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SHORT-TERM SAFETY OF COVID-19 VACCINES IN THE UNDERAGE POPULATION OF BUENOS AIRES

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ABSTRACT

Introduction: COVID-19 vaccines were developed in record time and only received emergency use authorization. There is still a limited data on the safety of paediatric vaccines for this disease.

Objective: To determine the adverse events attributable to vaccination/immunization (ESAVI) associated with COVID-19 vaccines administered to individuals under 18 years of age.

Methodology: An active pharmacovigilance process was carried out through a prospective, observational, and descriptive study on the short-term safety of paediatric SARS-CoV-2 vaccines. Children older than 6 months and younger than 18 years who had received at least one dose of a SARS-CoV-2 vaccine at Elina de la Serna Hospital in Montes de Oca between February and August 2023 were included. Data were collected via a WhatsApp survey conducted at 24 hours and 7 days post-vaccination. Variables considered included age, place of residence, recorded comorbidities, vaccine type and dose administered, and concomitant vaccinations. Data are presented as percentages, means, or rates, with corresponding confidence intervals.

Results: A total of 545 children were included in the study, with a mean age of 9.6 years (95% CI: 5–13.8). Of the vaccines administered, 46.7% (n=129) were Moderna Pediatric, 32.6% (n=90) Pfizer Bivalent, 14.9% (n=41) Pfizer Pediatric, 4.7% (n=13) Beijing Institute, and 1.1% (n=3) Moderna

Bivalent. At the time of vaccination, 12.1% (n=33) of patients had comorbidities. At 24 hours, 58.3% (n=161) of participants reported fever or injection site pain, and 25.4% (n=70) of them still had symptoms at 7 days. Only 2.2% (n=6) reported symptoms that required medical consultation. No hospitalizations or deaths were recorded. The relative risk (RR = 0.79) indicates that those vaccinated with Pfizer Bivalent had a 21% lower risk of presenting symptoms at 24 hours compared to those vaccinated with Moderna Pediatric. The symptoms can be considered mild, as only 4 patients required medical consultation.
Conclusion: COVID-19 vaccination in children showed a low incidence of serious ESAVI in the short-term post-immunization period.

Keywords: Drug-Related Side Effects and Adverse Reactions, COVID-19 Vaccine, Pediatrics, Pharmacovigilance.

INTRODUCTION

Human health is influenced by climate changes, culture and social movements like globalization, that has intensified interactions between people, animals, and the environment. Technological advancement facilitated, rapid international mobility eliminating health borders. In this context, the emergence of SARS-CoV-2 in December 2019 and its declaration as a pandemic by the WHO in March 2020 highlighted global vulnerability to emerging diseases, causing a global health, economic, and social crisis[1].

Although the course of coronavirus disease is usually milder and has a better prognosis than in underage population,[2] SARS-CoV-2 may cause serious illness and COVID-19-related complications such as respiratory failure, myocarditis, and multisystem inflammatory syndrome (MIS-C) in children[3].

On August 11, 2020 with more than 2.5 million deaths worldwide at that time, the world's first registered vaccine against COVID-19 was registered by the Ministry of Health of the Russian Federation. This vaccine was developed using human adenoviral vectors with their reproductive genes deactivated by the Gamaleya National Research Center for Epidemiology and Microbiology[4]. The vaccine was registered by rapid approval based on phase I and II studies, an aspect that earned criticism from the scientific community[5], although after the preliminary analysis of phase III published in The Lancet, which showed an efficacy of 91.6%, it had greater acceptability[6]. By then, the race among pharmaceutical companies had been launched, and to the inactivated version of the coronavirus itself, others were added with adenoviruses into which SARS-CoV-2 RNA, or messenger RNA, was inserted. Thus, from December 2020 and throughout 2021; WHO, FDA, EMA, and other competent regulatory authorities around the world have authorized the Oxford-AstraZeneca[7,8]; Pfizer-BioNTech[8], Moderna[8]; Johnson & Johnson[8], CanSino[8], Sinopharm8, CoronaVac[8,9], Sinovac[8,10] vaccines, among others, for emergency use; although none of them are destinated for use in the pediatric population.

