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Audit of compliance with Kawasaki disease diagnostic criteria and timely administration of IVIG

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Abstract

Background: Kawasaki disease (KD) is an acute pediatric vasculitis and a leading cause of acquired heart disease in children. **Objective:** To assess compliance with Kawasaki disease diagnostic criteria and timely administration of IVIG in a tertiary care hospital.**Methods:** This retrospective clinical audit included 75 pediatric patients diagnosed with Kawasaki disease at Tertiary Care Hospital, Faisalabad from October 2024 to June 2025. Audit standards were based on American Heart Association guidelines. Data were collected using a structured proforma and included documentation of fever duration, principal clinical criteria, evaluation of incomplete KD, laboratory investigations, echocardiography, IVIG dosing, and timing of administration. **Results:** The mean age was 3.8 ± 2.1 years, with 61.3% of patients under five years and 61.3% male. Fever duration ≥5 days was documented in 90.7% of cases, while complete documentation of all five principal criteria was achieved in 72.0%. Incomplete KD accounted for 28.0% of cases, with appropriate evaluation documented in 81.0%. Baseline laboratory investigations and echocardiography were performed in 96.0% and 93.3% of patients, respectively. Coronary artery abnormalities were identified in 12.0% of cases. IVIG was administered in 97.3% of patients, with correct dosing

in 94.7%. **Conclusion:** Compliance with IVIG administration standards was generally high; however, gaps were identified in documenting diagnostic criteria and in timely treatment.

Introduction

Kawasaki disease (KD) is an acute, self-limiting systemic vasculitis that mainly focuses on medium-sized arteries, especially the coronary arteries, and mainly in children below five years of age [1]. KD has become the leading cause of acquired heart disease in children in the developed world and is gaining prominence in the developing world since it was first described in 1967 [2]. The etiology is still not well understood, but existing evidence indicates an abnormal immune response to either infectious or environmental antigens in genetically predisposed individuals. Inflammatory cascade causes endothelial injury of the vessels, and it can cause coronary dilation of arteries, aneurysm development, thrombosis, and ultimately long-term ischemic heart disease unless it can be well managed [3]. Clinically, Kawasaki disease is typified by nonpurulent conjunctival injection on both sides coupled with high-grade fever that lasts at least 5 days, plus a complex of major manifestations, such as bilateral conjunctival injection, polymorphous erythema, and fissure of the lips or strawberry tongue, alteration of the extremity (e.g., edema or desquamation), and lymphadenopathy of the cervix. Nevertheless, the range of the disease is wide [4]. Undifferentiated or incomplete Kawasaki disease- patients failing to meet the entire clinical criteria are also becoming common, with increasing instances being reported, particularly in children under six months of age and in older children. These cases are highly difficult to diagnose and are linked with the increased risk of coronary complications because of the delay in recognition and treatment [5].

The American Heart Association (AHA) has developed a set of standardized diagnostic criteria and management algorithms to assist clinicians in identifying and treating at an early stage. To be diagnosed with classic KD, one must have at least 5 days of fever and 4 of the 5 primary clinical features [6]. In suspected unresolved cases, positive laboratory results include elevated inflammatory markers, anemia, hypoalbuminemia, thrombocytosis, and echocardiographic abnormalities. These requirements should be strictly followed to reduce diagnostic ambiguity and ensure early treatment initiation [7]. Combined with aspirin, intravenous immunoglobulin (IVIG, 2 g/kg, single dose) has become the most important treatment. IVIG used in the first 10 days of illness, preferably in the first 7 days, can greatly reduce the risk of having an aneurysm at the coronary aneurysm, from about 20-25% in untreated patients to less than 5% with this treatment [8]. The time of IVIG administration can thus be viewed as an important outcome determinant and an indicator of the quality of care. Late treatment has been linked to ongoing inflammation, augmented IVIG opposition, and a higher risk of abnormalities of the coronary artery [9].

