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Adverse effects of COVID-19 Pfizer-BioNTech vaccine in children aged 5-18 years in Saudi Arabia

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ABSTRACT

Coronavirus disease 2019 (COVID-19) can infect children of all ages. Despite the fact that children have a lower risk of exposure and are tested less frequently than adults, their incidence is similar to that of adults. The most effective way to prevent COVID-19 infection is by vaccination. The study's objective was to document vaccination side effects in children aged 5 to 18 years. This cross-sectional study had 303 participating kids between the ages of 5 and 18 in its sample. During the months of March and April 2022, a validated modified questionnaire was circulated as a Google form to KSA citizens via social networking sites. The questionnaire asked questions about the participant's background, socio-demographic information, vaccination history, the mild and major adverse effects of the Pfizer vaccine and how those symptoms affected the child's health and quality of life. There was a total of 303 responses; all of them received two doses of the Pfizer-BioNTech covid-19 vaccine. They were 163 female children (54 %) and 140 males (46 %). The most frequently reported minor adverse effects were body tiredness (88.2%), moderate fever (76.5%), mild headache (72.3%) and discomfort, redness and swelling at the injection site (90.7%). The most reported severe side effects were severe headache (32.8%) and high fever (21.8%). Only five children (4.2%) required hospitalization for 1-3 days. The most common side effects for the Pfizer Covid-19 were the mild and moderate one including pain, redness and swelling at the injection site, fatigue, fever and headache. Most of the symptoms were not severe to need hospital admission.

Keywords: COVID-19, SARS-CoV-2, Children, Pfizer-BioNTech vaccine, side effects.

1. INTRODUCTION

Coronavirus-2 which causes severe acute respiratory syndrome causes COVID-19. The first case of the illness was recorded in Wuhan, Hubei province, China, in December 2019 and it has since spread all over the world. The WHO (World Health Organization) proclaimed (COVID-19) a global pandemic on March 11, 2020. More than 516 million COVID-19 cases had been confirmed as of May 8, 2022 and more than 6 million deaths had been documented globally (Ossom-Williamson et al., 2020). As of May 8, 2022, there have been nearly 750.000 confirmed cases in Saudi Arabia with over 9,000 deaths.

COVID-19 can infect children of all ages. Even though children have a lower risk of exposure and are tested less frequently than adults, their incidence is much the same as that of adults (Bittmann, 2022). In studies in which children and adolescents were tested for acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection without concern to symptoms, infection rates in 5 years of age and older children were equal to or higher than those in adults (Dawood et al., 2022; Hobbs et al., 2020). Since COVID 19 first surfaced in December 2019, it has sparked a global crisis that has a negative influence on various areas, including education, the economy and public health (Shadmi et al., 2021). Most nations, including Saudi Arabia, used preventative measures during the pandemic, such as social isolation, mask use, a stay-at-home policy and shutdown. In respect of preventative measures, once the disease has expanded to pandemic, community immunity is required. As a result, it was determined that extensive vaccination campaigns were the only method effective for generating population immunity (Randolph and Barreiro, 2020; Jones and Helmreich, 2020).

Vaccination is the most reliable method of preventing infection with COVID-19. For the purpose of preventing COVID-19 in children aged 5 to 11 years, the Advisory Committee on Immunization Practices (ACIP) suggests the Pfizer-BioNTech COVID-19 vaccine (Fortner and Schumacher, 2021). In December 2020, the Pfizer-BioNTech COVID-19 Vaccine received its first emergency use approval from the United State FDA (Food and Drug Administration) (Woodworth et al., 2021). One of the first nations to launch COVID-19 vaccination efforts was Saudi Arabia. Before any other COVID-19 vaccines, the Pfizer-BioNTech COVID-19 mRNA vaccine was the first to receive Saudi Arabian approval.

The vaccination was first approved for some high-risk groups, such as healthcare workers and elderly persons with chronic conditions. After that, everyone could access it without charge, with the exception of kids and women who are pregnant. However, Saudi Arabia recently authorized the use of this vaccination for both pregnant women and children between ages of five and eighteen. In Saudi Arabia, more than 64 million doses of COVID-19 vaccination had been delivered (Assiri et al., 2021). There isn't a vaccine out there that has no negative effects or consequences. With any vaccine, expect local adverse symptoms such as pain, redness and swelling, as well as systemic side effects such as headache, nausea, malaise, muscle aches, shivering and fever (Kimmel, 2002; Omeish et al., 2021).

Other serious adverse effects, such as anaphylactic reaction to a vaccine or one of its components, have been documented. Furthermore, blood clotting events have been linked to the administration of COVID-19 vaccines, including those made by Pfizer, Astra Zeneca and Moderna vaccines (Lee et al., 2021). The aim of the study is to identify Pfizer vaccine side effects reported among children living in Saudi Arabia. The safety of the Pfizer-BioNTech vaccine among children is another goal.