The COVID-19 vaccines were developed in record time, thanks to a combination of exceptional factors that did not compromise quality or safety, with only the long-term Phase III phase remaining. Among the reasons for this record time was the condensation of clinical phases, which allowed Phases I, II, and III to overlap, but not be omitted. This was possible thanks to unprecedented coordination between regulatory agencies, researchers, and pharmaceutical companies. The widespread availability of volunteers allowed for rapid recruitment for clinical trials. High viral circulation allowed for efficacy results to be obtained in much shorter times than usual, and unprecedented global financial investment facilitated access to cutting-edge technologies and production in parallel with the final phases of clinical studies. The emergency authorizations granted by regulatory agencies such as the FDA, EMA, and ANMAT were based on robust safety and efficacy data. The products subsequently obtained full authorizations upon completion of long-term follow-up requirements. Safety studies describe adverse events (AEs) according to the severity of the condition and whether they are associated with local or systemic symptoms or signs[11]. Among the most common local AEs with COVID-19 vaccines are injection site pain, redness, swelling, and adenopathy. Among the

systemic AEs described are asthenia, fever, headache, chills, myalgia, and arthralgia[3,11]. To date, the systems implemented to monitor the safety of these vaccines have identified four types of serious adverse reactions associated with the COVID-19 vaccine: anaphylaxis; thrombosis and thrombocytopenia syndrome (TTS); myocarditis and pericarditis; and Guillain-Barré syndrome (GBS). Reports of fatal cases were extremely rare[12].

Each population has unique characteristics that make it essential to have local surveillance systems to detect adverse events, especially those related to medicines and vaccines. Active pharmacovigilance has proven to be more effective than spontaneous reporting, increasing the detection of adverse events supposedly attributable to vaccination (ESAVIs)[13]. Although these systems are key to ensuring vaccine safety, public acceptance depends on multiple factors, including trust, sociocultural contexts, and individual perceptions.

In the case of messenger RNA vaccines against COVID-19, while their efficacy and safety have been demonstrated in adults, the evidence in children aged 5 to 11 years is more limited, and not all studies confirm so far, their effectiveness in preventing severe forms of the disease in this population. Messenger RNA (mRNA) vaccines against COVID-19 have been tested in adults and have been shown to be safe and effective measures for preventing SARS-CoV-2 infection, severe progression, and persistent sequelae known as post-COVID conditions. As these vaccines are now widely available for adolescents and children, the evidence base for these populations is growing. However, the benefit of mRNA vaccines in children aged 5 to 11 years does not have the same quality and quantity of evidence as in adults. While randomized clinical trials showed vaccine efficacy of 85% to 95% in preventing symptomatic SARS-CoV-2 infection in the 5- to 11-year-old population, not all studies have confirmed its efficacy in preventing acute COVID-19 and hospitalizations due to SARS-CoV-2-related illnesses.

Authorizations in children were based on bridging studies, a strategy widely accepted by regulatory agencies. Controlled clinical trials were used, including evaluation of safety, immunogenicity, and comparative data with the adult population, based on the principle of immunological extrapolation. Specific designs were also developed for age groups, with dose and schedule adjustments.

This study was conducted to determine the incidence of ESAVIs in Buenos Aires population aged 6 months to 18 years with COVID-19 vaccines approved and validated globally for the pediatric population in Argentina.

METHODS

A prospective, observational, descriptive study was conducted on the safety of pediatric SARS-CoV-2 vaccines, using pharmacovigilance tools to actively detect adverse effects associated with these vaccines. The study period ran from February to August 2023, coinciding with the vaccination campaign established in Argentina. The sample size was determined by convenience, based on the availability of participants during the data collection period. Children between 6 months and 18 years of age vaccinated with at least one dose against SARS-CoV-2 at the Elina de la Serna Montes de Oca Hospital (HESMO) were included. Before vaccination, parents and/or guardians signed a consent form authorizing the child to receive the COVID-19 vaccine and at that time, they were also informed about the contacts that the healthcare staff would perform in order to detect any events that might occur related to vaccination.

