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ORIGINAL RESEARCH

Early diagnosis and clinical characterization of complete versus incomplete Kawasaki disease in children in Rui'an City: a retrospective study

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Abstract

Backgrounds: The aim of this study was to analyze the clinical characteristics of complete Kawasaki disease (CKD) and incomplete Kawasaki disease (IKD) in children in Rui'an City, with a view to providing a basis for early recognition of IKD by clinicians. **Methods**: 94 children with suspected Kawasaki disease (KD) admitted to our hospital between October 2017 and October 2023 were selected as the study subjects. **Results**: The duration of fever in the IKD group was significantly longer than that in the CKD group ($p < 0.05$), while the incidence of rash, fingertip changes, conjunctival congestion, and cervical lymph node enlargement were significantly lower than that in the CKD group ($p < 0.05$). In contrast to the CKD group, the IKD group exhibited significantly elevated levels of C-reactive protein (CRP), platelet count (PLT), N-terminal brain natriuretic peptide precursor (NT-proBNP) and albumin (ALB) ($p < 0.05$), whereas the level of alanine aminotransferase (ALT) was significantly lower ($p < 0.05$). In the IKD group, a greater percentage of children exhibited sinus tachycardia compared to the CKD group ($p < 0.05$). The incidence of coronary artery lesions (CAL) was significantly higher in the IKD group than in the CKD group ($p < 0.05$). There were 14 cases (15.91%) in the IKD group and 6 cases (6.38%) in the CKD group showed resistance to gammaglobulin treatment ($\chi^2 = 4.217$, $p = 0.040$). **Conclusions**: Children with IKD experienced prolonged fever duration, a notably reduced rate of positive clinical symptoms, and marked irregularities in lab parameters such as CRP, PLT, NT-proBNP and ALB, as well as a significantly higher incidence of CAL. A thorough examination incorporating data from various angles in clinical settings can provide valuable insights for diagnosing and treating pediatric patients with IKD in Rui'an City.

Keywords

Complete Kawasaki disease; Incomplete Kawasaki disease; Clinical features; Rui'an City

1. Introduction

Kawasaki disease (KD), also known as cutaneous mucocutaneous lymph node syndrome, is an acute, self-limiting vasculitis that occurs mainly in childhood. KD can affect various systems in the body, with a particular impact on the coronary arteries, which can result in cardiac complications and, in more serious instances, sudden fatality [1, 2]. Therefore, KD has become a major clinical concern in pediatrics. KD is usually categorized into Complete Kawasaki disease (CKD) and Incomplete Kawasaki disease (IKD). Currently, the identification of CKD and IKD predominantly depends on clinical presentations. However, the clinical features of IKD are often non-specific and exhibit only partial KD diagnostic criteria. This circumstance complicates clinical diagnosis, rendering the condition susceptible to underdiagnosis or misdiagnosis, thereby heightening the likelihood of coronary complications [3]. Therefore, analyzing IKD and CKD is of great significance for improving the accuracy of diagnosis, timely intervention and treatment and improving the prognosis of children. Identifying certain early symptoms or laboratory indicators that exhibit a greater prevalence or specificity in children with IKD could potentially raise awareness among clinicians regarding suspected cases. In addition, it may be useful to develop monitoring indicators and follow-up programs based on specific clinical problems or complications that may occur in children with IKD during follow-up to improve the overall management of children with IKD. Being a region with a high population density, the prevalence of KD among children in Rui'an serves as a typical example. At present, there is a dearth of comprehensive studies on the clinical features of KD in children from Rui'an, specifically regarding the

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variances between CKD and IKD. In view of this, this study retrospectively analyzed children with KD admitted in recent years, and analyzed the clinical characteristics of children with CKD and IKD. We hope to provide some reference value for the clinical early diagnosis of children with KD in Rui'an City.

