# System spectrum analysis and six-month outcome of patients with paediatric inflammatory multisystem syndrome temporarily associated with severe acute respiratory syndrome coronavirus-2 at a tertiary hospital in eastern India

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**Abstract**

***Background:*** Whilst there are plenty of studies on patients with paediatric inflammatory multisystem syndrome temporarily associated with severe acute respiratory syndrome coronavirus-2 (PIMS-TS), there is a scarcity of studies worldwide regarding follow up of these patients.

***Objectives:*** To assess the clinical, laboratory and imaging data and outcome of patients with PIMS-TS in the 6-month follow-up.

***Method:*** A retrospective cohort study was conducted in the Department of Paediatrics, Vivekananda Institute of Medical Sciences, Ramakrishna Mission, Seva Pratisthan, Kolkata, India on all children under 12 years of age admitted from 1st March to 31st August 2021 with World Health Organisation criteria of PIMS-TS.

***Main outcome measures:*** Clinical features of different systems, routine laboratory investigations, liver and renal function tests, acute phase reactants, cardiac markers like NT-proBNP, urine analysis, echocardiogram, ultrasonography of abdomen and magnetic resonance imaging of brain.

***Results:*** Twenty-one patients (13 male, 8 female) were included in this study. Median age of presentation was 3 years; 3 patients had pre-existing comorbidities; all patients had elevated inflammatory markers at baseline; 14 patients had significant findings on echocardiography on admission; all patients were discharged in stable condition. At the 6-month follow-up, 2 patients had raised C-reactive protein; significant dilatation of coronary artery persisted in 2 patients; gastrointestinal symptoms, respiratory symptoms, cutaneous manifestations and neurological features resolved in all patients.

***Conclusions:*** Though many patients had very serious presentations, most of them were completely free clinically, laboratory-wise and imaging-wise by 6 months.

(Key words: MIS-C, PIMS-TS)

## Introduction

Following the spread of the coronavirus disease-2019 (Covid-19) pandemic a new disease entity emerged, termed paediatric inflammatory multisystem syndrome temporarily associated with Covid-19 (PIMS-TS) or multisystem inflammatory syndrome in children (MIS-C)[1]. UK National Health Service first alerted the world regarding the multisystem involvement of children following Covid-19 infection in April 2020[2]. Since then, the World Health Organisation (WHO), Royal College of Paediatrics and Child Health, US Centres for Disease Prevention and Control have all produced several definitions for this multisystem inflammatory disorder following Covid-19 pandemic[3,4,5].

Children with PIMS-TS typically have a history of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) infection in the weeks before presentation[6,7]. Clinical manifestations include fever, cardiac manifestations, gastrointestinal symptoms, polymorphous rashes, conjunctivitis and respiratory failure[6,7,8]. Children with PIMS-TS often look like children with Kawasaki disease or toxic shock syndrome[9]. Many look very unwell and need admission to the paediatric intensive care unit[6,7]. Initial investigations revealed evidence of hyperinflammation with C-reactive protein (CRP) levels greater than 100mg/L as well as elevated erythrocyte sedimentation rate (ESR), hypertriglyceridaemia, hyponatraemia, and elevated serum ferritin and D-dimer[6,7,8]. Although the acute phase of PIMS-TS has been characterised, the short-term, medium-term and long-term effects remain unclear[7,10].

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## Method

A cohort study was conducted at Ramakrishna Mission Seva Protistan (Vivekananda Institute of Medical Sciences) Kolkata from 1st March 2021 to 31st August 2021.

Though we collected data of patients during the study period, we were unable to get ethical clearance before commencing the study because the Institutional Ethics Committee (IEC) did not meet during the Covid-19 epidemic. The IEC started meeting only from the end of 2021 and hence we were able to get ethical clearance for the study only retrospectively in February 2022.

***Setting:*** Ramakrishna Mission Seva Pratishthan is a Private hospital in Kolkata City of Eastern India with 650 beds. On an average 150 patients attend paediatric outpatient department (OPD).

***Inclusion criteria:*** Patients aged 12 years or younger fulfilling the preliminary case definition of PIMS-TS by WHO and admitted in the hospital.

