheral blood cells has emerged as an important research hotspot because of its relative methodological simplicity. Platelets and eosinophils play an important role in allergic diseases, but relevant studies on newborns with FPIAP remain scarce. The purpose of this study was to investigate the changes of eosinophil and platelet levels in children with allergic enteritis, and to explore its application value in the differential diagnosis of newborns with FPIAP. **Methods**: This retrospective study included 41 newborns with FPIAP admitted to The Affiliated Yangming Hospital of Ningbo University from December 2022 to December 2024 and 80 healthy newborns who underwent physical examination during the same period as controls. Data of all selected newborns and their mothers were collected from their medical records. The morning venous blood samples of the two groups were collected. White blood cell count, neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelets and hemoglobin were detected using an automatic blood cell analyzer. Logistic regression analysis was used to analyze the risk factors of newborns with FPIAP. Receiver operating characteristic (ROC) curve was used to analyze the diagnostic value of these blood parameters for newborns with FPIAP. **Results**: The results showed that eosinophils and platelets in the FPIAP group were significantly higher than those in the control group ($p < 0.05$). Logistic regression analysis showed that elevated levels of eosinophils and platelets were risk factors for newborns with FPIAP ($p < 0.05$). The combined detection of peripheral blood platelet and eosinophil counts yielded an area under the ROC curve of 0.862 for the diagnosis of FPIAP in newborns, with a specificity of 0.825 and a sensitivity of 0.805. **Conclusion**: Newborns with FPIAP feature increased eosinophil and platelet counts, which provide an invaluable diagnostic reference for the allergic disease when used in combination.

Keywords: food protein-induced allergic proctocolitis; newborn; eosinophils; platelets; diagnosis

1. Introduction

Food protein-induced allergic proctocolitis (FPIAP) is a non-immunoglobulin E (IgE)-mediated food allergy characterized primarily by blood-related symptoms and is most commonly observed in newborns and infants. Recent years have witnessed an upward trend in the incidence of food allergic diseases owing to a shift in dietary patterns and the expanded food diversity [1]. The prevalence of FPIAP varies considerably, estimated at about 0.16% in healthy children and up to 64% among children with bloody stools [2]. Clinical manifestations include diarrhea, abdominal distension, and hematochezia, with severe cases potentially complicated by growth retardation and malnutrition.

Due to the nonspecific nature of its clinical symptoms, the current diagnostic approaches for FPIAP rely on detailed medical history inquiry, avoidance of suspected food allergens, and clinical recurrence of symptoms following food allergen reintroduction after symptom relief [3]. However, these approaches have certain limitations in clinical practice, posing challenges for timely diagnosis and treatment. Therefore, it is clinically important to identify early and sensitive laboratory indicators.

Eosinophils are conventionally recognized as key contributors to the development of IgE-induced allergic reactions [4,5]. However, an increasing number of studies have confirmed that eosinophils also play an important role in non-IgE-mediated allergic diseases [6,7]. The activation of eosinophils will release a variety of toxic proteins, such as eosinophil cationic protein, which are involved in the occurrence of intestinal inflammatory diseases [8]. Platelet count is a routinely measured blood parameter in clinical practice. A prior study has reported a significant increase in peripheral blood platelet levels in children with FPIAP, and these quantitative changes may be related to the occurrence of the disease [9]. Zhang et al. [10] found that neutrophil infiltration promotes the development of food allergy and intestinal injury. At present, studies on neutrophil, eosinophil and platelet counts in newborns with FPIAP remain relatively scarce, and their inter-relationships and connection with allergic enteritis are very much obscure. In light of this, this study aims to investigate changes in peripheral blood eosinophil, neutrophil and platelet counts in newborns with FPIAP and analyze their utility in the diagnosis and differential diagnosis of newborns with FPIAP.

Table 1. Comparison of general data of the two groups of newborns.

	Control group (n = 80)	FPIAP group (n = 41)	t/Z/χ^2	p
Sex, n (%)			1.336	0.248
Male	36 (45.00)	23 (56.10)		
Female	44 (55.00)	18 (43.90)		
Gestational age (days), M (Q1, Q3)	273 (266, 276)	273 (268, 273)	0.321	0.748
Birth weight (g), mean ± SD	3285.88 ± 346.33	3430.98 ± 553.56	1.768	0.080
Delivery mode, n (%)			0.179	0.672
Cesarean delivery	30 (37.50)	17 (41.46)		
Natural labor	50 (62.50)	24 (58.54)		
Intrauterine distress, n (%)			Fisher	0.165
No	75 (93.75)	41 (100.00)		
Yes	5 (6.25)	0 (0.00)		
Amniotic fluid contamination, n (%)			Fisher	0.548
No	78 (97.50)	41 (100.00)		
Yes	2 (2.50)	0 (0.00)		
Pre-onset feeding pattern, n (%)			1.021	0.600
Breastfeeding	40 (50.00)	22 (53.66)		
Formula feeding	20 (25.00)	7 (17.07)		
Mixed mode	20 (25.00)	12 (29.27)		

