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Multisystemic inflammatory syndrome in children (MIS-C) possibly related to COVID-19 Pfizer-BioNTech mRNA (BNT162b2) vaccine. A case report

Síndrome multisistémico inflamatorio en niños (MIS-C) posiblemente asociado a vacuna COVID-19 Pfizer-BioNTech mRNA (BNT162b2). Reporte de caso

Mónica Cecilia Mercado Uribe, Pedro Antonio Martínez Arce, Martín Guerrero Becerra

Abstract

INTRODUCTION: During the SARS-CoV-2 pandemic, COVID-19 vaccines were authorized and administered worldwide. The AEFI, (ESAVI in Spanish) epidemiological surveillance system in Mexico is in charge to identify, follow and report all the events suspected associated to vaccination. In Mexico COVID-19 vaccination started in the group of children aged 5 to 17 years in June 2022. The vaccination program for children only used the Pfizer-BioNTech mRNA (BNT162b2) vaccine. To date 7 million doses (46% of vaccinated people) have been administered to this group of age, which is approximately 5% of the COVID-19 cases in Mexico.

CASE REPORT: Five-year-old male hospitalized because of abdominal pain and fever. One day before, he received second dose of Pfizer-BioNTech mRNA (BNT162b2) vaccine. During hospital stay appendicitis was ruled out and he presented: high inflammatory markers, and more than two signs of multisystem involvement (hepatitis, myocardial failure, and hematological disturbances). Patient met criteria of MIS-C according to the American College of Clinical Rheumatology Guidelines, CDC and WHO. There was a SARS-CoV2 PCR and antibodies against spike virus negatives, as occurs in 5% of cases. The case had a good resolution.

CONCLUSION: COVID-19 vaccines administered in Mexico in are safe and efficient. Pfizer-BioNTech mRNA (BNT162b2) vaccine was administered to children. No reports of MIS-V were found in Mexico. Severe AEFI reporting general rates are 0.010 per 1000 doses applied. As of Aug 31, 2021, 21 335 331 individuals aged 12–20 years had received one or more doses of a COVID-19 vaccine, making the overall reporting rate for MIS-C after vaccination 1·0 case per million individuals receiving one or more doses in this age group. The reporting rate in only those without evidence of SARS-CoV-2 infection was 0·3 cases per million vaccinated individuals.

PALABRAS CLAVE: Multisystem inflammatory syndrome in children (MIS-C), COVID-19 Vaccine Pfizer-BioNTech mRNA (BNT162b2), multisystem inflammatory syndrome following SARS-CoV2 vaccination MIS-V. A case report.

Resumen

INTRODUCCIÓN: Las vacunas contra SARS CoV-2, son una suspensión de microorganismos mundialmente aprobadas para el manejo y prevención de la emergencia epidémica. El Sistema de Vigilancia para Eventos Supuestamente Atribuibles a Vacunación o Inmunización (SVESAVI), es un sistema pasivo que está a cargo de vigilar, identificar y supervisar la vacunovigilancia de todas las vacunas y biológicos que se administran en el país, recibe notificaciones de todas las instituciones públicas y privadas del sistema nacional de salud. En junio 2022, la vacunación contra SARS-CoV2 en México inició en niños del grupo de edad de 5 a 17 años, con vacuna Pfizer-BioNTech mRNA

Infectología pediátrica, Hospital Civil de Guadalajara "Fray Antonio Alcalde". Universidad de Guadalajara. Guadalajara, Jalisco, México

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Correspondencia
Mónica Cecilia Mercado-Uribe
monicauribe_99@yahoo.com.mx

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(BNT162b2), la única de siete vacunas disponibles, debido a que su rango de edad representa el 5% de la población afectada. 7 millones de dosis administradas (46% del total de dosis para aplicar en este grupo poblacional).

REPORTE DE CASO: El paciente que presentamos cursó con fiebre, rash, conjuntivitis, hepatitis, falla miocárdica, leucocitosis, linfopenia, trombocitopenia y reactantes de fase aguda elevados, según los criterios definitorios para MIS-C de las Guías del American College of Clinical Rheumatology. Los anticuerpos contra la proteína de espiga para SARS-CoV2 PCR resultaron negativos, como ocurre en 5% de los casos. La evolución del caso fue favorable.