***Exclusion Criteria:*** Patients who did not attend clinic for follow up 6 months after discharge.

***Data collection and analysis:*** The PIMS-TS patients who were admitted were prospectively examined by multiple specialities in a PIMS-TS multidisciplinary outpatient clinic that had been set up in November, 2020. Patients were examined by the multidisciplinary team at 6 months after discharge from hospital. Clinical records were evaluated retrospectively by 2 investigators who had collected hospital admission and 6 months follow-up data. Recent SARS-CoV-2 infection was established by reverse transcription polymerase chain reaction (RT–PCR) of nasopharyngeal sample, serology positivity, a clear epidemiologically established link to an infected contact or a combination of the above. Serology testing checked IgG antibodies to the SARS–CoV-2 spike protein. Follow up serological assay was done on IgG antibodies against the SARS- CoV-2 spike protein. Treatment was done according to the WHO protocol.

All echocardiogram reports were evaluated by qualified paediatric cardiologists (as per qualification criteria of National Medical Council, India). Coronary artery diameters were measured as per standard guideline[11] and indexed with Z scores[12]. Coronary Z scores more than 2.5 were considered as dilated[11]. Abdominal ultrasound examination was done to rule out various abnormal features found in PIMS-TS that were reported earlier like ascites, bowel wall thickening, mesenteric inflammation.

***Outcomes:*** Various outcomes were assessed at the 6-month follow-up after discharge from hospital. PedsQL 4.0 Generic Core Scales were used to measure physical functioning, social functioning, emotional functioning, and school functioning. Higher scores indicated better HRQOL. Number of items in physical, social, emotional, and school functioning was 8, 5, 5 and 3 respectively. Each item was scaled from 0 (never) to 4 (almost always). Scores were converted on a scale from 0 to 100.

*Scoring procedure* –

- Step 1: Transformation score – items were reverse scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0
- Step 2: Calculation of scores
    - *Scores by dimensions*: if missing items in the scale was more than 50%, the scale scores were not added. Mean score = sum of the items over the number of items answered
    - *Psychosocial health summary scores* = sum of the items over the number of items answered in emotional, school and social functioning scales
    - *Physical health summary score* = physical functioning scale scores
    - *Total score* = sum of the items over the number of items answered on all the scales

***Ethical issues:*** The study was approved and ethical clearance retrospectively given by the Institutional Ethics Committee of Ramakrishna Mission Seva Pratishthan Vivekananda Institute of Medical Sciences, Kolkata on 19th February 2022. The ethics committee also approved waiver of consent since patients' identities were not disclosed.

***Statistical analysis***: We used descriptive statistics to summarise key clinical, radiological and laboratory features. We used non-parametric statistical tests (Mann-Whitney U test) for continuous distributions (age, laboratory investigations, inotropic support, mechanical ventilation duration and hospital stay duration). We used Chi squared test or Fisher's exact test for nominal data (sex, serology positivity SARS-CoV-2 PCR), proportion of patients with hypertension, proteinuria, echocardiogram, abdominal imaging, ventilation and inotrope requirement, treatment with methylprednisolone, IV immunoglobulin or tocilizumab. Comparison was made among patients 5 years and younger versus those older than 5 years.

## Results

This study included 30 patients. At presentation, mean age was 4.3 years, median age 3 years (IQR 6 - 2 = 4 years); 18 patients were male and 12 were female. Patients' demographic characteristics, clinical features and treatment are shown in Table 1.

Systemic symptoms in individual patients are shown in Table 2.

**Table 1:** ***Baseline demographic characteristics, clinical features and treatment summaries of cohort (n=30)***

| Characteristic | Number |
|---|---|
| *Sex* | |
| Male | 18 |
| Female | 12 |
| *Comorbidities* | 05 |
| SARS-CoV-2 PCR positive at admission | 02 |
| SARS-CoV-2 IgG positive at admission | 27 |
| *Clinical features at presentation* | |
| Fever | 30 |
| Rash | 17 |
| Bilateral non-purulent conjunctivitis | 13 |
| Mucocutaneous signs | 14 |
| Hypotension / shock | 06 |
| Diarrhoea | 09 |
| Vomiting | 13 |
| Pain in abdomen | 10 |
| *Treatment summaries* | |
| Mechanical ventilation | 03 |
| Mean duration of ventilation (days) | 2.6 |
| Inotropic support | 06 |
| Mean duration of inotropic support (days) | 03 |
| Low molecular weight heparin | 03 |
| Total time of admission (days) | 07 |
| *Immunotherapies* | |
| IV methylprednisolone | 30 |
| IV immunoglobulin | 16 |
| Tocilzumab | 01 |
| No immunomodulation | Nil |