2. Materials and methods

2.1 Patients

The clinical data of children with KD admitted to our hospital between October 2017 and October 2023 were retrospectively analyzed. Inclusion criteria: (1) met the diagnostic criteria of pediatric KD; (2) all were between 5 months and 5 years old; (3) had no history of major diseases or resuscitation; (4) the clinical data were complete. Exclusion criteria: (1) Combined with connective tissue diseases such as systemic lupus erythematosus and juvenile rheumatoid arthritis; (2) Accompanied by inherited metabolic diseases and congenital heart disease; (3) Accompanied by cardiac, liver, renal and other vital organ insufficiency. The study was approved by the Ethics Committee of the hospital (Approval No. YJ2024155) and informed consent was obtained from the guardians of the children.

According to the latest data, the population of Rui'an has reached 1,535,000 in 2023. The larger population base will help identify more KD cases for more in-depth research. Meanwhile, significant progress has been made in the establishment of healthcare security measures in Rui'an City. This includes advancing the development of a tiered diagnosis and treatment system and endorsing the implementation of novel payment methods for healthcare insurance. These efforts contribute to enhancing the availability and standard of healthcare services, ultimately offering improved healthcare security for KD patients. These factors make Rui'an City representative and important in KD research, and thus it was selected as a representative area for this study. Finally, a total of 182 children were included in this study (Fig. 1). Among them, 94 cases were children with CKD and 88 cases were children with IKD.

2.2 Diagnostic criteria

The diagnostic criteria for Kawasaki disease refer to those of the American Heart Association (AHA) [4]: fever lasting more than 5 days with at least 4 of the following 5 main features: (1) changes in the extremities: erythema and edema of the hands and feet in the acute phase, and membranous desquamation of the fingertips during the convalescent phase; (2) polymorphic rash; (3) bilateral painless bulbar conjunctival congestion without exudate; (4) changes in the lips and oral changes: flushed and chapped lips, strawberry tongue, and diffuse redness of the mucous membranes of the mouth and pharynx; and (5) swollen cervical lymph nodes ($\geq$1.5 cm in diameter), usually unilateral.

The clinical diagnostic criteria for IKD [5] were as follows. When the child had fever for more than 5 days, two to three of the symptoms listed above and coronary artery changes confirmed by cardiac ultrasound. When the child developed two or three of the symptoms listed above, and the C-reactive protein (CRP) was more than 30 mg/L, accompanied by three of the following indicators: (1) albumin index was less than or equal to 30 g/L; (2) anemia; (3) liver function abnormalities; (4) platelet counts were significantly increased after 7 days of the onset of the disease (more than 450 $\times$ 10^9/L); (5) the total number of leukocytes in the acute phase was more than or equal to 15 $\times$ 10^9/L; (6) more than 10 leukocytes/HP visible in routine urine.

Criteria for determining coronary artery lesions (CAL) [6]: coronary artery examination was performed using an EPIQ5 Dutch Philips color Doppler ultrasound (Philips, The Netherlands). Normal reference ranges of coronary arteries: at age less than 3 years, the inner diameter of the coronary arteries of the children was less than 2.5 mm; at age 3–9 years, the inner diameter of the coronary arteries was less than 3 mm; at age 9–14 years, the inner diameter of the coronary arteries was less than 3.5 mm. Coronary artery dilatation (CAD) refers to the condition where the internal diameter of the coronary artery exceeds the normal range but remains below 4 mm. On the other hand, coronary artery aneurysm (CAA) is characterized by an internal diameter within the range of 4–8 mm. Lastly, giant coronary artery aneurysm (GCAA) is identified by an internal diameter equal to or exceeding 8 mm.