CONCLUSIÓN: Las vacunas aplicadas en nuestro país contra el SARS CoV-2, han sido aprobadas para su uso en población pediátrica y son seguras. En México, no encontramos reportes de MIS-V asociado con la vacuna Pfizer-BioNTech mRNA (BNT162b2); los eventos adversos serios relacionados a vacunas para SARS CoV-2 son 0.010 casos por cada 1000 dosis de vacunas aplicadas.

PALABRAS CLAVE: Síndrome Inflamatorio Multisistémico en niños (MIS-C), *COVID*-19, Vacuna Pfizer-BioNTech mRNA (BNT162b2), síndrome inflamatorio multisistémico secundario a la vacunación para SARS-CoV2 (MIS-V). Reporte de caso.

INTRODUCTION

During the COVID-19 outbreak in Mexico, in 2022 after the isolation recommendations were lifted, an increase of 30% was reported. The increase of cases was present in other countries as part of The World Health Organization (WHO). The strains identified were SARS-CoV-2 BA.4, BA.5, and others derived from Omicron. In 2022 a total of 599 million cases of COVID-19 were confirmed[1].In our country, during 2022, 1,013 deaths corresponded to children under 18 years of age, 27% less than one year of age, mortality rate 0.7 / 100 000 habitants[2]. This mortality rate corresponded only to COVID-19 cases during the year. To control this pandemic, the World Health Organization (WHO) aims to achieve 70% vaccination of high-risk groups[3].

In Mexico, COVID-19 vaccination started with the group of children aged 5 to 17 years in June 2022. The vaccination program for children only used the Pfizer-BioNTech mRNA (BNT162b2) vaccine. To date 7 million doses (46% of total doses for this age group) have been administered[4].

The Events Supposedly Associated to Vaccination or Immunization Epidemiological Surveillance System, (SVESAVI in Spanish) it's a passive system that receive notifications of public and private institutions, but is not in charge of the vaccines administration.

An Event Supposedly Associated to Vaccination or Immunization Epidemiological (AEFI), is a suspected event associated to vaccination, has two outcomes. Severe AEFI, include any important clinical manifestation present within the first moment the patient receives the vaccine, until 30 days after the vaccine administration.

Does not resolve in the next 15 days or are cause of death.

It needs treatment, or hospitalization to prolong the treatment.

Can leave disabilities or sequelae.

They are a cause of malformation in the newborn.

Temporality is related to the kind of AEFI, and every vaccine administered. The non-severe AEFI will be the opposite[5].

In the United States of America, The Centers for Disease Control and Prevention (CDC), considers

patients with Multisystem Inflammatory Syndrome in children (MIS-C) a severe AEFI[6].

Ethics. The patient's parents gave their consent for the publication of the case.

CASE PRESENTATION

Five-year-old male, resident of Guadalajara, Jalisco, Mexico. Hospitalized with a presumptive diagnosis of appendicitis. History of present illness: started four days before hospitalization with sore throat, headache, and low-grade fever. Treated with paracetamol, naproxen and ambroxol. He came to the emergency room because of intense generalized abdominal pain.

Past medical history: Denied allergies, past hospitalizations, and surgeries. Denies the use of chronic medications. A day prior to any symptoms , he received a second dose of Pfizer-BioNTech mRNA (BNT162b2) vaccine. Family history: only child of a 24-year-old mother, achondroplasia. 51-year-old father, with right hip injury, both parents received three doses of COVID-19 vaccines.