*(Source – Case record sheets of patients admitted with MIS-C)*

*Before initial treatment, mean duration of symptoms was 5.9 days, median 6 days (IQR 7 - 5 = 2 days). Rash was commoner as presenting feature in patients 5 years and younger, while pain in abdomen was more common in patients older than 5 years. 4 patients had comorbidities – 2 had asthma, 1 had autism and 1 had both tuberous sclerosis and beta thalassaemia trait.*

**Table 2: Systemic symptoms in individual patients**

| Patient | Fever | No. of days of fever | Rash | B/L non-purulent conjunctivitis | Mucocutaneous inflammation signs | Hypotension or shock | Diarrhoea | Vomiting | Abdominal pain | Neurological symptoms | Respiratory symptoms |
|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | P | 6 | P | P | Oral | | | P | | Drowsy/ irritable | |
| 2 | P | 8 | P | P | Oral | | | | P | Coma/ Convulsion | |
| 3 | P | 10 | P | | | | | | P | Irritable | |
| 4 | P | 4 | P | P | | | | P | | Irritable | P |
| 5 | P | 3 | P | P | Oral | P | | | P | Irritable/ Drowsy | |
| 6 | p | 5 | P | | | | P | p | | Headache | |
| 7 | P | 6 | P | | Oral | P | | | | Irritable | P |
| 8 | P | 7 | P | | Oral | | | P | | | P |
| 9 | P | 5 | P | | Oral | P | | | | Irritable | P |
| 10 | P | 8 | | | | | P | P | | Irritable | |
| 11 | P | 5 | P | | Oral | | P | P | P | | |
| 12 | P | 3 | | | | | P | P | P | | |
| 13 | P | 6 | P | | Oral | | | | | Irritable/ Drowsy | P |
| 14 | P | 8 | | P | Oral | | P | | | | |
| 15 | P | 5 | P | P | | | | P | | Irritable | P |
| 16 | P | 6 | P | P | | | P | | | | P |
| 17 | P | 8 | P | | | P | | | | | |
| 18 | P | 6 | P | | Oral | | | | | | P |
| 19 | P | 6 | | | | | P | P | | | |
| 20 | P | 5 | P | | | | P | | | Convulsion | |
| 21 | P | 4 | P | P | | | P | P | | | |
| 22 | P | 7 | P | | | | | P | | | |
| 23 | P | 4 | | P | | | | | P | Irritable | P |
| 24 | P | 8 | P | | Oral | | | | | Irritable | P |
| 25 | P | 5 | P | P | | P | | | P | Drowsy | |
| 26 | P | 6 | | | Oral | P | | P | | | |
| 27 | P | 7 | P | | Oral | | | P | | | |
| 28 | P | 5 | P | P | Oral | | | | P | | |
| 29 | P | 7 | P | P | | | | | P | | P |
| 30 | P | 6 | P | P | Oral | | | | P | Convulsion | P |

*P = Present*

- ***Number of patients based on the 3 types of PIMS-TS or MIS-C:*** 6 patients had MIS-C with shock or multi-organ dysfunction syndrome (MODS), 10 patients had Kawasaki phenotype and 14 patients had MIS-C without shock.

- During admission, all patients had raised markers of systemic inflammation. ESR, CRP, serum ferritin, aspartate transaminase and alanine transaminase were normal by the 6-month follow-up.

- Two of 30 patients had SARS-CoV-2 PCR test positive on admission and 27 of 30 patients initially tested positive for SARS-CoV-2 IgG serology; one patient was not in these groups but had household contact with Covid-19, thus meeting the WHO diagnostic criteria.

- Among 27 of 30 patients who had positive serology at presentation, seropositivity was seen in 1 patient at the 6-month follow-up. One patient with RT-PCR positive report an admission (among 2) seroconverted at the 6-month follow-up.

- Six of 30 patients presented with hypotension or shock. Nineteen of 30 patients had significant abnormalities on the initial echocardiogram. Six children required inotropic support; 21 of 30 patients had raised troponin and 20 had raised N terminal pro brain natriuretic peptide (NT-pro BNP); by 6 months, systolic function and concentration of troponin and NT-Pro BNP were normal in all patients.