The data collection instrument was a survey conducted via a web form (Google Forms). Each patient/parent who met the selection criteria was contacted via WhatsApp within 24 hours and 7 days, requesting them to complete the survey. The participant or their parent or guardian (in the case of children under 12 years of age) reported any signs and symptoms that could be related to the vaccine administration. The questionnaire included a list of known drug-associated reactions (ESAVIs) such as injection site pain, fatigue, headache, myalgia, arthralgia, chills, fever, lymphadenopathy, urticaria, and gastrointestinal symptoms, as well as a self-report section[8]. The survey administered at 24 h and 7 days followed the same format.

The presence of ESAVIs of any severity and intensity was established as the study's dependent variable. The data of the participants enrolled in this study included age, demographic data, residence,

recorded comorbidities, vaccine type and dose administered, and concomitant vaccinations against other types of microorganisms (one week before and one week after) as independent variables.
A descriptive analysis of the variables was performed. Excel was used to consolidate and analyze the databases. Data are presented as percentages, averages, or rates, according to the type of variable, with their confidence intervals.
The research was conducted on a coded, unnamed database, devoid of any data that could be used to identify participants. The protocol was evaluated and approved by the Provincial Ethics Committee of the Manuel B. Gonnet Hospital, under Regulation No. 2222-2023. Registration was made in the Provincial Registry of Research Ethics Committees, dependent on the Central Research Ethics Committee - Ministry of Health of the Province of Buenos Aires, Ref/File No. EX-2025-00832562--GDEBA-CCISMSALGP.

RESULTS

A total of 545 children who had received at least one dose of the COVID-19 vaccine were enrolled in the study, while 276 did answer to both surveys. Fifty-two point two percent (n=144) were male. The mean age was 9.6 years (95% CI: 5–13.8). Ninety-three percent (n=262) of the study subjects resided in the city of La Plata, of whom 52.1% (n=144) lived within the urban core (Table 1).

TABLE 1. General characteristics of the patients enrolled in the study (Participants n 276)

Parameter	**Data**	**Results**
Number of doses	1 dose	96% (n=265)
	2 dose	4%(n=11)
Sex	Female	47% (n=132)
	Male	53% (n=144)
Age	Average	9,6 years (IC 95%: 5-13,8)
Home Location	La Plata	93,0% (n=262)
	● Center	● 52,1% (n=136)
	● Suburbs	● 29,6%(n=78)
	● Residencial	● 18,3%(n=48)
	other city	7%(n=14)
Existence of Comorbidities and number	Without comorbidities	87,9% (n=243)
	With comorbidities	12.1% (n=33)
	1	88%(n=29)
	2	9%(n=3)
	3	3%(n=1)
Type of Comorbidities	Chronic lung disease	58%(n=19)
	Obesity	24%(n=8)
	Cardiovascular disease	12%(n=4)
	Chronic kidney disease	3%(n=1)
	Others	3%(n=1)

Regarding comorbidities, 87.9% (n=243) of patients had no known conditions at the time of vaccination, while 12.1% (n=33) had at least one comorbidity. The most significant preexisting conditions were chronic lung disease (58% (n=19); obesity (24% (n=8); and cardiovascular disease (12% (n=4). Chronic lung disease was defined as chronic obstructive pulmonary disease (COPD), cystic fibrosis, interstitial lung disease, and severe asthma,[16] while cardiovascular disease was defined as heart failure, coronary artery disease, valvular heart disease, cardiomyopathies, pulmonary hypertension, and congenital heart disease with uncorrected heart failure and/or cyanotic lesions.
The months with the highest number of doses administered (53% of the total period) were March and April, coinciding with the fall season and the start of the school year in Argentina (Table 4).

During the study, 35% (n=97) of enrolled patients received their third dose, 27% (n=75) received a second dose, 24% (n=66) received their fourth dose, while 13% (n=36) received their first dose and 1% (n=3) received a fifth dose. No deaths were recorded at the time of data analysis.

