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Investigating IgG Levels in Pediatrics with Kawasaki Disease and Its Association with Clinical Outcomes: A Cross-Sectional Study

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Abstract

Background: Kawasaki Disease is a type of systemic vasculitis. Patients diagnosed with Kawasaki Disease require a regimen of aspirin and intravenous immunoglobulin (IVIG). Timely diagnosis and proactive treatment can prevent complications associated with Kawasaki Disease. Therefore, this study was conducted to investigate the levels of IgG in Kawasaki patients and its correlation with clinical outcomes at Taleghani Hospital in Gorgan in 2022.

Methods: This cross-sectional study was conducted on 36 Kawasaki patients admitted to Taleghani Hospital in Gorgan in 2022. Patients were categorized into two groups based on Kawasaki criteria: complete and incomplete. Levels of IgG and primary disease characteristics, laboratory findings, and echocardiographic results were measured and recorded. Data was collected using a researcher-made checklist through observation, examination, and interview. Data were analyzed using an independent t-test and a Chi-square test at the 0.05 level, as determined by SPSS version 23.

Results: The results showed that the average age of the children was 26.43 ± 21.88 months, with 63.9% of the samples aged between 1 and 5 years. 89.2% did not have coronary involvement, and 91.7% responded to treatment. Leukopenia was present in 2.8% of children, leukocytosis in 75%, and 36% were in the acute phase. Inflammatory factors ESR and CRP were positive in 72.2% of children. The average IgG level in female children was higher than in males, but this difference was not significant. The frequency of laboratory diagnosis was less in boys than in girls, but this difference was also not significant.

Conclusion: Timely diagnosis and proactive treatment (IVIG) can prevent complications associated with Kawasaki Disease. Paraclinical findings play a significant role in determining the response to treatment and clinical outcomes.

Keywords: Kawasaki disease, Pediatric, IgG level

Conflicts of Interest: None declared
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Introduction

Kawasaki disease (KD) is a self-limiting acute systemic inflammatory disease prevalent during childhood, which may be triggered by the immune system's response to exposure to unknown agents (1-3). Though primarily affecting children, it can also affect adults, albeit with a higher severity but less frequency (4). The clinical phenotype and natural course of KD vary among individuals. This disease is characterized by common findings, including edema, erythema, desquamation, and strawberry tongue. Still, due to its systemic nature, it can also involve other parts of the body, resulting in various clinical symptoms and complications (5).

KD, primarily diagnosed based on clinical findings, is typically managed using aspirin and intravenous immunoglobulin (IVIG). Despite treatment, KD can sometimes lead to cardiac complications in affected children. Most

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↑What is "already known" in this topic:
Approximately 10-20% of KD patients are resistant to treatment. Para-clinical examination findings play a crucial role in determining treatment response and clinical outcomes, including the level of Immunoglobulin G (IgG).

→What this article adds:
Timely diagnosis and proactive treatment can prevent complications associated with Kawasaki Disease. Paraclinical findings play a significant role in determining the response to treatment and clinical outcomes.

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patients recover without complications within 10 to 11 days after the fever period. However, some patients develop prolonged fever and/or severe complications such as coronary artery aneurysms (6). The intensity of systemic inflammation is reflected in different laboratory parameters. Early detection of KD remains challenging due to patients presenting before full clinical criteria are apparent and an increase in incomplete KD phenotypes. Therefore, appropriate guidelines for early diagnosis in these patients are needed (4). Furthermore, KD increases the likelihood of concurrent diseases, such as respiratory infections (7).

In a study by Nakamura and colleagues in Japan in 2010, 23,337 new cases of KD were reported, indicating an incidence of 215.3 and 218.6 per 100,000 individuals in two consecutive years (8). Holman and colleagues in the USA in 2010 reported an incidence rate of 62.9 per 100,000 individuals, with 84% of the 528 KD patients studied being under the age of 5 (9). An important consideration is the difference in KD-related cardiac complications and the course and extent of response to treatment, especially among children under 5, who form the most affected and common age group, compared to older children. This emphasizes the importance of separate evaluations based on the type of complications and the understanding of associated factors (10-12).

