Original Article

Clinical and Coronary Profile of SARS-CoV-2 Antibody–Positive Children with Incomplete Kawasaki Disease: A Retrospective Study

Chirag Soni[1], Prity Modi[2], Chaudhari Govind[3]

[1]Senior Resident, Department of Paediatrics, Ananya College of Medicine and Research, Kalol, Gujarat, India. [2]Resident Doctor, Department of Paediatrics, Fortis Escorts Hospital, Jaipur, Rajasthan, India. [3]Resident Doctor, Department of Paediatrics, Gheesibai Mittal Hospital, Ajmer, Rajasthan, India

Abstract

Background: Initially incomplete or atypical Kawasaki disease-like in children appearing in the post-COVID-19 period is not only challenging to diagnose and prognosticate, but also with respect to coronary artery involvement. Prior exposure to SARS-CoV-2 has also become increasingly evident in such presentations and requires a systematic analysis of clinical, laboratory, and echocardiographic results. **Material and Methods:** The children participating were six months to 5 years of age and had incomplete or atypical Kawasaki disease and positive SARS-CoV-2 antibody status. Medical records were analysed and provided demographic information, presentation symptoms, vital parameters, haematological and inflammatory parameters, and two-dimensional echocardiography results. The coronary arteries were evaluated using 2D echocardiography. Descriptive and inferential statistics were used to conduct the analysis, with $p < 0.05$ taken as significant. **Results:** The sample included 250 children; in which case it was predominantly male (74.0%). The 45-5-year age group (36.4%) was the most prevalent. All participants had fever, non-purulent conjunctivitis (91.6%), and mucocutaneous changes (69.6%). The average admission temperature was 101.8 ± 2.4 °C, and the oxygen saturation was preserved (97.2 ± 3.2% oxygen status). Laboratory analysis disclosed elevated inflammatory markers, with mean percentages of C-reactive protein of 68.8 ± 12.4, ferritin of 1521.2 ± 423.2, and D-dimer of 1684.3 ± 128.4. Dilation of the coronary artery was found in 30.4% of the children. Lower body weight and higher total leukocyte count, C-reactive protein, ferritin, and D-dimer levels were significantly associated with coronary dilatation. **Conclusion:** Early echocardiographic assessment and close attention to the inflammatory parameters are a prerequisite to the prompt identification of at-risk children in coronary involvement.

Keywords: Kawasaki disease; SARS-CoV-2 antibodies; Coronary artery dilatation; Echocardiography.

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Introduction

Kawasaki disease (KD) is an acute childhood vasculitis that mainly affects children below the age of five years and is the number one cause of acquired heart disease in children in developed nations, which is mostly caused by the involvement of the coronary arteries in conditions that are not treated or diagnosed promptly.[1] Classic KD is characterised by constant fever and a set of clinical signs characterised by conjunctival injection, mucocutaneous rash, and cervical lymphadenopathy.[1,2] A partial form of KD, in which only some of the classical criteria are present, can delay diagnosis and increase the risk of developing coronary abnormalities.[1,3] Following the outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, a new hyperinflammatory syndrome, referred to as multisystem inflammatory syndrome in children (MIS-C), was defined. The onset of MIS-C is similar to that of SARS-CoV-2 infection, occurring several weeks later, and has similar clinical manifestations to KD, such as fever, mucocutaneous involvement, gastrointestinal symptoms, and elevated inflammatory markers.[4,5] It isn't easy to distinguish MIS-C from KD because of this overlap in phenotypes. Still, epidemiologic and immunologic surveillance suggest that MIS-C is triggered by prior SARS-CoV-2 infection and may be age-specific, milder, and differ in organ involvement from classic KD.[5,6]

Numerous observational studies demonstrated an upsurge in Kawasaki-like presentations and incomplete KD phenotypes in the presence of SARS-CoV-2 seropositivity, with a significant percentage of children showing serological evidence of prior infection despite negative polymerase chain reaction results on presentation.[7] The findings are enough to indicate that there is a temporal connection between previous exposure to SARS-CoV-2 and the development of KD-like inflammatory

Address for correspondence: Dr. Chirag S. Soni, Senior Resident, Department of Paediatrics, Ananya College of Medicine and Research, Kalol, Gujarat, India
E-mail: cssoni309@gmail.com

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syndromes in children, which may have consequences on the outcome of the coronary artery. It is imperative to study the clinical and laboratory features of coronary artery expansion within the context of reducing diagnostic and treatment approaches.

