

# Management of Febrile Infants Under 3 Months of Age with SARS-CoV-2 Infection in the Emergency Department

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## ABSTRACT

**Objective:** Febrile infants with a proven viral infection are at lower risk for a potentially serious bacterial infection (SBI). Our objective is to describe the management of young febrile infants with COVID-19 in the emergency department.

**Methods:** Febrile infants <3 months with a positive PCR (polymerase chain reaction) test for SARS-CoV-2 between March 2020 and October 2022 were included in a cross-sectional study. The indication for complementary tests, hospital admission and antibiotic therapy was analyzed. We performed a global analysis and by age subgroups (<29 d and ≥29 d).

**Results:** A total of 172 patients were included in the study, out of which 32 (18.6%) were <29 days old. Bacterial cultures were performed on 160 patients (93%), with urine cultures being the most frequently requested (151 patients; 87.8%). Overall, 39 infants (22.7%) were hospitalized, and 17 infants (9.9%) received antibiotics. In the subgroup analysis, patients <29 days had performed more frequently urine culture (100 vs. 85%;  $p = 0.015$ ), blood culture (96.9 vs. 43.6%;  $p < 0.001$ ), and cerebrospinal fluid culture (18.8 vs. 1.4%;  $p < 0.001$ ). They also had a higher admission rate (68.8 vs. 12.1%;  $p < 0.001$ ) and antibiotic prescription (21.9 vs. 7.1%;  $p = 0.02$ ). SBI was identified in 10 patients (9 with urinary infections and 1 with bacteremia), while no invasive bacterial infection (IBI) was diagnosed in patients aged ≥29 days.

**Conclusions:** The identification of SARS-CoV-2 led to less aggressive management in a significant number of cases compared with usual practice. The low prevalence of IBI would support its inclusion in the management algorithms for febrile infants, especially in patients aged ≥29 days. The nonnegligible prevalence of urinary infection would make it necessary to maintain its screening.

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## Introduction

Infants under 3 months of age experiencing fever without source (FWS) pose a major challenge in the Emergency Department (ED). Despite the most frequent cause being viral infections, the immaturity of their immune systems means that these patients are at higher risk of having a serious potentially life-threatening bacterial infection (SBI), for which early diagnosis and treatment are of vital importance. Given how difficult it is to distinguish between these two etiologies, adopting a more conservative approach is still the normal practice in this age group, although there is variation between management guidelines, especially in recommendations for children aged 1-3 months.<sup>1</sup>

It is widely described in the literature how febrile infants with confirmed viral infections, especially respiratory infections caused by respiratory syncytial virus (RSV), influenza viruses, etc. are less likely to have an SBI compared to those without a detected viral infection.<sup>2,3</sup> Despite this, the evaluation and management of these patients is highly variable in current clinical practice.<sup>4</sup>

It is reasonable to expect that SARS-CoV-2 infections in infants would be similar to other respiratory virus infections. Although some authors have evaluated the risk of bacterial co-infection in these patients, describing also a lower risk of SBI,<sup>5-10</sup> recommendations for the assessment and management of possible SBI in infants with SARS-CoV-2 infection are not yet established. The diagnosis of a SARS-CoV-2 infection could influence medical decisions and support less aggressive investigation and management, saving on diagnostic tests, antibiotic treatment, and hospital admissions, thus optimizing use of health resources.

The objective of this study is to describe the management of infants under 3 months of age with SARS-CoV-2 infection in the ED.

## Materials and Methods

This was a cross-sectional study carried out in the ED of an urban tertiary-care pediatric hospital. It is a reference center for an area of 1.8 million inhabitants and has an average rate of about 110,000 ED attendances annually. This is a sub-study related to previous work that included infants under 3 months of age seen at the ED for FWS between March 2020 and October 2022 on whom a polymerase chain reaction (PCR) test for SARS-CoV-2 on nasopharyngeal aspirate was performed.<sup>11</sup>

Infants under 3 months with FWS and a positive PCR test for SARS-CoV-2 were identified through the hospital's electronic medical records. Patients with an abnormal Pediatric Assessment Triangle (PAT) and those who did not have the PCR test result available during their ED visit were excluded. For patients with recurrent visits at the ED after a diagnosis of SARS-CoV-2 infection, only the index visit was included.