Table 4. Description of the doses applied during the study period		
Doses applied during the study period (n=276)		
Month of vaccination	February	15%(n=41)
	March	31%(n=86)
	April	22% (n=61)
	May	16%(n=44)
	June	10%(n=28)
	July	5%(n=14)
	August	1%(n=3)
Dose received	1st dose	13%(n=36)
	2nd dose	27% (n=75)
	3rd dose	35% (n=97)
	4th dose	24% (n=66)
	5th dose	1%(n=3)
Vaccine received	Moderna Pediatric	46,7% (n=129)
	Pfizer Bivariate	32,6% (n=90)
	Pfizer Pediatric	14,9% (n=41)
	Beijing Institute	4,7% (n=13)
	Moderna Bivariate	1,1% (n=3)
Vaccine received	COVID-19 vaccine only	94,5% (n=261)
	1	3,2%(n=9)
	2	1,1%(n=3)
	4	0,7%(n=2)
	3	0,5%(n=1)

Type of vaccines administered

Of the total vaccine doses administered (n=276), 46.7% (n=129) were Moderna Pediatric Pfizer Bivariate 32.6% (n=90), Pfizer Pediatric 14.9% (n=41), Beijing Institute 4.7% (n=13), and Moderna Bivariate 1.1% (n=3).

From the 276 doses administered, 94.5% (n=261) received the COVID-19 vaccine alone, while 5.5% (n=15) received at least one other vaccine simultaneously on the day of immunization.

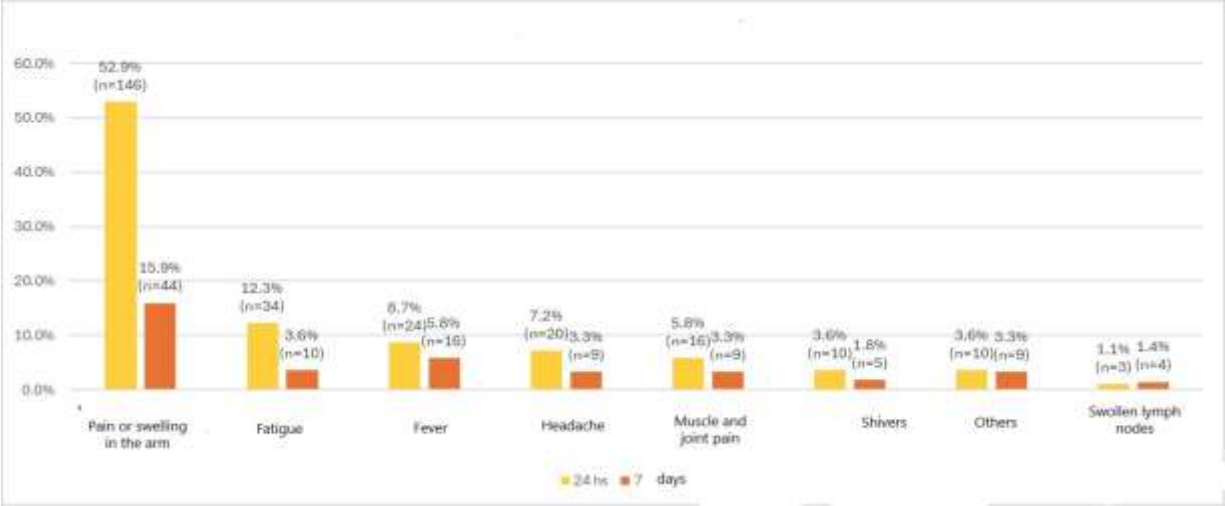
Description of ESAVIs and the Need for Healthcare Care

Asymptomatic cases at 24 hours were 41.7% (n=115), and 74.6% (n=206) at seven days.

In the first 24 hours after vaccination, 58.3% (n=161) of participants reported fever, pain at the injection site, or other vaccination-associated symptoms. This rate decreased to 25.4% (n=70) at seven days. The most common symptoms were pain or swelling at the injection site, fatigue, and fever at both 24 hours and seven days (Chart 1).

Only 2.2% (n=6) of participants reported symptoms that required medical consultation at a health service within seven days.