Materials and Methods

Setting and duration of the study: This research was conducted at the Department of Paediatrics, Fortis Escorts Hospital, Jaipur. The study period was 24 months, from November 2022 to December 2024.

Study design: An institution-based, retrospective, analytic observational study was conducted. The review of patient records was done to estimate clinical characteristics and outcomes in eligible children.

Study population: The study population included children aged 6 months to 5 years who were either admitted to the PICU or assessed in the OPD. Potential candidates were eligible if they had been diagnosed with incomplete or atypical Kawasaki disease and tested positive for SARS-CoV-2 antibodies.

Inclusion criteria: Children included in the study needed to meet the following exclusion criteria:

- Age between 6 months and 5 years.
- Referral to PICU or the outpatient department of the children's medical department.
- Incomplete or atypical Kawasaki disease clinical diagnosis.
- Serological proof of previous SARS-CoV-2 infection (COVID-19 positive-antibody).
- KD-like type of clinical presentation and a normal baseline two-dimensional echocardiography (2D-ECHO) investigation.

Exclusion criteria: The children excluded from the study were the following:

- Infants under the age of 6 months old and children over age five with the diagnosis of multisystem inflammatory syndrome in children (MIS-C) and SARS-CoV-2 positivity.
- Children who were known to have conditions other than COVID-19 antibody-associated illness.

Sampling method: A consecutive sampling method was adopted. All cases that fit the study period were recruited non-randomly, and the recruitment process was successful, as the cases available during the study period were used.

Data collection process: Medical records of pediatric patients who presented to the OPD with symptoms such as fever, cough, and cold were reviewed after obtaining Institutional Ethics Committee approval. Erythematous rash, bilateral conjunctival congestion, mucocutaneous changes, and changes in the oral cavity commonly accompanied those. Besides this, other children showed gastrointestinal manifestations such as abdominal pain, vomiting and diarrhoea.

A preliminary assessment was conducted on children whose clinical manifestation was indicative of Kawasaki disease. Patients whose characteristics did not match those of Kawasaki disease were filtered out at this stage. Suspected incidences were recommended to have 2D-ECHO to determine cardiac involvement. All children who had no signs of cardiac abnormalities on echocardiography were no longer analysed. When the echocardiogram results showed a pathological alteration, COVID-19 antibody testing was performed. Children whose SARS-CoV-2 antibody results were negative were excluded from the final analysis. In contrast, those with positive antibody results underwent further investigation to determine whether Kawasaki disease-like illness was associated with prior COVID-19 infection.

Outcome variable: The primary outcome observed in the study was coronary artery dilation among participants recruited to the study.

Sample size estimation: A formula used to determine sample size in case-control studies was applied to calculate the sample size.

$$(r+1)\, p*(1-p*)(Z\beta+Z\alpha/2)2$$
$$n = r(p1-p2)2$$

In which r is the ratio of controls to cases (we assume r = 1), p 8 is the mean proportion exposed, Z 8 is the standard normal deviate for 80 per cent power (0.84), and Z 2.5 is the standard normal deviate to get the 5 per cent level of significance (1.96). It estimated the expected effect size (p1-p2) to be 0.3, which is a medium effect size, consistent with previous evidence. Under this method, a calculated sample size of 220 cases was used. Nonetheless, any eligible child who came to Fortis Escorts Hospital during the study period was included, which meant the analysis sample could be close to 250 cases.

Data management and statistical analysis: Data collected was confirmed as complete and internally consistent, then entered into a Microsoft Excel spreadsheet. The Statistical Package for the Social Sciences (IBM SPSS, version 22) was used to conduct statistical analysis. The data were summarised using descriptive statistics. Categorical variables were presented as frequencies and proportions. The continuous variables were presented as mean ± s.d. Student t-test and analysis of variance (ANOVA) were applied to inferentially analyse continuous variables, and the Chi-square test and Cochran Q test were applied to inferentially analyse continuous and categorical variables, respectively. A p-value below 0.05 was deemed significant.

Ethical considerations: The study analysis was pre-reviewed and approved in accordance with the Institutional Ethics Committee requirements of the study institution. The caregivers of the participants were informed in their local language about the purpose of the study, their rights, and that participation was voluntary. The study guaranteed patient information confidentiality. The collected data were de-identified and stored in a password-protected database accessible only by the research team.