The diagnostic criteria of KD should also include a 5-day-long fever, followed by changes in the oral mucosa, bilateral non-exudative conjunctivitis, polymorphous rash, cervical lymphadenopathy, erythema, and oedema, and then desquamation of the extremities [10]. Classic or complete KD may be diagnosed when a person has a minimum of 4 days of fever and at least 4 of the 5 following clinical presentations [11]. Nevertheless, because this criterion cannot detect all children with KD, the diagnosis of incomplete KD must be considered in children with unexplained prolonged fever and some major clinical features of the disease [12]. Incomplete KD is a diagnosis that is difficult to arrive at, particularly since fever is a common manifestation of children being brought into the hospital. Infants less than 6 months with no conjunctivitis or mucosal alterations are at a higher risk of not being detected early enough, 15-20 percent of patients who do not fit the laboratory criteria of full KD still show aneurysms, and hence urgent treatment and echocardiogram observation are crucial in this population [13].

Objective

To assess compliance with Kawasaki disease diagnostic criteria and timely administration of IVIG in a tertiary care hospital.

Methodology

This was a retrospective clinical audit conducted at Tertiary Care Hospital, Faisalabad from October 2024 to June 2025. A total of 75 pediatric patients diagnosed with Kawasaki disease during the audit period were included.

Audit Standards

Audit standards were predetermined before data collection based on recommendations of AHA. These criteria involved the appropriate documentation of a five or more days fever, documentation of the five key clinical criteria (bilateral non-exudative conjunctivitis, oral mucosal changes, polymorphous rash, extremity changes and cervical lymphadenopathy), appropriate assessment of incomplete Kawasaki disease where a full criteria was not met, providing baseline laboratory investigation and echocardiography, administration of IVIG at a recommended dose of 2 g/kg and administration of IVIG within 10 days of the onset of fever. All children younger than 16 years alive in the included study and with a clinical diagnosis of Kawasaki disease in the study period were available to participate in the audit. Complete and incomplete cases of Kawasaki disease were analyzed. Other confirmed patients with alternative diagnoses or incomplete medical records were not included to have the proper assessment of compliance.

Data Collection

It was a retrospective study based on electronic medical records and inpatient case files using a structured audit pro forma. The information that was extracted comprised demographic data like age and gender, the length of time one was experiencing the fever, the recording of the main clinical characteristics, lab parameters like CRP, ESR, platelets count, hemoglobin, liver tests and echocardiographic results, admission date, confirmed diagnosis date, the date of IVIG administration, and the total dose stipulated on IVIG administration. The time intervals were estimated to determine delays, such as the time of the emergence of fever to hospital admission, the time of admission to the diagnosis, and the time of the emergence of fever to IVIG administration. The key outcome measures were the percentage of patients meeting the full diagnostic criteria, the percentage of incomplete cases well assessed based on the guidelines, the percentage of patients who receive IVIG within 10 days after falling ill, and the proportion of patients who received the correct dose of IVIG, 2g/kg. The completeness of documentation and echocardiographic findings of coronary abnormalities were also secondary outcomes.

Data Analysis

Data were entered into SPSS version 26.0 for statistical analysis. Categorical variables were summarized as frequencies and percentages, while continuous variables were expressed as mean ± standard deviation. Compliance rates for each audit standard were calculated and compared with predefined benchmarks to identify gaps in adherence to recommended practice.

Results

Data were collected from 75 patients; overall mean age was 3.8 ± 2.1 years. A majority of patients (61.3%) were younger than five years, with a mean age of 3.1 ± 1.4 years within this subgroup, while 38.7% were aged five years or older with a mean age of 5.2 ± 1.8 years. There

was a clear male predominance, with males accounting for 61.3% of cases and females comprising 38.7%.

Table 1: Demographic Characteristics of Patients (N = 75)

Variable	Category	n (%)	Mean ± SD
Age (years)	Overall	75 (100%)	3.8 ± 2.1
Age Group	<5 years	46 (61.3%)	3.1 ± 1.4*
Age Group	≥5 years	29 (38.7%)	5.2 ± 1.8*
Gender	Male	46 (61.3%)	
Gender	Female	29 (38.7%)	

*Mean age within subgroup.

Fever duration of ≥5 days was documented in 90.7% of cases. Complete documentation of all five principal diagnostic criteria was achieved in 72.0% of patients. Among individual clinical features, oral mucosal changes were most frequently recorded (88.0%), followed by bilateral conjunctivitis (84.0%) and polymorphous rash (77.3%). Extremity changes (69.3%) and cervical lymphadenopathy (65.3%) were less consistently documented.