During the study period, SARS-CoV-2 testing was universally indicated for young febrile infants presenting at the ED regardless of hospital admission. The initial diagnostic test used (Xpert® Xpress CoV-2 plus test (Cepheid, Sunnyvale, CA)) was replaced in December 2020 with a multi-test that allowed for the simultaneous identification of SARS-CoV-2, Influenza A/B, and RSV (Xpert® Xpress CoV-2/Flu/RSV plus test (Cepheid, Sunnyvale, CA)).

According to the protocol for the management of febrile infants, a complete sepsis panel is performed on patients under 29 days of age and hospital admission with empirical intravenous antibiotic treatment is indicated pending cultures. Urine and blood tests are carried out on infants between 29 and 89 days of age. Based on the results obtained, together with the clinical criteria, a lumbar puncture (LP), hospital admission, and/or empirical antibiotic treatment are considered for this age group. In addition, during the yearly flu season, a rapid diagnostic test (RDT) for influenza viruses A and B is performed: if positive, patient management is individualized accordingly.<sup>12</sup>

The following variables were collected in a previously designed questionnaire: age, sex, comorbidities, close contact with a confirmed COVID-19 case, characteristics of the fever, complementary diagnostic tests performed, identification of a SBI, indication for hospital admission, empirical antibiotic treatment, and clinical evolution. In addition, in the patients discharged home, data from the re-consultations for the same febrile process were also collected.

### Definitions

FWS: rectal temperature  $\geq 38$  °C or axillary temperature  $\geq 37.5$  °C, documented at home or in the ED, in which the origin cannot be identified even after a detailed medical history has been taken and physical examination performed.

SBI: growth of pathogenic bacteria in urine,

blood, and/or CSF. Urinary tract infection (UTI) was defined as a count higher than 50000 colony-forming units (CFU/mL) of a single pathogen in urine samples collected via catheter or higher than 10000 CFU/mL in samples collected via urinary catheterization along with a positive urine study (visualization by a microbiologist using a Gram stain, associated with elevated nitrites and/or leukocytes). Bacteremia and bacterial meningitis were considered as an invasive bacterial infection (IBI).

**Table 1.** Demographics and clinical features of the 172 included patients

Characteristics	n=172
<b>Age (days)</b>	49 (32-62)
Age < 29 days	32 (18.6)
<b>Male sex</b>	101 (58.7)
<b>Comorbidities</b>	3 (1.7)
Cardiovascular disease	2 (1.2)
Uropathy	1 (0.6)
<b>COVID-19 positive contact</b>	65 (37.8)
<b>Fever</b>	
Duration (hours)	8 (4-16)
Maximum temperature (°C)	38.2 (38-38.5)
Febrile at the ED	48 (27.9)

Categorical variables are reported in terms of absolute frequencies and rates and continuous variables in terms of median value with interquartile range. ED: emergency department.