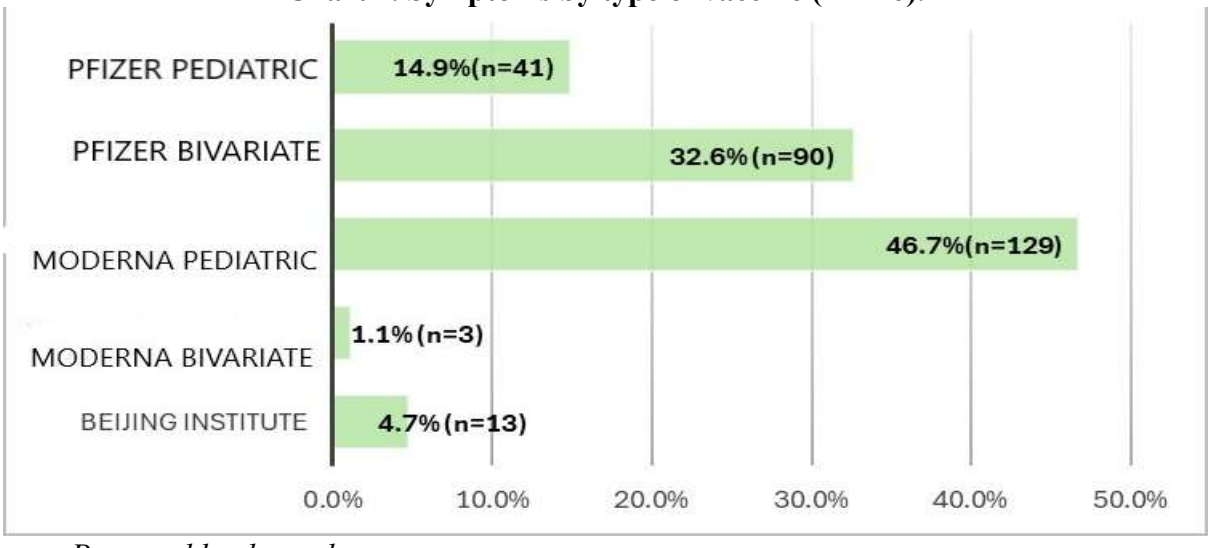
Chart 1. Signs and symptoms reported post-vaccination (n=276).



Source: Prepared by the authors.

Among participants who received the Moderna Pediatric vaccine (n=129) (Chart 2), 18.3% (n=38) reported some symptoms at 24 hours, while 8.7% (n=18) did so at 7 days. There were no medical consultations at 24 hours caused by vaccination, and two patients consulted for pain in the arm at 7 days.

Chart 2. Symptoms by type of vaccine (n=276).



Source: Prepared by the authors

Among the patents belonging tod the group that received the Pfizer Bivariate vaccine (n=90), 23.8% (n=21) presented symptoms at 24 hours, and 8.6% (n=7) did so at 7 days. The majority of participants did not experience symptoms at either 24 hours (52.4%, n=47) or 7 days (84.5%, n=76). Only two participants required medical attention 7 days after receiving the Pfizer Bivariate vaccine.
The relative risk (RR=0.79) indicates that those vaccinated with the Pfizer Bivariate vaccine had a 21% lower risk of presenting symptoms at 24 hours compared to those vaccinated with the Moderna Pediatric vaccine. Symptoms can be considered mild since only four patients required medical consultation.