Results

The number of children aged 6 months to 5 years included in the analysis was 250. The age group that had the highest number of participants was the age of 4 5 years (36.4%), next there was the age of 3 4 years (22.0%). Newborns below the age of one year made up 11.6% of the research subjects. There

were more male children (74.0 per cent) than female children (26.0 per cent). The average weight of the sample was 16.41g -3.8 kg, and the average height was 94.8g -12.7 cm [Table 1].

It was observed that all enrolled children had fever (100%). The most common related clinical presentation was non-purulent conjunctivitis, observed in 91.6% of participants, followed by mucocutaneous changes, observed in 69.6%. Gastrointestinal: gastrointestinal manifestations were prevalent, with 59.2 per cent reporting abdominal pain, 16.8 per cent reporting diarrhoea, and 16.0 per cent reporting vomiting. The cervical lymphadenopathy was reported to be present in 26.4% participants, and erythematous rash was identified in almost half (49.6%) of the reported participants. The average body temperature at admission was 101.8 °C. The average heart rate was 107.6 with a standard deviation of 5.9 beats per minute, and the mean respiratory rate was 28.5 with a standard deviation of 9.3 per minute. There were no significant changes in oxygen saturation levels, and the mean SpO2 was 97.2 ± 3.2% [Table 2].

Admission laboratory assessment indicated a mean red blood cell haemoglobin level of 13.1 /3.2 g/dl. There was an increased average total number of leukocytes (17.3 +3.5 x 10 -1/cc), platelet counts of 1.8 + 1.1 lakh/cc, mean C-reactive protein of 68.8 + 12.4 mg/L, and ferritin of 1521.2 + 423.2 ng/mL. The presence of coagulation was indicated by an increase in D-dimer, with an average of 1684.3 dynamics/128.4 ng/mL. Renal function parameters did not exceed adequate levels, and the mean serum creatinine was 0.6 ± 0.2 mg/dL [Table 3].

The echocardiographic analysis of the two-chamber views showed that coronary artery dilatation was present in 76 children, representing 30.4 per cent of the study population. The remaining 174 children (69.6%) did not exhibit any signs of coronary artery dilatation [Table 4].

The markers of inflammation and coagulation were much greater in the dilatation group. Mean leukocyte count was also significantly higher in children with dilatation of the coronary artery (19.3±4.1 10 3/cc) than in those without (16.2±6.2 10 3/cc; p = 0.041). On the same note, the mean C-reactive protein, ferritin, and D-dimer levels were significantly elevated in children with coronary involvement (All < 0.001). These results demonstrate a positive association between the intensity of the inflammatory reaction and the presence of coronary artery expansion [Table 5].

Table 1: Demographic and Anthropometric Characteristics of the Study Participants

Variable	n	%
Age group (years)		
< 1 year	29	11.60%
1–2 years	35	14.00%
2–3 years	40	16.00%
3–4 years	55	22.00%
4–5 years	91	36.40%
Sex		
Female	65	26.00%
Male	185	74.00%
Anthropometry	mean ± SD	
Weight (kg)	16.4 ± 3.8	
Height (cm)	94.8 ± 12.7	

Table 2: Presenting Symptoms and vitals of Study Participants at Admission

Variable	n	%
Presenting symptoms		
Fever	250	100%
Non-purulent conjunctivitis	229	91.60%
Mucocutaneous changes	174	69.60%
Abdominal pain	148	59.20%
Erythematous rash	124	49.60%
Cervical lymphadenopathy	66	26.40%
Diarrhoea	42	16.80%
Vomiting	40	16.00%
Vitals at admission	mean ± SD	
Temperature (°F)	101.8 ± 2.4	
Heart rate (/min)	107.6 ± 5.9	
Respiratory rate (/min)	28.5 ± 9.3	
SpO_2 (%)	97.2 ± 3.2	

Table 3: Hematological and Inflammatory Parameters of Study Participants at Admission

Parameter	Mean ± SD
Hemoglobin (g/dL)	13.1 ± 3.2
Total leukocyte count (×10^3/cc)	17.3 ± 3.5
Platelet count (lakh/cc)	1.8 ± 1.1
C-reactive protein (mg/L)	68.8 ± 12.4
Serum creatinine (mg/dL)	0.6 ± 0.2

Ferritin (ng/mL)	1521.2 ± 423.2
D-dimer (ng/mL)	1684.3 ± 128.4

Table 4: Coronary Artery Status of Study Participants on 2D Echocardiography

Coronary artery status	n	%
Dilated	76	30.4%
Non-dilated	174	69.6%
Total	250	100%

Table 5: Factors Associated with Coronary Artery Dilatation among Study Participants