According to studies conducted on Iranian children, cardiac involvement is seen in 31% of KD patients. Considering that some patients have more than one cardiac issue, these cardiac problems include coronary artery aneurysms in 13%, pericardial effusion on echocardiography in 11%, ECG changes and cardiomegaly in 8%, and mild mitral valve insufficiency in 10% (13). Given that KD patients require aspirin and IVIG treatment in combination to reduce the occurrence of cardiac sequels, timely diagnosis and preventive treatment can mitigate the complications of KD. Additionally, implementing a cardiac rehabilitation program can improve the quality of life for these patients (14, 15). Approximately 10-20% of KD patients are resistant to treatment. Para-clinical examination findings play a crucial role in determining treatment response and clinical outcomes, including the level of Immunoglobulin G (IgG) (16). Accordingly, considering the subject's significance, this study aims to examine the IgG levels in KD patients and their correlation with clinical outcomes.

Methods

In this cross-sectional study, patients with Kawasaki disease were selected and investigated based on the diagnostic criteria below and with the final confirmation by a pediatric infectious disease specialist and a clinical immunology-allergy specialist at Taleghani Hospital, Gorgan, in 2020. Thus, a total of 36 confirmed Kawasaki patients were studied. The patients were categorized into two groups ,complete and incomplete, based on the Kawasaki criteria.

The complete group required the presence of fever (axillary >37.5) for at least five days and at least three other significant characteristics of the disease, including changes in extremities (erythema and edema of the palms and soles), peeling around the nails in the second and third weeks, polymorphous exanthema, bilateral bulbar conjunctival injection without exudate, changes in the lips and oral cavity (erythema, dryness, and cracking of lips, strawberry tongue, diffuse injection of oral and pharyngeal mucosa), cervical lymphadenopathy (1.5 cm or larger), usually unilateral, negative blood cultures, and the absence of other laboratory findings indicative of infection.

The incomplete group included persistent fever for five days or more and two or three major characteristics of the disease along with acute phase laboratory findings, including erythrocyte sedimentation rate (ESR) ≥ 40, and C-reactive protein.

(CRP) ≥ 3, and at least three findings from the following criteria: leukocytosis ≥ 15,000 per milliliter, anemia, alanine transaminase < 50 units per liter, platelet count ≥ 450,000 per microliter, pyuria (presence of more than ten white blood cells per milliliter of urine sample), albumin ≥ 3 milligrams per deciliter, and positive echocardiography findings such as coronary artery ectasia, mitral regurgitation, left ventricular dysfunction, and pleural effusion.

The IgG levels of the patients were measured in two phases, during the disease and after the treatment, and compared between the two groups with and without a response to treatment. Data were collected using a checklist designed based on the available information, including age, sex, ethnicity, IgG level, echocardiography results, response to treatment, glucose, leukocytes, platelets, lymphocytes, albumin, Hemoglobin (Hb), Mean corpuscular volume (MCV), Cardiopulmonary resuscitation (CPR), Erythrocyte sedimentation rate (ESR), White blood cell (WBC), Red blood cell (RBC), Aspartate aminotransferase (AST), Alanine transaminase (ALT), and alkaline phosphatase (ALP).

Statistical analysis

Quantitative variables were described using means and standard deviations, while qualitative variables were described using frequency distribution tables. The normality of the quantitative variables was assessed with the Shapiro-Wilk test. The independent t-test was used to compare the means, and the chi-square test was used to analyze the relationship between qualitative variables. The significance level was set at 0.05. The analysis was performed using SPSS software version 26.

Results

This study evaluated the data of 36 children diagnosed and hospitalized with Kawasaki disease at Taleghani Hospital in Gorgan City in 2020. The average age of the children was 26.43 ± 21.88 months, ranging from 1.5 to 96 months. Accordingly, 30.6% of children were under one year of age, and 63.9% were between 1-5 years. 66.7% of the children were male, 77.8% were of Persian ethnicity, and 16.7% were of Turkmen ethnicity (Table 1).

Among the 36 children with Kawasaki disease, the IgG level was measured for 36 patients. The average IgG was 834.83 ± 565.58 with a range of 112 - 2785. Of these, 33.3% had a normal IgG level, and 22.2% had an IgG level less than 700. In 89.2% of children, coronary in-

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Table 1. Demographic information of children with Kawasaki disease hospitalized at Taleghani Hospital in Gorgan

Variable	Level	Frequency	Percentage
Gender	Male	24	66.7
	Female	12	33.3
Age Group	Under 1 year	11	30.6
	1-5 years	23	63.9
	Over 5 years	2	5.5
Ethnicity	Persian	28	77.8
	Turkmen	6	16.7
	Sistani	2	5.5

Table 2. Clinical results of patients with Kawasaki disease hospitalized at Taleghani Hospital in Gorgan

Variable	Levels	Frequency	Percentage
IgG Level	Less than 700	7	19.5
	700 or more	29	80.5
Response to Treatment	Yes	33	91.7
	No	3	8.3

volvement was not observed in their echocardiography results, and 91.7% of children reported a response to treatment (Table 2).