2.3 Data collection

Clinical data of the children were collected through an electronic case system. (1) General information, including age, sex, duration of fever, clinical symptoms (high fever, fingertip changes, rash, oral mucosal changes, conjunctival congestion, cervical lymph node enlargement, cicatricial erythema, *etc.*). (2) Laboratory indicators, including C-reactive protein (CRP), neutrophil percentage, N-terminal brain natriuretic peptide precursor (NT-proBNP), white blood cell count (WBC), platelet count (PLT), hemoglobin (Hb), erythrocyte sedimentation rate (ESR), albumin (ALB) and alanine aminotransferase (ALT). (3) Electrocardiogram (ECG) findings, including tachycardia, conduction block, ST-T changes and Q-T interval prolongation. (4) Therapy. In the treatment of children, 2 g/(kg·d) of gammaglobulin was given intravenously for 1$\sim$2 days, and 30$\sim$50 mg/kg·d of oral aspirin was given orally in 3 times. If there is an insensitivity to gammaglobulin, a potential course of action could involve a repeat treatment with 2 g/kg of gammaglobulin, or alternatively hormone therapy such as methylprednisolone at a dosage of 20 mg/(kg·d) for a duration of 3 days. Following the abatement of fever, the dosage can be modulated to 2 mg/(kg·d) until the therapy is ceased after 14 days. Once the body temperature has normalized, aspirin may be administered at a reduced dosage of 3–5 mg/(kg·d) for a period of 6–8 weeks.

2.4 Statistical analyses

Data analysis was performed using SPSS 26.0 (IBM Corp., SPSS Statistics, Armonk, NY, USA). Count data were presented as examples and compared using the χ^2 test or Fisher's exact test. All measures were assessed for normality using the Shapiro-Wilk test. Continuous variables were presented as mean $\pm$ standard deviation and compared using Students'