Physical examination. HR: 89 bpm, RR: 26 pm, Temperature: 37.8ºC, BP: 98/55mmHg, Sat O2: 96%. The patient was alert, oriented and with facial signs of pain. Cranial nerves normal, symmetrical pupils. Pale skin, non-purulent conjunctivitis, red and swollen lips, strawberry tongue. He had no other mucous membrane involvement. The chest and neck had erythematous maculopapular rash, non-pruritic, non-enhancing, confluent on neck, anterior thorax, posterior and abdomen. Decapitated papules and hypopigmented macules lesions on both arms and legs. Lungs clear to auscultation, precordium without murmurs. Abdomen symmetrical, with distention. Bowel sounds present. No masses nor hepatosplenomegaly found. Blumberg positive. Symmetrical extremities, no edema noted. Motor and sensory examination of the upper and lower extremities is normal. Gait normal. Reflexes normal and symmetrical in both extremities. No palpable nodes in the cervical, supraclavicular, axillary nor inguinal.

During the hospital stay, appendicitis was ruled out clinically and with abdominal CT. He presented: high inflammatory markers, and more than two signs of multisystem involvement (hepatitis, myocardial failure, and hematological disturbances) (Table 1).

Patient met criteria of MIS-C according to the American College of Clinical Rheumatology Guidelines, CDC and the World Health Organization (WHO). He also met criteria of severe AEFI because, every case must be related to the vaccine administration immediately, until 30 days after. The case was associated with the COVID-19 vaccine (MIS-V), as the patient didn't have COVID-19 history, personal nor familiar. He also did not have laboratory tests that proved acute infection.

Treatment

As per the American College of Clinical Rheumatology guidelines, the patient received intravenous immunoglobulin 2g per kg IV, methylprednisolone 30mg per kg IV q8 hours, acetylsalicylic acid (ASA) 3mg per kg PO q24 hours, and enoxaparin 1mg per kg Subq. q12 hours. Additionally, he had acetaminophen for fever control 15mg per kg PO q8 PRN. On the third day of treatment, methylprednisolone and enoxaparin were discontinued. He continued ASA and acetaminophen. During the hospital stay, fever and abdominal pain subsided 24 hours after treatment. The rash disappeared after 48 hours after treatment, and he was discharged from the hospital after four days without symptoms.

Follow-up

At two weeks follow up visit, he was asymptomatic. Laboratory findings, erythrocyte

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Table 1. Laboratory test performed on patient.

	Laboratory results	Normal Range
Leucocytes	4020	4.60-10.20 10∧3/uL
Neutrophyles	1650 (41%)	0.0–6.0 10∧3/uL (37-80 %)
Linfocytes	1510 (38%)	3.00-8.00 10∧3/uL (10-50 %)
Platelets	74 410	142.00- 424.00 10∧3/uL
Hemoglobin	14.85	12.20 -18.10 g/dl
Glucose	78	60 -125 mg/dl
Urea Creatinin BUN	23 0.32 10.60	15 -39 mg/dl 0.50 -1.20 mg/dl 0.3 - 0.7 mg/dl
Prothrombin time Thromboplastin partial time I.N.R. Fibrinogen	25.3 13 1.18 389	9.50 - 13.0 % 25.50 - 35.5 % 0.00 - 0.00 200.0 - 480.0 md/dl
Gama glutamyl transferase Alanine transferase Aspartate aminotransferase Lactic Dehydrogenase Alkaline phosphatase Protein Albumin Total Bilirubin Direct Bilirubin Indirect Bilirubin	112 73 140 160 589 5.37 2.98 0.79 0.26 0.53	145 - 420 U/L 11- 54 U/L 0- 40 U/L 91.0 - 300.0 U/l 42.0 - 98.0 UI/l 6.4 - 8.20 g/dl 3.50 -5.0 g/dl 0.40 - 1.20 UI 0.00 -0.40 UI 0.00 –1.00 UI
Ferritin D Dimer Brain Natriuretic Peptide Troponin I Myoglobin Reactive C Protein	691.8 3381 2092 0.03 225 3.8	7 – 140 ng/ml 0.00 – 0.2500 ng/mL 0.00 – 100.00 pg/mL 0.00 -0.40 ng/mL 0.00 – 107.0 ng/mL 0.00 – 10.0 mg/l
Urinalysis	Protein traces	0.00
Hemocultive and urine cultive	Negative	
Abdominal tomography	Free fluid in the cavity and paramesocolic slides 12 Hounsfield Units, right pleural effusion 10 Hounsfield Units. Minimal pericardial effusion High density > 50 U Hounsfield.	No nodules, masses or consolidations, gas-occupied cecal appendage > 5 mm, no nodes
Echocardiogram	Ostium and right and left coronary arteries without alterations. Minimal pericardial effusion. LVEF 64%, RVEF 34%	Situs solitus, Atrioventricular conection and AV concordant. LVEF (50 - 70%) RVEF (55 - 65%)
SARS-CoV2 and Influenza virus PCR SARS-CoV2 Anti nucleocapsid antibodies*f* IgG IgM	Negative 0.97 0.51	Negative < 1.40 Negative < 1.00 Negative