Factor	Dilatation Present (n = 76)	Dilatation Absent (n = 174)	p-value
Age (months)	24.3 ± 8.2	26.1 ± 7.9	0.722
Weight (kg)	12.8 ± 3.1	14.4 ± 3.1	<0.001*
Height (cm)	93.8 ± 13.3	95.3 ± 12.4	0.431
Male sex, n (%)	52 (68.4)	133 (76.4)	0.521
Hemoglobin (g/dL)	12.8 ± 2.6	13.2 ± 3.2	0.265
Total leukocyte count (×10³/cc)	19.3 ± 4.1	16.2 ± 6.2	0.041*
Platelet count (lakh/cc)	1.7 ± 0.8	1.8 ± 0.9	0.441
C-reactive protein (mg/L)	71.2 ± 14.1	64.6 ± 8.4	<0.001*
Serum creatinine (mg/dL)	0.8 ± 0.4	0.6 ± 0.3	0.766
Ferritin (ng/mL)	1633.2 ± 382.8	1494.3 ± 421.3	<0.001*
D-dimer (ng/mL)	1833.2 ± 118.1	1563.2 ± 281.2	<0.001*

Discussion

In the retrospective study, almost a third of children who had incomplete Kawasaki disease-like disease and had positive SARS-CoV-2 antibody outcomes showed coronary artery dilation in echocardiography. This observation does not differ from multisystem inflammatory syndrome in children (MIS-C), where a high percentage also have coronary anomalies in the acute phase of the disease. CAD was detected in about 33% of MIS-C patients at presentation in a multicenter cohort of children in Vietnam, and most abnormalities resolved within 3 months of follow-up, indicating the dynamic nature of inflammatory coronary involvement in SARS-CoV-2-related pediatric hyperinflammation.[8,9]

We found strong correlations between coronary artery dilatation and elevated levels of inflammatory markers, such as total leukocyte count, C-reactive protein, ferritin, and D-dimer, and reduced body weight. Such trends in the laboratory reflect the hyperinflammatory phenotype reported in pediatric inflammatory syndromes associated with SARS-CoV-2. Comparative studies of KD vs. MIS-C cases have revealed that MIS-C patients often have significantly elevated levels of inflammatory biomarkers, such as ferritin and D-dimer, compared with classic KD, suggesting an extended hyperinflammatory environment contributing to vascular and cardiac pathophysiology,.[10]

There are significant clinical implications of the correlation of inflammatory burden and coronary involvement. Higher levels of inflammatory biomarkers were associated with worse cardiovascular sequelae of SARS-CoV-2-related conditions, and early identification and intervention are required to mitigate adverse consequences. In one of the studies, it was confirmed that coronary artery dilation and aneurysms are frequent in MIS-C cohorts and that the inflammatory markers are associated with these cardiovascular phenomena.[11] These support the applicability of thorough inflammatory profiling of pediatric patients with KD-like or MIS-C manifestations.

The incomplete KD and KD-like forms are epidemiologically on the rise in the post-COVID-19 period, which might indicate SARS-CoV-2 as a cause of uncontrolled immunogenic reactions in genetically predisposed children.[12] The results of a multicenter UAE study showed that the post-pandemic prevalence of incomplete KD cases was higher, contributing to changes in patterns of inflammatory diseases in children.[13] Even though distinguishing between incomplete KD and MIS-C is difficult due to similar clinical presentations, identifying these phenotypes remains necessary to promote tailored cardiac outcomes and treatment.

Conclusion

This cross-sectional observational cohort study shows that a significant percentage of children with incomplete or atypical Kawasaki disease-like illness, who had evidence of (or had previously) SARS-CoV-2 infection on echocardiographic findings, were found to have coronary artery dilatation. These results suggest the importance of increased clinical vigilance and cardiovascular evaluation of SARS-CoV-2 antibody-positive individuals with Kawasaki disease-like manifestations, despite no apparent hemodynamic damage at the time of admission. Regular echocardiographic screening and intensive surveillance of inflammatory indices can support the desired timely diagnosis of children at increased risk of coronary artery involvement. Prospective multicenter research is also justified to demystify the underlying pathophysiological processes further and to establish optimal surveillance and management strategies for this subgroup of pediatric patients.

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Conflicts of interest

There are no conflicts of interest.

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