FPIAP, food protein-induced allergic proctocolitis; SD, standard deviation; M, median. Fisher indicates Fisher's exact test; therefore, no t, Z, or χ^2 statistic is presented.

2. Methods

2.1 General Data

In this retrospective analysis, 41 newborns with FPIAP admitted to The Affiliated Yangming Hospital of Ningbo University from December 2022 to December 2024 were chosen as the FPIAP group, whereas 80 healthy newborns who underwent physical examination in the hospital during the same period were selected as the healthy group. The FPIAP group comprised 23 males and 18 females. Regarding feeding patterns, 22 newborns were exclusively breastfed, 7 were formula-fed, and 12 received mixed feeding. The control group included 36 males and 44 females; among them, 40 were exclusively breastfed, 20 were formula-fed, and 20 received mixed feeding.

2.2 Inclusion and Exclusion Criteria

Inclusion criteria for the FPIAP group are as follows: (1) Newborns who were aged 1–28 days upon admission; (2) Individuals who met the established diagnostic criteria of FPIAP [11,12], including typical clinical manifestations (such as bloody stool, diarrhea, and mucus in the stool) following intake of suspected food proteins (mainly milk proteins), with complete resolution of the symptoms within 2 weeks of complete avoidance of suspected allergens. In this study, a standardized diagnostic protocol was applied to all eligible study subjects. Ultimately, 36 cases (87.8%) underwent an open food "rechallenge" test (reintroduction of the suspected food under observation for symptom recurrence within 48–72 hours) to confirm the diagnosis. The remaining 5 cases (12.2%) did not undergo rechallenge due to parental concerns, and their diagnosis was based on the highly suggestive clinical criteria, namely a typical history and complete symptom resolution after allergen avoidance; (3) Newborns that were able to comply with clinical procedures as required. Exclusion criteria of the present study include: (1) Congenital metabolic diseases, chromosomal abnormalities, or congenital malformations; (2) Coexisting serious digestive system illnesses or other primary diseases; (3) Concurrent infectious diseases of any type; and (4) Incomplete clinical data.

Inclusion criteria for the healthy control group are as follows: (1) Newborns aged 1–28 days upon admission; (2) No history of gastrointestinal symptoms (e.g., bloody stool, diarrhea, mucus in stool) or diagnosed FPIAP; (3) Ability to tolerate standard feeding without symptom development; (4) Complete clinical data available. The exclusion criteria was same as the FPIAP group.

2.3 Observation Indices

Data of all the selected newborns (including sex, gestational age, birth weight, delivery mode, intrauterine distress, amniotic fluid contamination and feeding pattern) and the general data of their biological mothers (including age, body mass index [BMI], pregnancy complications, prenatal antibiotics and allergic history) were collected from their medical records. The morning venous blood samples of the two groups were collected, and the routine blood indices, such as white blood cell count, neutrophils, lymphocytes, monocytes, eosinophils, basophils, platelets and hemoglobin, were detected using an automatic blood cell analyzer (BC-6800, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shenzhen, China).

2.4 Statistical Analysis

SPSS 27.0 statistical software (IBM Corp., Armonk, NY, USA) was used to analyze and process the data. Categorical data were expressed as frequency or percentage and analyzed using the chi-square test or Fisher's exact test for inter-group comparisons. Shapiro–Wilk test was used to test the normal distribution of continuous data. Normally distributed data were expressed as mean $\pm$ standard deviation (SD) and analyzed using the independent samples *t*-test for inter-group comparisons. Data that did not conform to the normal distribution were expressed as median (interquartile range) [M (Q1, Q3)] and analyzed using the Mann–Whitney *U* rank sum test for inter-group comparisons. Before performing multivariate logistic regression analysis, tolerance values and variance inflation factor (VIF) are used to assess collinearity among all potential independent variables. Indicators with a tolerance >0.1 and a variance inflation factor (VIF) <5 were included in multivariate logistic regression analysis to identify factors influencing the development of FPIAP in newborns. The diagnostic performance of eosinophils and platelets was evaluated using receiver operating characteristic (ROC) curve analysis. An area under the curve (AUC) of 0.8 was considered indicative of good predictive value. A $p < 0.05$ was considered statistically significant.