f Chemiluminescence method. Alinity platform, Abbott Laboratories. LVEF Left Ventricular Ejection Fraction, RVEF Right Ventricular Ejection Fraction.

sedimentation rate (ESR) 25 mm/h (Range 0-10) C reactive protein (CRP) 0.044 mg/dL (0.01-0.21) Hg 13g/dL (11-14), leukocytes 7030 10^3/uL (5-15) neutrophils 3.29 10^3/uL (3-9), lymphocytes 2970 10^3/uL (3-8), platelets 340,000 10^3/uL (149-368).

SARS-Cov2 infection in children is usually asymptomatic or mild. The first cases of Multisystem Inflammatory Syndrome in children (MIS-C) were reported secondary to infection by the SARS-CoV2 virus in the United Kingdom (2020).[7]

The WHO and CDC, published in 2020 the definition of MIS-C, and in 2022 the American College of Clinical Rheumatology updated it. The update was needed because of several rheumatological clinical syndromes can present symptoms similar to those of MIS-C.

There are several studies comparing Kawasaki disease (KD) to MIS-C.

Some of the main differences between them are older age (>5 years), ethnic origin (Latin of African American), lymphopenia, thrombocytopenia and elevated acute phase reactants like ferritin, CRP, lactic dehydrogenase, and erythrocyte sedimentation rate. Also, MIS-C antibodies against SARS-CoV2, are more common than in KD[8,9,10].

All MIS-C definitions include fever, elevated inflammatory markers, at least two signs of multisystem involvement (cardiovascular, hematologic, gastrointestinal, dermatologic including rash and mucocutaneous involvement), and evidence of SARS-CoV-2 infection or exposure. All definitions include exclusion of other potential causes. Inflammatory markers present are: IL-6, IL-8, IL-10, IL-17, TNFa, INF g, decreased dendritic cells activity, HLA-DR monocytes, CD4 and CD8 T lymphocyte and detection of autoantibodies against cardiovascular and gastrointestinal endothelium[11].

Kawasaki disease (KD) pathogenesis is infiltration of leukocytes in the medium-caliber coronary arteries. It is a febrile illness that etiology has not yet been determined. Clinical manifestations are present in children age <5 years, non-purulent conjunctivitis, rash, and enanthema. Patients can have myocardial dysfunction. Most important complications of not receiving treatment are coronary aneurisms. Patients usually have a low viral load for SARS-CoV2 and is a differential diagnosis for MIS-C[12].

The Latin American MIS-C surveillance network reported 409 cases in 2021. All cases needed hospitalization in the intensive care unit (12.7%). The associated conditions were low socioeconomic status, immunodeficiencies, pre-existing conditions, pneumonia, respiratory distress syndrome, abdominal symptoms[13].

Cases of febrile illness in adult patients after Pfizer-BioNTech mRNA (BNT162b2) vaccination have been reported recently in the United Kingdom, and in the United States of America. These cases were two to four weeks after the first or second dose of Pfizer-BioNTech mRNA (BNT162b2) vaccine. Clinical manifestations were fever, diarrhea, vomiting, abdominal pain and hypotension. Laboratory findings were high inflammatory markers, troponin, N-terminal pro type B natriuretic peptide, neutrophilia and lymphopenia. They also presented hematologic disturbances like thrombocytopenia, high fibrinogen, and D-dimer. PCR for SARS-CoV-2 was positive in some cases, but in all of them the qualitative IgG antigenemia was positive [14-16].