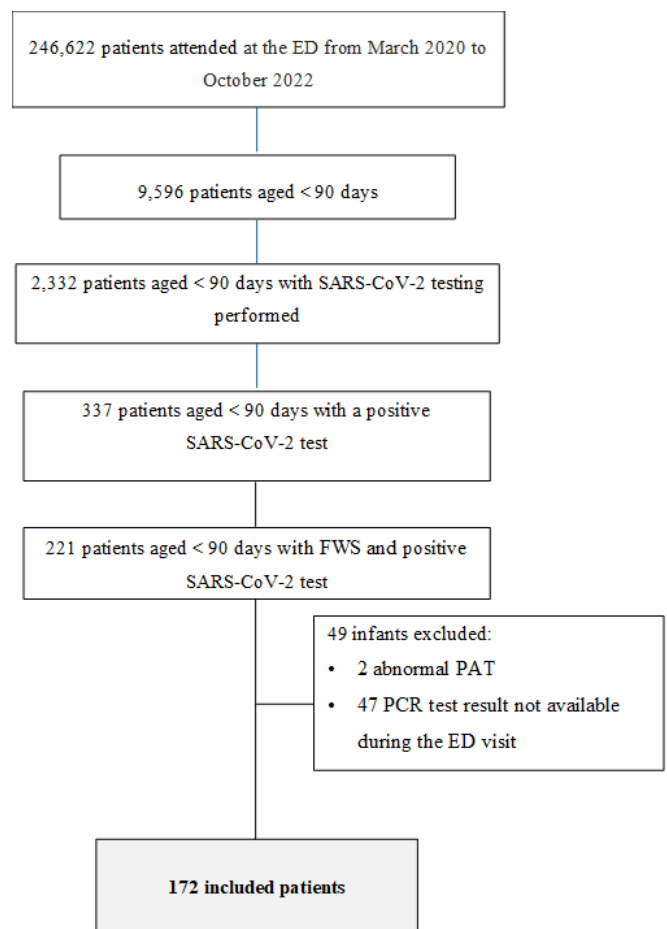
The data collected were analyzed using the software IBM® SPSS® Statistics for Windows®, version 29. The quantitative variables were expressed as median and interquartile range (IQR) and the categorical variables as count and percentage. Tests to study the distribution of the data (Kolmogorov-Smirnov) and to compare quantitative data (Student's T-Test, Mann-Whitney U test) and qualitative data (Chi-squared, contingency table, Fisher's exact test) were applied. Patient management regarding the performance of complementary diagnostic tests, indication for hospital admission, and/or empirical antibiotic treatment was analyzed globally and by age subgroup (<29 days and 29-89 days). The 95% confidence intervals were calculated for proportions using Wilson's method. *P*-values under 0.05 were considered significant.

This study was approved by the Research Ethics Committee of the hospital where the study was

performed (PIC-110-22). Since the data were extracted from computer records on which the information was anonymous, and no interventions were performed on patients, informed consent was not obtained.

## Results

During the study period 2,332 patients under 3 months were tested for SARS-CoV-2 by PCR; in 221 infants with FWS the PCR was positive. Among these, 49 (6.8%) had at least one exclusion criteria, yielding a final sample size of 172 patients (**Figure 1**).



**Figure 1.** Study flowchart

ED: Emergency Department; PAT: Pediatric Assessment Triangle

One-hundred and nineteen (69.6%) patients were recruited during the seventh pandemic period.<sup>13</sup> (**Figure 2**). The demographic and clinical characteristics of the patients included are detailed in **Table 1**.

Bacterial cultures were performed on 160 (93%) patients, with urine cultures (151, 87.8%) being the

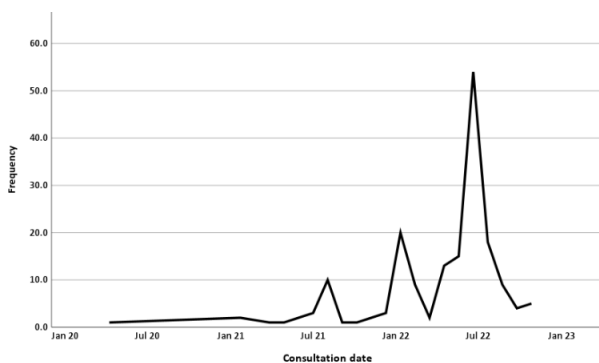
**Table 2.** Management of infants under 3 months of age with COVID-19 at the emergency department

Characteristics	Global n=172	Age		p
		< 29 days n=32	29 - 89 days n=140	
<b>Blood test</b>	94 (54.7)	31 (96.9)	63 (45)	<0,001
Blood culture	92 (53.5)	31 (96.9)	61 (43.6)	<0,001
<b>Urinalysis</b>	157 (91.3)	32 (100)	125 (89.3)	0,077
Urine culture	151 (87.8)	32 (100)	119 (85)	0,015
<b>Lumbar puncture</b>	8 (4.7)	6 (18.8)	2 (1.4)	<0,001
<b>Additional virus testing</b>	169 (98.3)	31 (96.9)	138 (98.6)	0,463
<b>Antibiotics prescription</b>	17 (9.9)	7 (21.9)	10 (7.1)	0,020
<b>Hospital admission</b>	39 (22.7)	22 (68.8)	17 (12.1)	<0,001