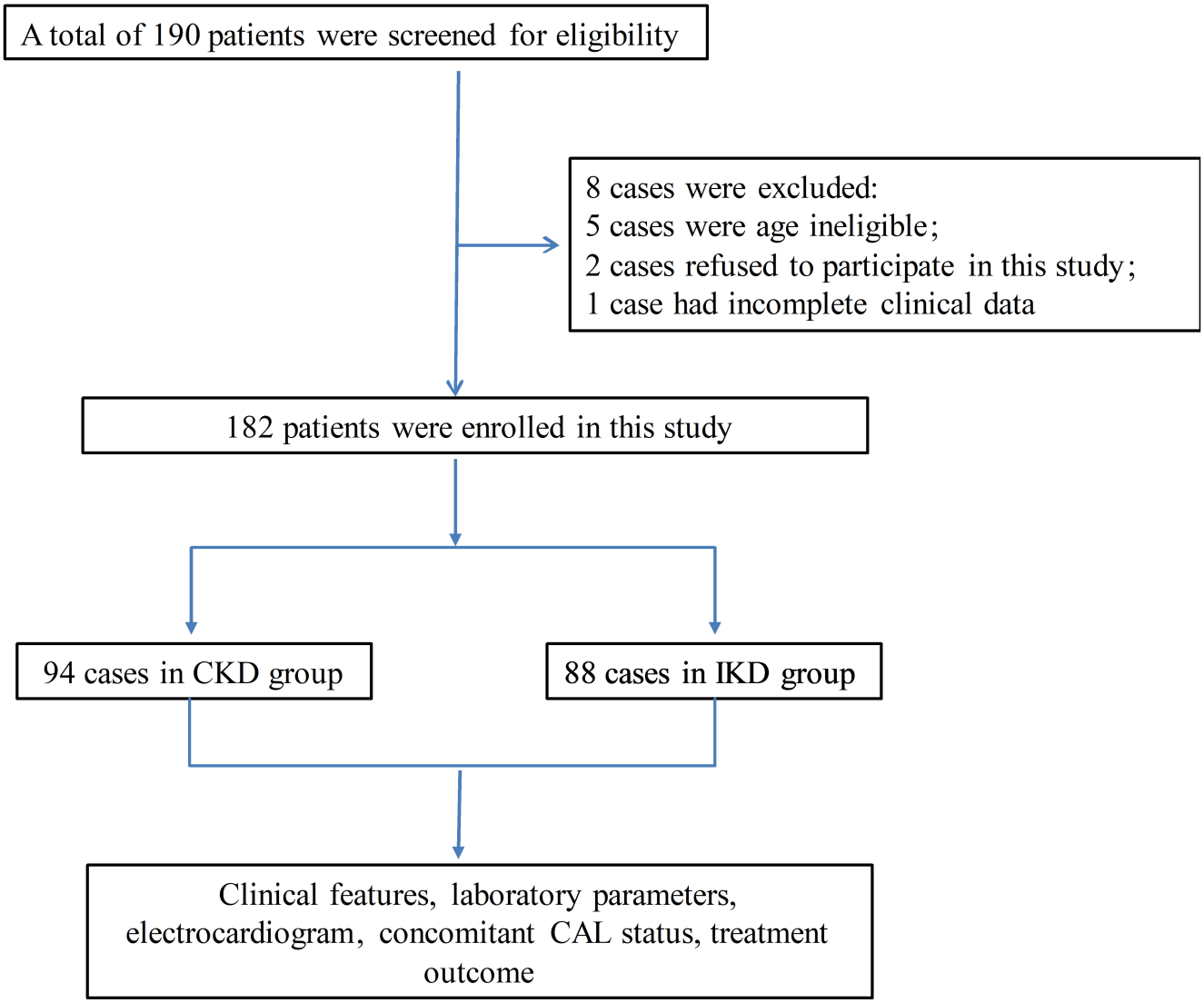

FIGURE 1. Flowchart. CKD: complete Kawasaki disease; IKD: incomplete Kawasaki disease; CAL: coronary artery lesions.

t-test. When it differed from normal distribution, it was classified as M (Q1, Q3) and subjected to Mann-Whitney U test. $p < 0.05$ indicates statistically significant differences.

3. Results

3.1 Comparison of the clinical characteristics of the two groups of children

In the IKD group, the fever lasted significantly longer than in the CKD group ($p < 0.05$, Table 1), Conversely, the incidence of rash, fingertip changes, conjunctival congestion and symptoms of cervical lymph node enlargement were lower in the IKD group compared to the CKD group ($p < 0.05$, Table 1). The differences in the age in months, gender, hyperthermia, and changes in oral mucosa between the two groups were not statistically significant ($p < 0.05$, Table 1).

3.2 Comparison of laboratory indicators in two groups of children

The levels of CRP, PLT, NT-proBNP and ALB were significantly higher in children in the IKD group than in the CKD group ($p < 0.05$, Table 2), and ALT was significantly lower than in the CKD group ($p < 0.05$, Table 2).

3.3 Comparison of electrocardiographic findings in two groups of children

In the IKD group, there was a higher percentage of children exhibiting sinus tachycardia compared to the CKD group ($p < 0.05$, Table 3), while the disparity in the prevalence of other abnormalities between the two groups did not reach statistical significance ($p > 0.05$, Table 3).

3.4 Comparison of complications of CAL in two groups of children

The incidence of CAL was significantly higher in the children in the IKD group than in the CKD group ($p < 0.05$, Table 4).

TABLE 1. Comparison of the clinical characteristics of the two groups of children.

Parameters	IKD group (n = 88)	CKD group (n = 94)	t/χ^2	p
Male (n (%))	51 (57.95)	49 (52.13)	0.623	0.430
Age in months (mean ± SD)	30.66 ± 5.57	32.11 ± 4.97	1.852	0.066
Duration of fever (*d*, mean ± SD)	8.31 ± 1.50	6.73 ± 1.11	7.987	<0.001
Clinical symptoms (n (%))				
High fever	86 (97.73)	91 (96.81)	0.144	0.705
Skin rash	34 (38.64)	62 (65.96)	13.612	<0.001
Finger tip changes	29 (32.95)	51 (54.26)	8.371	0.004
Oral mucosal changes	72 (81.82)	80 (85.11)	0.357	0.550
Conjunctival congestion	50 (56.82)	77 (81.91)	13.575	<0.001
Cervical lymph node enlargement	32 (36.36)	65 (69.15)	19.627	<0.001
Erythema of the cicatrices	14 (15.91)	7 (7.45)	3.189	0.074

Note: t denotes the value of t-statistic for t-test and χ^2 for chi-square test. IKD: incomplete Kawasaki disease; CKD: complete Kawasaki disease; SD: standard deviation.

TABLE 2. Comparison of laboratory indicators in two groups of children.