Table 2: Compliance with Diagnostic Criteria Documentation (N = 75)

Parameter	Standard Required	Achieved n (%)
Fever ≥5 days documented	100%	68 (90.7%)
Documentation of all five principal criteria	100%	54 (72.0%)
Bilateral conjunctivitis recorded	100%	63 (84.0%)
Oral mucosal changes recorded	100%	66 (88.0%)
Polymorphous rash recorded	100%	58 (77.3%)
Extremity changes recorded	100%	52 (69.3%)
Cervical lymphadenopathy recorded	100%	49 (65.3%)
Incomplete KD appropriately evaluated (n=21)	100%	17 (81.0%)

Baseline laboratory investigations were performed in 96.0% of patients, and echocardiography at diagnosis was completed in 93.3%. Coronary artery abnormalities were detected in 12.0% of patients, including coronary artery dilatation in 8.0% and small coronary aneurysms in 4.0%.

Table 3: Investigations and Echocardiographic Assessment (N = 75)

Parameter	Standard Required	Achieved n (%)
Baseline laboratory investigations performed	100%	72 (96.0%)
Echocardiography at diagnosis	100%	70 (93.3%)
Coronary artery abnormalities detected	—	9 (12.0%)
Coronary artery dilatation	—	6 (8.0%)
Small coronary aneurysm	—	3 (4.0%)

IVIG was administered in 97.3% of patients, with correct dosing (2 g/kg) achieved in 94.7%. Timely administration within 10 days of fever onset was observed in 85.3% of cases, which did not meet the predefined target of ≥90%. Delayed IVIG beyond 10 days occurred in 12.0% of patients. The mean duration from fever onset to IVIG administration was 7.2 ± 2.8 days, while the mean time from hospital admission to confirmed diagnosis was 1.6 ± 0.9 days.

Table 4: IVIG Administration and Timeliness (N = 75)

Parameter	Target Standard	Achieved n (%)/Mean ± SD
IVIG administered	100%	73 (97.3%)
Correct IVIG dose (2 g/kg)	100%	71 (94.7%)
IVIG within 10 days of fever onset	≥90%	64 (85.3%)
Delayed IVIG (>10 days)	0%	9 (12.0%)
Fever onset to IVIG (days)	≤10 days	7.2 ± 2.8
Admission to diagnosis (days)	≤2 days	1.6 ± 0.9

The largest compliance gap was observed in complete documentation of all five principal diagnostic criteria (28.0% gap), followed by evaluation of incomplete cases (19.0% gap). Smaller gaps were noted in documentation of fever duration (9.3%), echocardiography performance (6.7%), correct IVIG dosing (5.3%), laboratory investigations (4.0%), and IVIG administration within 10 days (4.7% below the 90% target). IVIG administration itself demonstrated high compliance, with only a 2.7% gap from the ideal standard.

Table 5: Overall Audit Compliance Summary Against Predefined Standards (N = 75)

Audit Standard	Target Compliance	Achieved n (%)	Gap (%)
Fever ≥5 days documented	100%	68 (90.7%)	9.3%
Documentation of all five principal criteria	100%	54 (72.0%)	28.0%
Appropriate evaluation of incomplete KD (n=21)	100%	17 (81.0%)	19.0%
Baseline laboratory investigations performed	100%	72 (96.0%)	4.0%
Echocardiography at diagnosis	100%	70 (93.3%)	6.7%
IVIG administered	100%	73 (97.3%)	2.7%
Correct IVIG dose (2 g/kg)	100%	71 (94.7%)	5.3%
IVIG within 10 days of fever onset	≥90%	64 (85.3%)	4.7% below target