3. Results

3.1 General Data of Two Groups of Newborns

The results presented in Table 1 show that there were no significant differences in sex, gestational age, birth weight, delivery mode, feeding pattern, intrauterine distress and amniotic fluid contamination between the two groups ($p > 0.05$). According to Table 2, there were no significant differences in age, BMI, gestational hypertension, intrahepatic cholestasis of pregnancy, gestational diabetes mellitus, hypothyroidism, prenatal antibiotic use and allergy history between the two groups ($p > 0.05$).

3.2 Comparison of Routine Peripheral Blood Indices Between the Two Groups of Newborns

According to Table 3, the eosinophil and platelet counts in the FPIAP group were significantly higher than those in the control group ($p < 0.05$). There were no significant differences in white blood cell count, neutrophil count, lymphocyte count, monocyte count, basophil count and hemoglobin level between the two groups ($p > 0.05$).

3.3 Analysis of Risk Factors of Newborns With FPIAP

Eosinophils and platelet do not have multicollinearity. The tolerance and VIF of eosinophils are 0.908 and 1.101. The tolreance and VIF of platelet are 0.908 and 1.101. With the occurrence of FPIAP as the dependent variable, indicators identified as statistically significant in univariate analysis (Table 3) were taken as the independent variables and included in multivariate logistic regression analysis. The results showed that increased levels of eosinophils and platelets were risk factors for newborns with FPIAP ($p < 0.05$, Table 4).

3.4 ROC Curve Analysis

An ROC curve analysis was conducted to evaluate the diagnostic performance of eosinophil and platelet levels for neonatal FPIAP. The AUC values for peripheral blood platelet and eosinophil counts in the context of FPIAP diagnosis were 0.742 and 0.808, respectively, with corresponding specificities of 0.762 and 0.812, and sensitivities of 0.683 and 0.707. The combined diagnosis model for newborns with FPIAP demonstrated improved performance, with an AUC of 0.862, specificity of 0.825, and sensitivity of 0.805 ($p < 0.05$, Table 5 and Fig. 1).

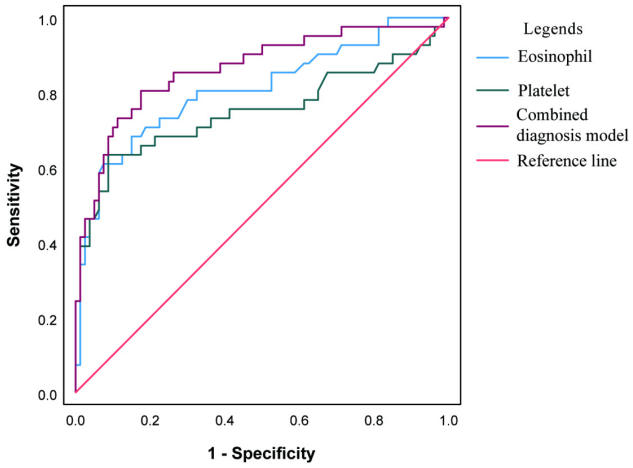

Fig. 1. Receiver operating characteristic (ROC) curve for eosinophils, platelets and their combined diagnosis model in newborns with FPIAP.

4. Discussion

Food protein-induced allergic proctocolitis (FPIAP) is a common food allergic reaction, predominantly affecting newborns and infants, with most clinical manifestations being nonspecific. While bloody stool represents the primary symptom, patients with FPIAP also present with diarrhea and abdominal pain. Some infants may also present with eczema, feeding refusal, irritability, and other symptoms. In severe cases, malnutrition, hypoproteinemia, anemia and growth or developmental delays can occur. These symptoms typically resolve within 48–72 hours following avoidance of allergen intake and recur upon its reintroduction [13].

The elimination diet followed by an oral food challenge is considered the gold standard for diagnosing FPIAP. However, in clinical practice, the oral challenge test has certain limitations [14], including the potential risk of severe allergic reactions and poor compliance of parents. There-

Table 2. Comparison of general data of the newborns' mothers.