The frequency of laboratory findings in children with Kawasaki disease showed that 2.8% of children were diagnosed as leukopenic, and 75% had leukocytosis. 8.3% of children had thrombocytopenia, and 36.1% were in the acute phase of the disease. 2.8% of children had lymphopenia, 2.8% were diagnosed with hypoalbuminemia, and 63.9% had a normal albumin level. All children had a neutrophil level equal to or greater than 1500 (normal). CRP in children with Kawasaki disease was positive in 86.1%, and ESR was reported positive in 80.6%. Furthermore, 72.2% of children had a positive CRP and an ESR greater than or equal to 40 (Table 3).

The results of the urine test for patients showed that the number of white blood cells in 91.7% of children was less than 10, which was considered a negative result, and the number of red blood cells in 94.4% of children was less than 5. Furthermore, 80% of children had negative glucose. Also, liver test results showed that 52.8% of children had a normal ALT level, 77.8% of children had a normal AST level, and 77.8% of children had a normal ALP level (Table 4).

In comparing the mean IgG level in children by sex, the mean IgG level in girls and boys was 833.86 ± 1208.17 and 253.5 ± 648.17, respectively, which this difference was not statistically significant (P = 0.161). In determin-

Table 3. Laboratory findings of children with Kawasaki disease hospitalized at Taleghani Hospital in Gorgan

Variable	Level	Frequency	Percentage
Leukocytes (per mcL)	Less than 4000 (Leukopenic)	1	2.8
	4000 - 11000 (Normal)	8	22.2
	More than 11000 (Leukocytosis)	27	75
Platelets (per mcL)	Less than 150000 (Thrombocytopenic)	3	8.3
	150000 - 450000 (Normal)	20	55.6
	More than 450000 (Acute phase)	13	36.1
Lymphocytes	Less than 1000 (Lymphopenia)	1	2.8
	1000 or more	35	97.2
Albumin	Less than 3 (Hypoalbuminemia)	1	4.2
	3 - 4.8 (Normal)	23	95.8
Hb	Normal (11-12)	6	16.7
	Abnormal	30	83.3
MCV	Normal (70-80)	16	44.4
	Abnormal	20	55.6

Table 4. Urine test results and liver tests of children with Kawasaki disease hospitalized at Taleghani Hospital in Gorgan

Variable		Level	Frequency	Percentage
Urine Test	WBC	Negative (less than 10)	33	91.7
		Positive (10 or more)	3	8.3
	RBC	Negative (less than 5)	34	94.4
		Positive (5 or more)	2	5.6
	Glucose	Negative	29	90.6
		1+ and 2+	3	9.4
Liver Tests	ALT	Normal (less than 25)	19	52.8
		Abnormal (25 or more)	17	47.2
	AST	Normal (less than 45)	28	77.8
		Abnormal (45 or more)	8	22.2
	ALP	Normal	28	77.8
		Abnormal	8	22.2

Table 5. Relationship between sex and diagnosis of Kawasaki based on laboratory criteria

Variable	Level	Diagnosed according to laboratory criteria		*P*-value
		Yes (frequency percentage)	No (frequency percentage)	
Sex	Boy	6 (25%)	18(75%)	0.312
	Girl	5 (41.7%)	7 (58.3%)	
Age group	Less than one year	4 (36.4%)	7 (63.6%)	0.691
	1-5 years	6 (26.1%)	17 (73.9%)	
	More than 5 years	1 (50%)	1 (50%)	

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ing the relationship between sex and the diagnosis of Kawasaki according to laboratory criteria, the results showed that 41.7% of girls and 25% of boys were diagnosed with Kawasaki disease, with a higher prevalence in girls than boys, but this difference was not statistically significant. The diagnosis of Kawasaki according to laboratory criteria also showed that it is more common in the age group under one year than in the common age group (2-5 years). Only two cases were examined in older ages with a diagnosis of Kawasaki, of which only one was positive regarding laboratory indices. According to the laboratory indicators, 36% of the children matched the diagnosis of Kawasaki, but these differences were not statistically significant (Table 5).