Categorical variables are reported in terms of absolute frequencies.

most frequently requested. Table 2 shows the microbiology studies performed overall, and by age subgroup. Eight (4.7%) patients underwent LP, 6 due to being aged <29 days, and 2 aged > 29 days with abnormal laboratory parameters. Indications for blood analysis and LP were significantly higher in infants aged <29 days. No patients had a chest X-ray performed. Thirty-nine patients (22.7%) were admitted, seventeen (9.9%) with empirical antibiotic treatment (Table 2). The median hospital stay was 72 hours (IQR: 48 - 96 hours). During their hospital stay, one patient developed bronchiolitis and another acute gastroenteritis (neither had positive virology). All admitted patients had a good clinical outcomes, with none requiring ICU admission. Of the 133 (77.3%) cases discharged home, 15 (11.2%) returned to consultation for the same febrile illness; outpatient management was indicated for all of them.

abnormality. The prevalence of SBI was 5.8% (95% CI: 3.2 - 10.4%), without significant differences between the age groups (9.4% in those aged <29 days vs. 5% in those aged 29-89 days;  $p= 0.397$ ). Nine (5.2%) patients had a UTI (*Escherichia coli* (7 cases), *Enterobacter cloacae* and *Klebsiella pneumoniae* (one case each)); none had a history of urinary pathology. One patient (0.6%) had bacteremia with *Streptococcus agalactiae*: this was a 16-day-old male with a 4-hour history of fever, and whose mother's vagino-rectal swab had previously been culture-negative for *S. agalactiae*; both parents had been diagnosed with COVID-19 in the days preceding the baby's illness. No cases of bacterial meningitis were diagnosed, and no SBI were diagnosed among the 133 infants managed as outpatients. Two (1.2%) infants had enterovirus viraemia.



**Figure 2.** Distribution of cases of infants under 3 months of age with COVID-19 in the different pandemic periods (n= 172).

The main analytical findings are summarized in Table 3, with lymphopenia being the most frequent

## Discussion

A diagnosis of SARS-CoV-2 infection has conditioned a less aggressive management in a significant proportion of febrile infants under 3 months of age with FWS related to standard practice, especially in relation to IBI screening in infants over 28 days of age and the indication for hospital admission and antibiotic treatment. The low incidence of IBI found, as well as the favourable clinical outcomes in these patients, would support the incorporation of SARS-CoV-2 testing into the management algorithm for young febrile infants.<sup>11,14</sup>

Our results are in line with previous single-center studies<sup>5-8</sup> that show a low prevalence of SBI in very young febrile infants with SARS-CoV-2 infection.

**Table 3.** Main laboratory findings at the emergency department

CHARACTERISTICS	GLOBAL	SBI	Non-SBI	P
<b>Blood count</b>	<b>N=91*</b>	<b>n=10</b>	<b>n=81</b>	
<b>White blood cell count (per mm3)</b>	6100	7550	6100	0,542
WBC > 15,000/mm3	1 (1.1)	1 (1.2)	0 (0)	1
WBC < 5,000/mm3	33 (36.3)	4 (40.0)	29 (35.8)	1
<b>Lymphocyte count (per mm3)</b>	2700	2900	2600	0,513
Lymphocytes < 3,000/mm3	49 (53.8)	5 (50)	44 (54.3)	1
Lymphocytes < 1,500/mm3	17 (18.7)	1 (10)	16 (19.8)	0,681
<b>Absolute neutrophil count (per mm3)</b>	1900	2000	1900	0,546
ANC < 1,000/mm3	10 (11.0)	2 (20)	8 (9.9)	0,302
<b>Biomarkers</b>	<b>n=94</b>	<b>n=10</b>	<b>n=84</b>	
<b>C-reactive protein ≥ 20 mg/l</b>	4 (4.3)	2 (20)	2 (2.4)	0,055
<b>Procalcitonin ≥ 0,5 ng/ml</b>	3 (3.2)	2 (20)	1 (1.2)	0,029

\* In three patients' blood count was not available because blood sample was clotted.

Categorical variables are reported in terms of absolute frequencies and rates and continuous variables in terms of median value. WBC: white blood cell count. ANC: absolute neutrophil count. SBI: serious bacterial infection.