Parameters	IKD group (n = 88)	CKD group (n = 94)	t/χ^2	p
CRP (mg/L, mean ± SD)	52.61 ± 6.03	35.99 ± 5.53	19.404	<0.001
WBC ($\times10^9$/L, mean ± SD)	14.52 ± 3.62	15.19 ± 4.08	1.172	0.243
PLT ($\times10^9$/L, mean ± SD)	378.88 ± 54.99	351.80 ± 51.00	3.447	0.001
Hb (g/L, mean ± SD)	119.02 ± 10.83	121.52 ± 12.21	1.456	0.147
ESR (mm/h, mean ± SD)	42.19 ± 7.48	40.23 ± 6.99	1.826	0.069
NT-proBNP (ng/L, mean ± SD)	323.06 ± 54.97	285.93 ± 50.63	4.744	<0.001
ALB (g/L, mean ± SD)	36.52 ± 4.02	32.29 ± 3.38	7.713	<0.001
ALT (U/L, mean ± SD)	37.53 ± 6.02	41.09 ± 7.07	3.636	<0.001
Neutrophil percentage (%, mean ± SD)	63.41 ± 11.23	64.93 ± 8.85	1.007	0.315

Notes: CRP: C-reactive protein; WBC: white blood cell count; PLT: platelet count; Hb: hemoglobin; ESR: erythrocyte sedimentation rate; NT-proBNP: N-terminal brain natriuretic peptide precursor; ALB: albumin; ALT: alanine aminotransferase; IKD: incomplete Kawasaki disease; CKD: complete Kawasaki disease; SD: standard deviation. In the table, t denotes the value of t-statistic for t-test and χ^2 for chi-square test.

TABLE 3. Comparison of electrocardiographic findings in two groups of children.

Electrocardiographic findings (n (%))	IKD group (n = 88)	CKD group (n = 94)	χ^2	p
Tachycardia	30 (34.09)	16 (17.02)	7.012	0.008
Conduction block	6 (6.82)	6 (6.38)	0.014	0.906
ST-T changes	2 (2.27)	3 (3.19)	0.144	0.705
Q-T interval prolongation	2 (2.27)	1 (1.06)	0.410	0.522

IKD: incomplete Kawasaki disease; CKD: complete Kawasaki disease.

TABLE 4. Comparison of complications of CAL in two groups of children.

CAL Complications (n (%))	IKD group (n = 88)	CKD group (n = 94)	χ^2	p
CAD	22 (25.00)	12 (12.77)		
CAA	5 (5.68)	4 (4.26)	6.079	0.014
GCAA	3 (3.41)	1 (1.06)		

IKD: incomplete Kawasaki disease; CKD: complete Kawasaki disease; CAD: Coronary artery dilatation; CAA: coronary artery aneurysm; GCAA: giant coronary artery aneurysm; CAL: coronary artery lesions.

The relative proportion of each subtype of CAL within the group was shown in Fig. 2.

3.5 Comparison of treatment effects between two groups of children

There were 14 (15.91%) insensitive to gammaglobulin treatment in the IKD group and 6 (6.38%) insensitive to gammaglobulin treatment in the CKD group ($\chi^2 = 4.217$, $p = 0.040$).

4. Discussion

KD, as one of the childhood immune disorders, the basal pathological changes often involve the coronary arteries and complications such as coronary artery dilatation (CAD) and coronary artery aneurysm (CAA) occur [7]. Emphasizing the importance of early detection in IKD is crucial. While diagnostic criteria for CKD are well-established [8], a consistent standard for the early diagnosis of IKD is currently lacking. Diagnosis of IKD primarily relies on clinical symptoms, imaging studies and laboratory findings. With the increase of IKD cases, its complications, critical illnesses, and gammaglobulin insensitivity have also gradually increased, so the early diagnosis of IKD has become a hotspot of concern and difficulty. In this study, we analyzed the clinical cases of CKD and IKD in Rui'an from 2012 to 2019, hoping that it would help to identify the clinical features of children with IKD in Rui'an at an early stage, and provide a reference for their early diagnosis and treatment.