- By 6 months, echocardiograms of 17 of the initially abnormal 19 patients became normal; 2 patients had significant coronary artery dilatation. One patient's coronary artery diameter normalized at the 6-month follow-up and another at 9 months follow-up.

- Out of 10 patients who had significant coronary artery dilatation, left coronary artery was significantly dilated in 6 patients and left anterior descending artery in 4 patients.

- Pericardial effusion was present in 17 patients.

- Sixteen of 30 patients had neurological symptoms at presentation. Symptoms seen were irritability (n=11), drowsiness (n=4), convulsions (n= 3) and headache (n=1). All patients with abnormal neurological symptoms had no symptoms at the 6-month follow-up. Neurological examination was normal in all.

- Renal involvement (raised creatinine, proteinuria, hypoalbuminaemia or a combination of the above) was present in 5 of 30 during hospital course but none required renal replacement therapy. On follow-up at 6 months, none of the patients had any features of renal involvement.

- Gastrointestinal (GI) involvement (diarrhoea, abdominal pain or vomiting) was present in 24 of 30 patients before or during hospital admission; 6 of 10 patients who had abdominal pain imaging during admission had clinically significant abnormalities (oedematous gut loop in 3, hepatomegaly in 3 and splenomegaly in 3). Persistent GI symptoms were present in one patient (abdominal pain) at the 6-month evaluation. All patients with abnormal abdominal imaging on presentation became normal at the 6-month follow-up.

- Evidence of coagulopathy (prothrombin time, partial thromboplastin time, elevated D-Dimer) was present in 26 of 30 patients during the hospital course. None had thrombi. No pulmonary embolism was reported.

- Twelve of 30 patients presented with upper or lower respiratory symptoms or both (cough, pharyngitis, coryza, nasal discharge, nasal obstruction). Before or during hospital course. 3 of 30 patients were given mechanical ventilation. Average duration of ventilation was short (2.6 days).

- Mucus membrane or dermatological involvement (polymorphous rash, bilateral non-purulent conjunctivitis or mucocutaneous inflammation signs in mouth, hands or feet) was present in 21 of 30 before or during hospital course.

- There was gradual improvement of patients in both inflammatory markers and systemic symptoms at the 6-month follow-up. No deaths were reported. None of the patients were re-admitted to hospital.

Out of 21 patients aged 5 years or less, 19 patients' parents participated in PedsQL 4.0 Generic Core

Scale assessment and out of 9 patients aged more than 5 years, 8 patients participated in PedsQL 4.0 Generic Core Scale assessment. PedsQL responses at the 6-month follow-up revealed mild impairment by parental report mostly in emotional and psychosocial scale. No patient was in the severe impairment group (Table 3).

Table 4 compares the PedsQL 4.0 Generic Core Scale assessment of our study with that of a UK study[16].

**Table 3:** ***PedsQL 4.0 Generic Core Scales at 6-month follow-up***

| Report | Physical scale | Emotional scale | Social scale | Scholastic scale | Psychological scale |
|---|---|---|---|---|---|
| *Self-report (n=8) in children aged more than 5 years* | | | | | |
| No | 5 | 7 | 6 | 6 | 7 |
| Mild | 2 | 1 | 1 | 1 | 1 |
| Severe | 1 | 0 | 1 | 0 | 0 |
| No data | 0 | 0 | 0 | 1 | 0 |
| *Parental report (n=19) in children aged 2 to 5 years* | | | | | |
| No | 15 | 14 | 15 | 14 | 14 |
| Mild | 3 | 5 | 3 | 3 | 4 |
| Severe | 1 | 0 | 1 | 1 | 1 |
| No data | 0 | 0 | 0 | 1 | 0 |

**Table 4:** ***PedsQL 4.0 Generic Core Scales – Comparison of our study with the UK study***[16]

| **Self-report – severe impairment** | | | | | | |
|---|---|---|---|---|---|---|
| | **Physical scale** | **Emotional scale** | **Social scale** | **School scale** | **Psychosocial scale** | **Total** |
| *Our study* | 12% | 0 | 12% | 0 | 0 | |
| *UK study*[16] | 8% | 22% | 5% | 8% | 8% | 8% |
| **Parental report – severe Impairment** | | | | | | |
| | **Physical scale** | **Emotional scale** | **Social scale** | **School scale** | **Psychosocial scale** | **Total** |
| *Our study* | 3% | 0 | 3% | 3% | 3% | 3% |
| *UK study*[16] | 13% | 18% | 5% | 11% | 18% | 18% |

**Discussion**

Since PIMS-TS or MIS–C was identified in April 2020 and reported, we were vigilant about diagnosing PIMS-TS or MIS–C. Until March 2021, we diagnosed few patients with PIMS -TS. Over the next 6 months until August 2021, we diagnosed 30 cases with PIMS–TS. In this retrospective study, we reported clinical, laboratory and imaging profile of those 30 patients diagnosed with PIMS–TS within a span of 6 months and their clinical, laboratory and PedsQL (4.0) scoring at the 6-month follow up.