	Control group (n = 80)	FPIAP group (n = 41)	t/Z/χ^2	p
Age (years), M (Q1, Q3)	29 (27, 32)	31 (29, 33)	1.856	0.064
BMI (kg/m^2), mean ± SD	26.50 ± 3.05	26.70 ± 3.34	0.318	0.751
Gestational hypertension, n (%)			1.053	0.305
No	70 (87.50)	33 (80.49)		
Yes	10 (12.50)	8 (19.51)		
ICP, n (%)			Fisher	0.113
No	80 (100.00)	39 (95.12)		
Yes	0 (0.00)	2 (4.88)		
GDM, n (%)			0.882	0.348
No	61 (76.25)	28 (68.29)		
Yes	19 (23.75)	13 (31.71)		
Prenatal antibiotics, n (%)			0.802	0.371
No	38 (47.50)	23 (56.10)		
Yes	42 (52.50)	18 (43.90)		
Hypothyroidism, n (%)			Fisher	1.000
No	76 (95.00)	39 (95.12)		
Yes	4 (5.00)	2 (4.88)		
Allergic history, n (%)			Fisher	0.226
No	77 (96.25)	37 (90.24)		
Yes	3 (3.75)	4 (9.76)		

BMI, body mass index; GDM, gestational diabetes mellitus; ICP, intrahepatic cholestasis of pregnancy. Fisher indicates Fisher's exact test; therefore, no t, Z, or χ^2 statistic is presented.

Table 3. Comparison of routine peripheral blood indices between the two groups of newborns.

	Control group (n = 80)	FPIAP group (n = 41)	t/Z	p
WBC count ($\times 10^9$/L), M (Q1, Q3)	10.70 (9.30, 12.35)	10.60 (8.80, 12.20)	0.808	0.419
Neutrophil count ($\times 10^9$/L), M (Q1, Q3)	4.32 (3.25, 5.14)	4.41 (3.57, 5.20)	1.876	0.061
Lymphocyte count ($\times 10^9$/L), M (Q1, Q3)	3.90 (3.11, 4.66)	3.15 (2.70, 4.13)	1.810	0.070
Monocyte count ($\times 10^9$/L), M (Q1, Q3)	1.34 (1.06, 1.67)	1.45 (1.05, 1.63)	0.545	0.586
Eosinophil count* ($\times 10^9$/L), M (Q1, Q3)	0.47 (0.29, 0.60)	0.97 (0.62, 1.32)	6.038	<0.001
Basophil count ($\times 10^9$/L), M (Q1, Q3)	0.09 (0.00, 0.12)	0.05 (0.02, 0.24)	0.091	0.927
Platelet count* ($\times 10^9$/L), mean ± SD	289.21 ± 67.34	382.02 ± 125.22	4.554	<0.001
Hemoglobin (g/L), mean ± SD	166.09 ± 22.64	160.15 ± 30.14	1.217	0.226

WBC, white blood cell; *: compared with the healthy group, $p < 0.05$.

fore, many cases are diagnosed as FPIAP based solely on medical history, a positive response to dietary allergen avoidance, and exclusion of other diseases that can cause symptoms, such as hematochezia. The most common clinical differential diagnosis includes the identification of FPIAP and neonatal necrotizing enterocolitis. The clinical manifestations of the two are similar. At present, the clinical methods for distinguishing between the two are unclear, resulting in an increasing incidence of misdiagnosis and missed diagnosis, as well as unnecessary fasting or antibiotic treatment in children. In severe cases, it even affects the growth, development and nutritional status of children. Thus, this has spurred more research designed to explore reliable auxiliary tests that facilitate the diagnosis of FPIAP in newborns and infants.

Detection of peripheral blood cells has emerged as an important research hotspot in the context of FPIAP diagnosis due to methodological simplicity, ease of operation, and less trauma to children. Evidence suggests that dysregulated neutrophils can contribute to the initiation and amplification of allergic responses [15,16]. However, in this study, although the level of peripheral blood neutrophils in the FPIAP group was higher than that in the control group, there was no significant difference. This was inconsistent with the results of a previous study [17], possibly due to the relatively small number of cases included in these studies. Small-sample studies are generally subject to random sampling variation and selection bias. These factors may mask the inherent difference in neutrophil count between the FPIAP group and the control group, resulting in non-significant results observed in this study.

Several studies have shown that platelets may play an important role in allergic diseases [18,19]. In allergic asthma, platelets promote the migration of white blood

Table 4. Multivariate logistic regression analysis of the factors associated with neonatal FPIAP.

	β	SE	Wald	OR	95% CI	p
Eosinophil count	3.090	0.719	18.495	21.984	5.376–89.902	<0.001
Platelet count	0.010	0.003	10.933	1.010	1.004–1.015	<0.001

OR, odds ratio; CI, confidence interval; SE, standard error.

Table 5. ROC analysis of eosinophil and platelet levels for newborns with FPIAP.