Fever is a primary indicator of KD, and the presence of atypical clinical symptoms in IKD can result in delayed diagnosis, potentially extending the duration of fever [9, 10]. Similarly, it was observed in this study that the IKD group had a longer duration of fever and a low percentage of rash, fingertip changes, conjunctival congestion and cervical lymph node enlargement compared to CKD. Furthermore, the extended persistence of fever in IKD indicates the intricacies of autoimmune response, where the immunoregulatory abnormalities may lead to a protracted inflammatory state. Prolonged fever is likely to increase the discomfort of the child and may cause further damage to the organs of the body. Therefore, clinicians should be alert to IKD in children with prolonged fever.

In the diagnosis of KD, it is crucial to consider symptoms like rash, alterations in fingertip appearance, conjunctival congestion and the swelling of cervical lymph nodes. The rash is usually polymorphic and nonspecific, mostly erythematous papules, but can occasionally show a scarlet fever-like rash and pustular eruptions, often observed in the first 5 days of disease fever, mainly on the trunk [11]. It has been reported that individuals with IKD may experience less vigorous immune system activation compared to those with CKD, resulting in a reduced likelihood of developing skin manifestations like rashes [12]. Fingertip changes include flushing and hard edema of the palms and soles of the feet in the acute phase, sometimes accompanied by pain and peeling or nail loss in the later phase. The prevalence of these symptoms is higher in patients with CKD [13, 14], whereas it is relatively rare in individuals with IKD, possibly due to the speculation that IKD presents with a less severe vasculitis or limited extent of involvement. Conjunctival congestion is a typical symptom of KD, which usually manifests as vasodilatation of the conjunctival tissue on the surface of the eye, making the white portion of the eye red or pink in color, and most often begins shortly after the onset of fever and is transient [15]. KD is fundamentally characterized by systemic vasculitis, which is initiated by the abnormal activation of the immune system. During the disease process, antigen-presenting cells internalize and handle pathogen-related antigens, triggering the activation of T and B lymphocytes. These lymphocytes then undergo proliferation