In our study the mean age at presentation was 4.3 years, median age 3 years (IQR 6 - 2 = 4 years). The median age was lower than in other studies from India and elsewhere. A study from South India[13] showed median age as 6 years and it was 7 years in another study from Pune[14]. A study from Great Ormond Street Hospital (GOSH), UK, revealed a median age of 9 years[7]. In our study there were 60% male children. Male predominance (52%) was also observed in a study from Pune[14]. We reported 5 (16.6%) comorbidities. In our study most of the cases showed clinical improvement, their laboratory inflammatory markers became normal and there was no mortality. In the study from Pune[14] there was 1 death among 25 reported children. In another study from south India[13], there were no reported deaths.

In our study, RT-PCR was positive in 2 (6.6%) children and IgG against Covid-19 was positive in 27 (90%) children. In a study from South India[13] RT-PCR was positive in 16.6% children and IgG against Covid-19 was positive in 47%. One child (6%) was positive to both. In study from Pune[14], IgG was positive in 56%. In the Study from GOSH[7] RT-PCR was positive in 26% and IgG was positive in 87%.

All patients presented with fever; this was according to the WHO case definition where fever should be present for at least 3 days. In our study, mean duration of fever was 5.9 days. In a study from Mumbai[15] the mean duration of fever was 5.2 days. In our study, rash was present in 24 (80%) patients, compared to 63% in the South Indian study[13], 68% in the Pune study[14] and 65% in the Mumbai study[15]. In the study from GOSH, London[7], the percentage was 52%.

In our study 6 (20%) patients presented with shock. All 6 patients were managed with fluid resuscitation with 30 ml/kg bolus and all received dopamine. In the studies from Pune[14], South India[13] and Mumbai[15], 84%, 52% and 65% patients had features of shock. In the study from GOSH, London[7], the percentage was 50%. So, in our study the incidence of shock was much less than in other Indian studies. In our study 19 (63.3%) patients had significant abnormalities on echocardiogram after admission. Kawasaki disease like features were present in 10 (33.3%) which was similar to the 28% from Pune[14], 36.8% from South India[11] and 26% from Mumbai[15]. In the study from GOSH, London[7], the percentage was 22.4%.

In our study 10% patients required mechanical ventilation which is less than the 28% in the study from Pune[14]. No patient in the study from South India[13] needed mechanical ventilation. In the study from GOSH, London[7], the percentage was 39.6%. In our study 6 (20%) patients received inotropic support, while 31.5% patients from study in South India[13] and 39% from the study in Mumbai[15] received inotropic support. In the study from GOSH, London[7], the percentage was 50%. These are much less than the 80% from Pune study[14]. In our study 53.3% patients received intravenous (IV) immunoglobulin, compared to 72% in the Pune study[14], 79% in the South Indian study[13] and 65% in the Mumbai study[15]. In our study one patient out of 30 received Tocilzumab compared to one out of 25 in the Pune study[14], one out of 19 in the South India study[13] and 3 out 23 in the Mumbai study[15].

Our study involved more patients than other contemporary studies from India. We found lower median age of patients, more children presenting with skin rash, less incidence of shock, less requirement of inotropic support and IV immunoglobulin. In our study all laboratory parameters normalized at the 6-month follow up. Our study involved PedsQL 4.0 Generic Core Scales at the 6-month follow-up. None of the other Indian studies considered this scale on follow up. We compared our findings with another study in UK[16]. This is shown in Table 4. This table reveals that at 6 months follow up, there was comparatively less incidence of severe impairment.

**Conclusions**

When PIMS–TS presented in children aged less than 5 years, skin rash was more common, there was less incidence of shock, less use of IV immunoglobulin on the 6-month follow-up and clinical and laboratory parameters became normal in most. PedsQL Score was also better at the 6-month follow-up.

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