DISCUSSION

Deciding to introduce a new vaccine to minors is always a dilemma for authorities. In the case of the COVID-19 pandemic, this decision was even more difficult since, in the early months, it had been detected that younger child did not present more severe forms of the disease[11]. However, regarding the omicron variant, several studies had shown that adolescents had a greater capacity to transmit the disease. Regarding the alpha and delta variants, which predominated when adolescent vaccination began in different countries, it was shown that mRNA vaccines effectively prevented infection and transmission. This fact was not a minor element, since there was a fundamental concern at that time due to the evidence that the COVID-19 pandemic had an immediate and lasting impact on children's psychological, social, cognitive, and learning development, which led to a disruption in education and social life. This is why vaccination in this age group brought a positive externality to adolescents, which was a faster return to normal life and counteracted the consequences of confinement measures (disruption of schooling, psychiatric repercussions, etc.)[11].
In the case of vaccination in children aged 5 to 11, although the collective benefit was less clear as they were generally less infected, and by the time mRNA vaccines became available for this age group, the omicron variant was predominant and the effect of these vaccines on non-severe infections and transmission was still to be determined; The individual benefit was clear not only in somatic terms, but also in terms of schooling and mental health [14].
Because the level of antibodies against SARS-CoV-2 provided by the mother decreases significantly after 6 months of age, and because a high risk of infection and high transmissibility among children still existed in the first months of 2021, a global decision was made to recommend vaccination in children older than 6 months of age in a timely manner, in order to establish a stronger immune barrier as soon as possible to confront the constant mutation of the virus. For these reasons, in 2021, the WHO recommended that countries vaccinate their infant population over 6 months of age against COVID-19 [15].

In the present study, our results show that COVID-19 vaccines had a good short-term safety profile in the 6-month to 18-year age group. These findings are similar to safety data reported from pre-authorization trials for mRNA COVID-19 vaccines in pediatric ages,[16,17] which described mild to moderate transient injection site pain, fatigue, and headache,16,17,18 and similar to pharmacovigilance studies in Italy.[18]
The main results we can highlight from our study are that most children who developed ESAVIs had local manifestations that resolved without the need for healthcare services, as observed in other studies.[3]
Regarding comorbidities, these were infrequent in the population of children enrolled in this study, a fact that is not different from what other studies have shown with figures similar to ours. [19]
Other authors have reported that the majority of children developed local ESAVIs. 3,13 These included pain at the injection site and general symptoms such as fatigue, headache, and myalgia. These symptoms had also been previously detected in clinical trials, providing additional information, such as their increased frequency after the second dose. [19,20]

Our data show that in our population, in most AEFI cases, symptoms were mild and did not require medical attention. Recovery was achieved in less than 7 days, reflected in a decrease in symptoms reported at the second contact made per protocol.

There is no doubt that post-marketing safety monitoring and the reporting of suspected ESAVIs not described are the most appropriate strategies for evaluating less frequent adverse reactions associated with medications and vaccines.

Therefore, pharmacovigilance carried out by different healthcare centers plays a fundamental role in generating new evidence, especially at the local level.

Data extracted from spontaneous reports of ESAVIs due to COVID-19 were 0.23%–1.2% of events per 100,000 doses administered,20 a figure clearly lower than that of active FV studies such as the one developed in this study, which increases the registration rate by about 15 times.[13, 21,22]

Among the limitations of this study, it is worth highlighting that these were reports of suspected ESAVIs, where symptoms were only reported through an online survey rather than directly by a healthcare professional. That is, they were made by a family member who was invited to complete a form containing a list of known reactions and a self-report section. Most of the symptoms were associated with the symptoms described on the form. This limitation may have been exacerbated by the significant media coverage of the vaccination process, which could have led to the reporting of a previously known profile of suspected ESAVIs.

Another limitation is the small sample size, which prevented us from determining whether the similarities found between the most widely administered vaccines, Moderna Pediatric and Pfizer Bivariate, were due to confounding factors.

Another factor was the short surveillance period and the duration of the study, which did not extend beyond the second week, which is why the duration of symptoms could not be determined. However, the observation period is more than sufficient if we consider data from the literature in which an average duration for each symptom is described between 1 and 2 days, except for local pain and redness, whose duration is 3 days and 7 days for lymphadenopathy[18].

CONCLUSIONS

Active pharmacovigilance quadrupled the voluntary reporting rate for detecting ESAVIs in the pediatric population. The reported ESAVIs were not serious, demonstrating that COVID-19 vaccination is safe at the short-term period in this population.

Our findings support the data available in the literature on COVID-19 vaccination in children, which show a good safety profile of the mRNA vaccine in healthy children and those with comorbidities. We believe our data could be useful to reassure parents and promote pediatric vaccination. Further studies are clearly needed to evaluate the efficacy and the long term safety of the COVID-19 vaccine in children under 18 years of age and its degree of protection against new variants.

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