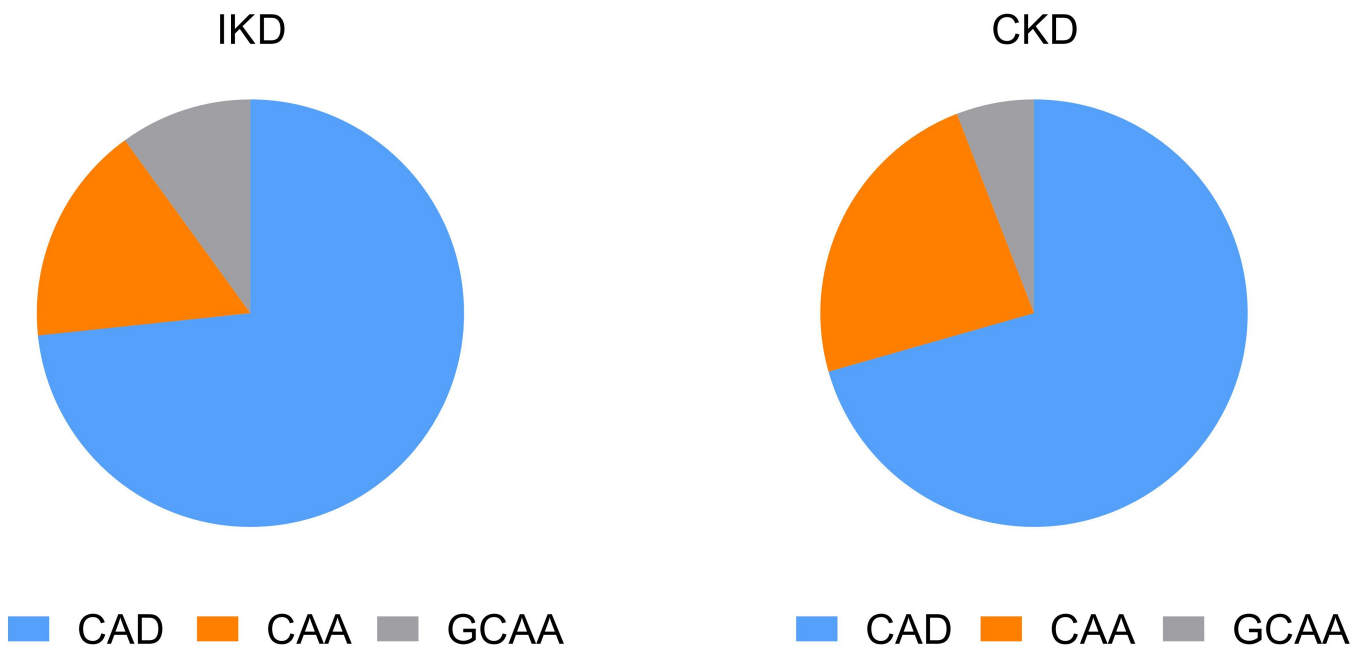

FIGURE 2. Relative share of each subtype of CAL within the group. IKD: incomplete Kawasaki disease; CKD: complete Kawasaki disease; CAD: Coronary artery dilatation; CAA: coronary artery aneurysm; GCAA: giant coronary artery aneurysm.

and differentiation within the cervical lymph nodes to initiate an immune reaction, leading to the enlargement of the lymph nodes [16]. The typical clinical manifestations of CKD, with relatively strong and concentrated inflammatory responses, may lead to more significant immune activation and inflammatory responses in the cervical lymph nodes, thus making it more likely to develop cervical lymph node enlargement. Nevertheless, IKD exhibiting atypical symptoms and a comparatively gradual or diffused inflammatory reaction results in a reduced occurrence of cervical lymph node swelling [17]. Kolko N *et al*. [18] found that the incidence of skin manifestations, conjunctival congestion, and lymph node enlargement was significantly higher in the complete Kawasaki group compared to children with IKD, which is consistent with the results of this study. Therefore, CKD and IKD exhibit variances in clinical presentations, and the scarcity of typical clinical signs in pediatric IKD cases further complicates the prompt identification of the condition.

The results of this study found that the levels of CRP, PLT, NT-proBNP and ALB were significantly higher in children in the IKD group than in the CKD group, and ALT was significantly lower than in the CKD group. CRP is an acute time-phase reactive protein synthesized by the liver, exhibits a rapid increase in plasma levels in the presence of conditions such as inflammation, infection, or tissue damage. In the context of KD, increased levels of CRP indicate the activation of the body's inflammatory response [19]. Although the clinical manifestations of IKD are less typical than those of CKD, the degree of inflammation may be no less or even more severe than that of CKD, and it is hypothesized that it may be related to the delay in the diagnosis of IKD, which leads to the persistence and further development of inflammation in the body. PLT serve as active components in blood clotting, playing a crucial role in halting bleeding and safeguarding against hemorrhage. Additionally, they function as immune cells that initiate and expedite numerous vascular inflammatory responses [20]. In a study by Kim SH *et al*. [21], it was reported that PLT is one of the auxiliary parameters to differentiate KD from simple febrile illness. During the inflammatory process associated with KD, there is an elevation in the secretion of different cytokines, including interleukin-6 and thrombopoietin. These cytokines play a role in promoting the growth and maturation of megakaryocytes in the bone marrow, subsequently resulting in enhanced platelet generation. In this study, the PLT level in the IKD group was higher than that in the CKD group, suggesting that inflammation may stimulate the bone marrow hematopoietic system more strongly in children with IKD. Under normal physiological conditions, ALB synthesis and catabolism are in a balanced state. Children with KD experience elevated catabolism, leading to heightened protein breakdown, along with impairment in liver synthesizing function [22]. To sustain normal physiological function in the body, the liver can enhance the synthesis of ALB to regulate plasma colloid osmotic pressure. Children with CKD have a higher percentage of typical symptom occurrence, which may be accompanied by a more focused and intense immune response, with immune cells infiltrating the liver or inflammatory factors directly damaging hepatocytes, leading to elevated ALT. On the contrary, the inflammatory reaction in IKD tends to be more dispersed or subtle, resulting in relatively mild liver damage and lower levels of ALT [12]. NT-proBNP is mainly secreted by ventricular myocytes, and its secretion increases significantly when the ventricular wall is strained or the pressure load is increased. Due to the delayed diagnosis of IKD, the degree of damage sustained by the heart during the prolonged inflammatory environment is more severe and the elevation of NT- proBNP levels is significantly higher. Previous studies have also found that NT-proBNP levels are notably increased in pediatric patients with IKD and may function as a reliable diagnostic marker for IKD, a finding that aligns with the outcomes of the present study [23].