These severe AEFI are also reported in children. Clinical presentation was associated with vaccination. Associated with cytokine storm and/or hyperreactivity of the immune system. This can be a result of dysregulation of the T-lymphocyte response. Most of the patients had negative SARS-CoV-2 PCR and positive antigenemia (60%). Both tests were positive in 34% and only 5% had both tests negative as this patient had[17].

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MIS-C, is a post-infectious disease that occurs between two and 6 weeks after the SARS-CoV-2 infection. MIS-C can overlap with other autoimmune problems or viral infections, like Cytomegalovirus, Adenovirus, Epstein-Barr Virus, Parvovirus, Enterovirus and Coxsackie viruses. The SARS-CoV-2 antigenemia can be present after infection or vaccination. Past infection shows positive anti-SARS-CoV-2 nucleocapsid antibody (ABBOT ARCHITECT SARS-CoV2 IgG) with a sensitivity and specificity close to 100%.

Anti-spike IgG antigenemia after vaccination with a sensitivity of 96.8% and a specificity of 99.6%[18].

In the United States of America (USA), from Dec 14, 2020, to Aug 31, 2021, there were 21 patients diagnosed with MIS-V. These patients were identified through the CDC MIS-C national surveillance system. The Vaccine Adverse Event Reporting System (co-administered by the CDC and US Food and Drug Administration and by the Clinical Immunization Safety Assessment Project). The mean age was 16 years, 13 males and 8 females. All hospitalized, 12 (57%) admitted to the intensive care unit, and no mortality. 15 patients (71%) had recent COVID-19. The reporting rate of MIS-V was 1.0 cases per million individuals who received one or more COVID-19 vaccines[19]. In Mexico, there are no reports of MIS-C associated with the Pfizer-BioNTech mRNA5 (BNT162b2) vaccine (MIS-V).

The safety and efficacy of vaccination in adolescents and children with Pfizer-BioNTech mRNA (BNT162b2) with one or two doses, shows that cases of Severe AEFI are very rare. Its potential for protection against severe systemic disease is superior. The presence of MIS-C can be present on patients that also have other hyperinflammatory conditions where immunity is compromised, such as in obese children, under 12 years of age, with some type of oncological pathology, corticosteroid therapy or theories, such as persistent antigenemia, determinants genetics, autoimmunity or formation of superantigens[20,21].

The SVESAVI in Mexico until July 21, 2022, reported 96 cases of severe AEFI (56 women) with COVID-19 vaccines. The serious/non-serious ratio was 0.067. In Mexico more than 35 million COVID-19 vaccines have been administered in all groups of age. The most used COVID-19 vaccine in Mexico is Astra/Zeneca, followed by the Pfizer-BioNTech mRNA (BNT162b2) vaccine. Both with severe AEFI reporting rates of 0.010 per 1000 doses applied[22].

CONCLUSIONS

This patient presented with a severe AEFI after the administration of the second dose of Pfizer-BioNTech mRNA (BNT162b2) vaccine. Clinical manifestations were fever, abdominal pain, rash, conjunctivitis, and hematological alterations such as thrombocytopenia, hepatitis and cardiac dysfunction. Corresponding to the diagnosis of MIS-V.

With absence of disease confirmed with PCR and negative antibodies to SARS-CoV2. The lack of economic resources, did not allow the research for other related viruses and in the follow-up visits, the patient is being studied for other autoimmune processes.

Safety of the COVID-19 vaccine approved for use in children in Mexico has been studied and reported. Moreover, Pfizer-BioNTech mRNA (BNT162b2) two doses had being protective against MIS-C children 12 to 18 years > 28 days after vaccination cases versus controls 91% (C.I. 95%= 78 – 97%)[23]. The AEFI reports are expected always when a massive application is being made. The refusal of COVID-19 vaccination continues. Misinformation and doubts about the novel illness makes people refuse to vaccinate.

It's necessary, to offer training to all sanitary personal, in order to be capable of to identify and to report every AEFI related to vaccination, during the first 24 hours after the detection of the event.

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