	Cutoff	AUC	95% CI	Sensitivity	Specificity	p
Eosinophil count	0.745×10^9/L	0.808	0.720–0.897	0.707	0.812	<0.001
Platelet count	335×10^9/L	0.742	0.634–0.850	0.683	0.762	<0.001
Combined diagnosis model	-	0.862	0.787–0.936	0.805	0.825	<0.001

ROC, receiver operating characteristic; AUC, area under the curve; CI, confidence interval.

cells to the lungs by releasing a variety of cytokines, thereby enhancing chronic inflammatory response and tissue damage [20,21]. In allergic reactions, eosinophils and platelets interact. Eosinophils can release platelet-activating factor to promote platelet activation and aggregation, while platelets can release granulocyte-macrophage colony-stimulating factor (GM-CSF) to inhibit the apoptosis of eosinophils and prolong their survival. In this study, the platelet count of newborns with FPIAP was significantly higher than that of the control group, which was consistent with the findings of Huang et al. [22].

In IgE-mediated allergic reactions, exposure to allergens triggers cytokine release from mast cells and basophils, promotes chemotaxis and aggregation of eosinophils, and subsequently produces allergic reactions. However, accumulating evidence also points to a crucial role of eosinophils in the development of non-IgE-mediated allergic diseases [23]. In this study, the ROC curve analysis was used to explore the utility of eosinophil and platelet counts, as well as their combination, in diagnosing FPIAP in newborns presenting with hematochezia. The results showed that both eosinophil and platelet counts demonstrated medium sensitivity and high specificity for FPIAP diagnosis. The combined model of the two indicators demonstrated higher specificity and sensitivity than individual measurements. In clinical practice, eosinophil and platelet counts may serve as useful markers for identifying newborns whose first symptom is bloody stool.

Several limitations of this study should be acknowledged. Firstly, although the sample size (n = 41 for the FPIAP group) was sufficient to detect significant changes in key indicators such as eosinophils, its statistical power is still insufficient for in-depth subgroup analysis (such as stratification by different feeding methods or symptom severity) or for identifying certain secondary indicators with smaller effect sizes, introducing a potential risk of type II error. Secondly, not all FPIAP cases in this study had completed the diagnostic "re-provocation" test, which may to some extent affect the specificity of the diagnosis. Finally, the findings of the present study are not generalizable to other studies due to its single-center and retrospective nature. Therefore, it is necessary to conduct prospective, multicenter studies involving larger samples in the future to validate our findings and establish more accurate diagnostic thresholds.

5. Conclusion

In summary, peripheral blood eosinophil and platelet levels in newborns with FPIAP were significantly higher than those in the control group, and both elevations served as independent risk factors for the condition. The combined model comprising eosinophil and platelet counts demonstrated high predictive value in diagnosis, which suggests that the combined detection of these indices provides a simple yet reliable auxiliary approach for diagnosing newborns with FPIAP. This approach facilitates early identification and differentiation of the condition, reduces misdiagnosis and missed diagnoses, and provides valuable clinical reference for clinicians.

Key Points

• Food protein-induced allergic proctocolitis (FPIAP) is the most common food-related allergic disease in newborns, with its incidence increasing annually.

• Avoidance-provocation test is the gold-standard approach for FPIAP diagnosis, but its clinical application has certain limitations.

• The results of univariate analysis showed that there were significant differences in eosinophil and platelet counts between the FPIAP group and the healthy control group.

• Logistic regression analysis indicated that elevated eosinophil and platelet levels are risk factors for FPIAP in newborns.

• Receiver operating characteristic (ROC) curve analysis demonstrated that the combined detection of eosinophils and platelets provides a more effective strategy for FPIAP diagnosis compared to the single-index detection.

Availability of Data and Materials

All data included in this study are available from the corresponding author upon reasonable request.

Author Contributions

FWC and QY had the original conception of the work. FWC and QY collected the clinical data. FWC and QY performed the research. QY drafted the manuscript. Both authors contributed to the important editorial changes in the manuscript. Both authors read and approved the final manuscript. Both authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of The Affiliated Yangming Hospital of Ningbo University (No. 2025-09-011), and all procedures complied with the Declaration of Helsinki. This study only analyzed existing clinical data, and strict privacy protection measures were in place. The research results do not alter current treatment protocols, do not involve commercial interests, pose no risk of infringement, and do not infringe upon the rights or interests of the participants. Based on these factors, the requirement for informed consent was waived.

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Conflicts of Interest

The authors declare no conflicts of interest.

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