Sinus tachycardia is characterized by the heart beating at a rate higher than the normal range, and this can be triggered by various factors such as emotional stress, systemic inflammatory response, cardiac issues, and other underlying causes [24]. Because the diagnosis of IKD is relatively difficult, inflammation may persist in the body for a long time without being effectively controlled, which will have a more significant impact on cardiac electrophysiology and lead to a higher incidence of sinus tachycardia. CAL is one of the more serious complications of KD, which can result in ischemic heart disease, myocardial infarction, and other detrimental outcomes in children, significantly impacting their long-term quality of life and overall well-being [25]. The results of this study found that children with IKD are at higher risk of coronary artery damage, which may be related to factors such as relatively atypical clinical manifestations and treatment timing. Rajasekaran *et al*. [26] indicated that the presence of inflammation in coronary artery lesions of children with IKD is influenced by a range of genetic and immunologic factors. They highlighted that the continued elevated expression of specific factors, such as interleukin-6 and NT-proBNP, are positively correlated with the risk of developing CAL. Although there are differences in research on the risk of CAL in patients with IKD in different countries, early diagnosis and close monitoring of inflammatory markers are common concerns. Therefore, it is imperative in future studies and medical care to closely observe the cardiac health of children diagnosed with IKD in order to promptly identify and address any possible coronary artery complications.

In the early stages of the disease, inflammation is in a rapidly progressive phase. Failure to administer gammaglobulin promptly could result in a worsening of the inflammatory reaction and hyperactivation of immune cells, compromising the efficacy of treatment. In contrast, CKD has typical symptoms and can be diagnosed and treatment initiated in a timelier manner. At this time, the inflammation is still in a relatively controllable stage, and gammaglobulin is more likely to play an immunomodulatory role, thus showing higher therapeutic sensitivity.

However, there were some limitations of this study. The present study did not follow up the children for a long period of time, which made it difficult to comprehensively assess the long-term complications of Kawasaki disease and the long-term effects on the growth and development of the children. The method of retrospective study, which depends on medical records and data that were available in the past, could be influenced by selection bias. We plan to conduct prospective

studies in the future to expand the sample source, enhance long-term follow-up, and explore the pathogenesis in depth to provide stronger support for clinical diagnosis and treatment. When evaluating the viability of future studies, it is essential to take into account certain crucial factors. The study design needs to be clear, including the purpose of the study, study hypotheses, sample size calculation, data collection methods, and statistical analysis plan, which may help to ensure the scientific validity and rigor of the study.

5. Conclusions

Compared to CKD, children with IKD have a longer duration of fever, less obvious clinical manifestations, but multiple laboratory indicators are significantly elevated, and there are differences in imaging findings and treatment effects. Combining information from multiple sources will aid in the early diagnosis of children with IKD in Rui'an City.

AVAILABILITY OF DATA AND MATERIALS

The authors declare that all data supporting the findings of this study are available within the paper and any raw data can be obtained from the corresponding author upon request.

AUTHOR CONTRIBUTIONS

DHZ—designed the study and carried them out. DHZ, MGZ, XW, WQB, MLP—supervised the data collection; analyzed the data; interpreted the data. DHZ, MLP—prepared the manuscript for publication and reviewed the draft of the manuscript. All authors have read and approved the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Ethical approval was obtained from the Ethics Committee of Rui'an People's Hospital (Approval no. YJ2024155). Informed consent was obtained from the guardians of the children.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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