In this sense, in our previous work that included 779 febrile infants under 3 months of age, including 221 with SARS-CoV-2 infection, the prevalences of SBI and IBI were significantly lower in those with SARS-CoV-2 infection (5.9% vs. 22.9% and 0.5% vs. 3.2%, respectively). We did not find any IBI in infants over 28 days of age with SARS-CoV-2 infection.<sup>15</sup> Two recently published multi-center studies<sup>9,15</sup> showed similar results, with bacteremia rates <0.1% in patients older than 28 days with SARS-CoV-2 infection. Moreover, a meta-analysis by Pérez-Porra *et al.*,<sup>16</sup> which analyzed the prevalence of IBI in 3943 febrile infants under 3 months with SARS-CoV-2, found prevalences of 0.53%-0.56% in patients aged ≤ 28 days and 0.11% in patients >28 days, suggesting that blood analysis could be avoided in older infants with SARS-CoV-2 infection. However, the prevalence of UTIs observed in our study, as well as in most of the studies mentioned, supports continued screening for this condition in febrile infants under 3 months of age with SARS-CoV-2 infection.

The behavior of SARS-CoV-2 in very young febrile infants seems similar to that of other respiratory viruses,<sup>2,3,17,18</sup> with concurrent IBI being very uncommon in this age group. Thus, incorporating rapid viral detection tests in the evaluation of these patients should be seriously considered to optimize their management.<sup>19</sup> Its incorporation could also achieve cost savings,

especially during times of high virus circulation.<sup>20</sup>

As in other studies,<sup>10,21-23</sup> the most common analytical finding was lymphopenia. In the adult population, this finding is related to the severity of the infection<sup>24</sup>. In a multi-center study performed in Spain, in which 74 children with COVID-19 admitted to the ICU were included, those with Multisystem Inflammatory Syndrome in Children (MIS-C) had significantly lower lymphocyte counts.<sup>25</sup> In our study, we found no correlation between SBI and lymphopenia; an association between lymphopenia and severity of COVID-19 could not be assessed because there were no severe COVID-19 -cases. As in previous studies,<sup>21,26</sup> acute phase reactants were elevated in only a very limited number of patients, with this proportion being higher in cases with SBI. However, the short duration of fever in most cases should be taken in account in interpreting the acute phase reactants results.<sup>14,27</sup>

The rate of viral co-infection was very low, with no cases of co-infection with the influenza virus or RSV found, even though said viruses were screened for in almost all the cases. Other studies performed in Spain around the time of our study showed similarly low co-infection rates,<sup>23,28</sup> which can be attributed to the low circulation of the influenza viruses and RSV in Europe due to the public health measures implemented to reduce spread of SARS-CoV-2. In addition, almost 70% of the cases in this

study were recruited during the seventh pandemic period, after the winter months had passed.

Among the limitations of this study are those inherent to its retrospective design. For example, since it was based on electronic medical records, there may have been a certain loss of clinical information. The absence of a non-SARS-CoV-2 control group, limits the ability to draw more accurate conclusions about the impact of SARS-CoV-2 identification on management practices. However, in our original work more SARS-CoV-2-negative patients had blood and CSF cultures performed and hospitalization rate and initiation of antibiotic treatment were also significantly higher in negative patients.<sup>11</sup> Another potential issue is that IBI screening was not performed in every case, which may have led to its prevalence being underestimated. However, the good clinical evolution of the patients makes this very unlikely. Lastly, it was a single-center study carried out in a tertiary pediatric hospital, so the management described may not be representative of the normal clinical practice in other healthcare environments.

In conclusion, identification of SARS-CoV-2 conditioned a less aggressive management approach in a significant number of febrile infants than would be usual standard practice. The low incidence of IBI found would support incorporation of SARS-CoV-2 testing into the flowcharts for the management of febrile infants, with blood culture not being mandatory for infants aged >28 days with SARS-CoV-2 infection. However, UTI screening should continue for these patients in view of the not-insignificant prevalence of UTI.

## Declaration

### Funding

None declared.

### Conflict of Interest

None declared.

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