Discussion

The present clinical audit assessed adherence to the diagnostic criteria for Kawasaki disease (KD) and the promptness of intravenous immunoglobulin (IVIG) administration in a sample of 75 pediatric patients. In general, the results indicate high compliance with treatment standards; however, deficiencies in documentation of diagnostic criteria and in timely IVIG administration were identified. The proportion of patients older than five years (61.3 percent) and being of the male gender (61.3 percent) were also in line with the established epidemiological trend of the Kawasaki disease. A similar study has been documented in the past among children below 5 years, with a male-to-female ratio of 1.5:1 to 1.7:1; hence, the representativeness of our sample. Data on fever duration <5 days achieved 90.7%, which, while satisfying, fell short of the optimal 100%. Only 72.0 per cent of patients were fully documented on all five major clinical criteria, suggesting a 28 per cent drop in documentation. The least consistently reported ones were extremity changes (69.3%), and cervical lymphadenopathy (65.3%). This is indicative of a universal problem in clinical practice in which some signs might be underperceived or under documented [14]. Past studies have also shown that incomplete documentation, rather than the absence of clinical signs, usually leads to

diagnostic uncertainty and delayed intervention. Kawasaki disease was found to have incomplete Kawasaki disease in 28.0 percent of the patients, which is also in line with the global trend of greater awareness in atypical presentations [15]. On a positive note, 81.0 percent of cases that were not fully assessed were assessed properly per the guideline. Nonetheless, approximately a fifth of incomplete cases did not receive a complete supportive assessment, which is a potentially significant clinical gap, since incomplete KD is more likely to produce coronary complications [16].

Baseline laboratory studies and echocardiography were performed in 96.0% and 93.3% of patients, respectively, which is highly consistent with the investigation's standards. Abnormalities of the coronary arteries were observed in 12.0% of the patients, with 8.0% having coronary dilatation and 4.0% having small aneurysms. This is a bit higher than the rate, which should be around 5 percent with optimal early treatment, suggesting that delays in diagnosis or treatment may have contributed in some cases [17]. Past studies have always revealed that the failure to administer IVIG in a timely manner has a high probability of leading to involvement of the coronary arteries [18]. There was high compliance with therapeutic guidelines: 97.3% of patients received IVIG, and 94.7% received the appropriate dose of 2 g/kg. Nonetheless, it was provided on time (within 10 days of the onset of fever) in 85.3% of cases, which is below the predetermined >90% threshold. Late IVIG was observed in 12.0% of patients, mainly due to late presentation or initial misdiagnosis, rather than delayed hospital administration [19]. The average time from post-onset fever to IVIG administration was 7.2±2.8 days, within the recommended treatment period, but this highlights the fluctuating timing. Past studies have proven that even a lateness of 10 days or more of treatment is linked to elevated IVIG resistance and cardiac problems [20].

Limitations

This audit is limited in several ways. First, it was a retrospective review of medical records, and thus relied on the accuracy and completeness of the recordings. Certain clinical displays might have been missed and not documented which could have underestimated actual adherence to diagnostic criteria. Second, the study was done in only one center and using a relatively small sample size of only 75 patients, thus, making it difficult to extend the findings to other centers or healthcare settings. Third, the measures of the processes (documentation and time of IVIG) and not the final long-term clinical outcomes, including progression or regression of coronary abnormalities, were audited.

Conclusion

It is concluded that overall compliance with established Kawasaki disease diagnostic criteria and IVIG administration standards was satisfactory; however, important gaps were identified in the complete documentation of clinical criteria and the timely administration of IVIG within the recommended 10-day window. While in-hospital diagnosis and treatment were generally prompt, delays were primarily related to incomplete documentation and late presentation.

Re-Audit Plan

Re-audit 6-12 months following implementation of corrective measures should be undertaken to review the progress in adhering to Kawasaki disease criteria of diagnosis and the use of IVIG in a timely manner. Similar audit standards, methodology, and data-collection pro forma would be applicable to ensure consistency and enable direct comparison with the baseline results. Cases of Kawasaki disease diagnosed new during the re-audit period are to be included. According to the gaps that have been identified, the following interventions must be in place before re-audit: provision of a standardized Kawasaki disease clinical checklist in admission

files, integration of an electronic documentation template to guarantee the capture of all five major criteria, reaffirmation of the AHA diagnostic algorithms by the departmental teaching sessions and development of a protocol that underlines the administration of IVIG within the 10 days of the onset of fever. Early cardiology referrals and compulsory baseline echocardiography within 24 hrs of diagnosis should also be promoted.

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