Discussion

Immunoglobulin therapy (IVIG) is utilized in primary immunodeficiency diseases as well as inflammatory or autoimmune disorders. In primary immunodeficiency, IVIG serves as a replacement therapy, with recommended dosages between 400 to 800 mg/kg per month and lower levels of IgG. A meta-analysis by Orange JS and colleagues in 2010 demonstrated a gradual reduction in pneumonia risk with lower IgG levels (down to a minimum of 1000 mg/dL). On the other hand, the role of IgG level in autoimmune and inflammatory diseases is not well defined. The efficacy of IVIG administration in acute-phase Kawasaki disease (KD) is now well established (17, 18). Previous studies have associated lower total protein, albumin, and predominantly IgG levels with more severe inflammation, coronary artery lesions, and lack of response to IVIG (19, 20). Low pre-treatment IgG levels have been reported as a risk factor for coronary abnormalities. However, other studies have not confirmed these findings (21-23).

This study highlights the critical importance of timely diagnosis and proactive treatment of Kawasaki Disease (KD) in pediatric patients. Our findings indicate that intravenous immunoglobulin (IVIG) therapy plays a vital role in preventing complications associated with KD, particularly in reducing the risk of coronary artery involvement. Despite the small sample size of 36 children, the data suggest that the majority of patients (91.7%) responded positively to treatment, underscoring the efficacy of IVIG in clinical practice.

Our study has distinct strengths and weaknesses compared to similar studies over the last 5 years. We evaluated 36 patients, a smaller sample compared to other studies (24, 25). Our study, similar to Sawaji et al. (26) has lower patient numbers due to the lower prevalence in our region and limited available samples. Interestingly, our study reports a higher prevalence of Kawasaki disease in boys (about 67%) compared to most previous studies, which report around 60% prevalence (19, 25). The cause of this difference is unclear and might change with larger sample sizes. In China, in a study by Yan Ding with a sample size ten times larger, the prevalence in boys was still reported to be around 67.5% (24). The age range of our study subjects is younger than those in the studies by Goto and Yumi Seo (19, 25). Reports of coronary involvement percentages from the studies by Ding, Hwang, Goto, and Seo are 25.7%, 22.27%, 8.3%, and 19.3%, respectively (19, 20, 24, 25). Response rates to treatment in the Hwang, Goto, and Ding studies were 10%, 28.5%, and 6.2%, respectively (20, 24, 25), while in our study, it was 8.3% - lower than Hwang and Goto (20, 25), but higher than Ding (24).

Furthermore, the study demonstrated that paraclinical findings, including IgG levels, inflammatory markers (ESR and CRP), and other laboratory parameters, significantly contribute to understanding the disease's progression and treatment response. Notably, while the average IgG levels were higher in female patients, the difference was not statistically significant, indicating that further research is needed to clarify the role of IgG in KD outcomes.

In our study, incomplete Kawasaki disease was diagnosed in 69.6% of cases, compared to 4% in Ding's study and 37.1% in Seo's study (19, 24). The ALT level did not increase in 52.8% of our cases, a number close to the 46.7% reported in Seo's study (19). In Ja-Young Hwang and colleagues' study, the average leukocyte count was around 16 in the group that did not respond to treatment and about 10 in the response group, which aligns with our overall leukocyte count average (20).

Our study aimed to elucidate the mechanism of IVIG action by examining the effects of variable IgG levels post-infusion on clinical outcomes. More studies are needed to apply our findings in clinical settings. Arguably, the timing of IgG measurement after infusion could influence its value. Thus, in future studies, only patients whose IgG level is measured 48 hours post-IVIG completion should be included.

Conclusion

By leveraging paraclinical findings, clinicians can better assess treatment responses and tailor interventions to improve clinical outcomes. Future studies with larger sample sizes and more comprehensive data collection are essential to validate our findings and explore the intricate relationships between IgG levels, treatment response, and long-term outcomes in KD patients.

The prevalence of non-response to treatment varies across different studies. Timely diagnosis and preventative treatment (IVIG) can mitigate complications of Kawasaki disease. Paraclinical findings play a crucial role in determining treatment response and clinical outcomes. In our study, no significant relationship was found between IgG level and clinical outcomes. Further research with larger sample sizes should be conducted.

Authors' Contributions

Design and study team: Seyed Mehdi Aghapour, Mousa Ghelichi-Ghojogh, Jabbar Parhiz, Sahar Delavari, Seyed Ali Aghapour. Conceptualization: Seyed Ali Aghapour, Jabbar Parhiz. Formal analysis: Mousa Ghelichi-Ghojogh. Writing, review & editing: Seyed Mehdi Aghapour, Mousa Ghelichi-Ghojogh, Sahar Delavari, Seyed Ali Aghapour.

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Ethical Considerations

The study protocol was reviewed and approved by Golestan University of Medical Sciences, Gorgan, Iran, with an ethical code (IR.GOUMS.REC.1400.405).

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Conflict of Interests

The authors declare that they have no competing interests.

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