2. METHODOLOGY

The Standing committee of Bioethics (SCBR) and deanship of scientific research at PSA University approved the research with approval No: SCBR-07-2022. An online survey that was self-administered was used in Saudi Arabia as part of a retrospective, cross-sectional study to gather information on the side effects that children between the ages of five and eighteen had after receiving the Pfizer-BioNTech (BNT162b2) vaccine. The questionnaire utilized Google Forms to generate a double language (Arabic and English) questionnaire that was given to Participants via social media between March and April of 2022. Participants in this research received two shots of the Pfizer-BioNTech vaccine.

The questionnaire was produced following an extensive review of the literature, which included Google Scholar, PubMed and other databases, with the goal of determining common mild, moderate and serious side effects following the Pfizer-BioNTech vaccine multiple sections were intended for the questionnaire. The first section includes an overview of the study's objectives, participant contact information to facilitate communication and general data collection about each participant, including the child's gender, age and history of type 1 diabetes, asthma and other chronic illnesses, as well as any prior SARS-CoV-2 infection. The second segment was designed to concentrate mostly on the mild and moderate adverse effects of the COVID-19 vaccination, such as soreness at the injection sites, exhaustion, headaches, low to moderate grade fever, nausea and vomiting. The third section for reporting the serious side effects as high grade fever, convulsions, chest pain, dyspnea, blood clots and anaphylaxis which might has been experienced by the study participants. In the fourth and final component, participants were asked to describe any doctor

visits following vaccination, hospital admissions following vaccination or medication use following vaccination, as well as how the side effects affected the child's health, activity level and quality of life.

The exclusion criteria were participants who did not offer informed consent, children blow 5 years, adults more than 18 years and children received one dose of the Pfizer-BioNTech vaccine. Children received a COVID-19 vaccination other than the Pfizer-BioNTech vaccine were also excluded.

For the data that was gathered, descriptive statistics were presented. For statistical purposes, additional descriptive analyses using the t-test and chi-square test were carried out for all participants, as well as for those who were shown side effects in comparison to those who weren't. For those who experienced mild and severe side effects, additional descriptive analyses were conducted using the t-test and chi-square test.

3. RESULTS

Social, history and demographic characteristics of the participants

There were a total of 303 responses; all of them received two doses of the Pfizer-BioNTech covid-19 vaccine. They were 163 female children (53.8%) and 140 males (46.2%). They were mainly of Saudi nationality. Saudi children were 254 (83.8%) with the median age was 14 years. A total of 11% of our participants have chronic diseases such as type 1 DM, bronchial asthma and congenital heart diseases. A total of 32% (97child) of the children had a previous Covid-19 infection. We divided our study participants into two categories, the first group did not experience any side effects 184 child (60.7%) and the second group which develop one or more side effects which were 119 children (39.3%) (Table 1, Figure 1, 2 and 3).

Table 1 Patient history, social and demographic characteristics of the participants (N=303)

Variable	Answer	Frequency	Percentage
Gender	Male	140	46.2
	Female	163	53.8
Age	5 to 9	39	12.9
	10 to 14	111	36.6
	15 to 18	153	50.5
Nationality	Saudi	254	83.8
	Non-Saudi	49	16.2
Allergy history	Yes	20	6.6
	No	283	93.4
Previous COVID 19 infections	Yes	97	32.0
	No	206	68.0
Medication history	Yes	18	5.9
	No	285	94.1
History of chronic diseases	No chronic disease	269	88.8
	Diabetes (type 1)	9	3.0
	Bronchial asthma	18	5.9
	Congenital heart diseases	6	2.0
	Blood clotting disorders	1	0.3
	Kidney diseases	0	0.0
	Cancer	0	0.0
	Others	3	1.0
The side effects after the Pfizer vaccine	Yes	119	39.3
	No	184	60.7

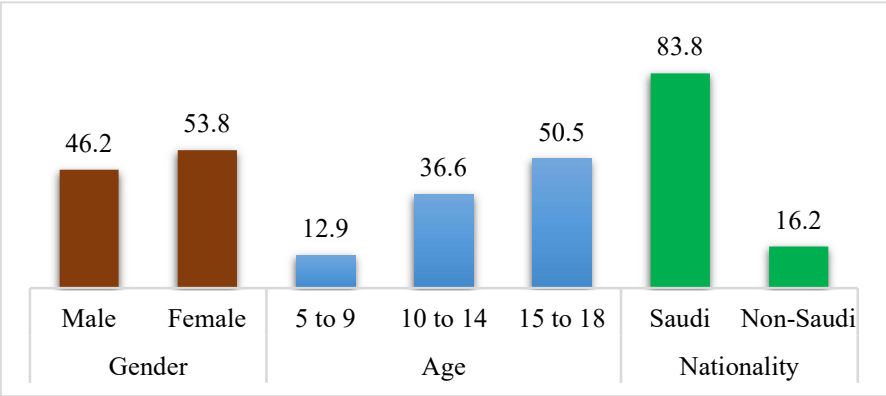

Figure 1 Percentage of gender, age and nationality

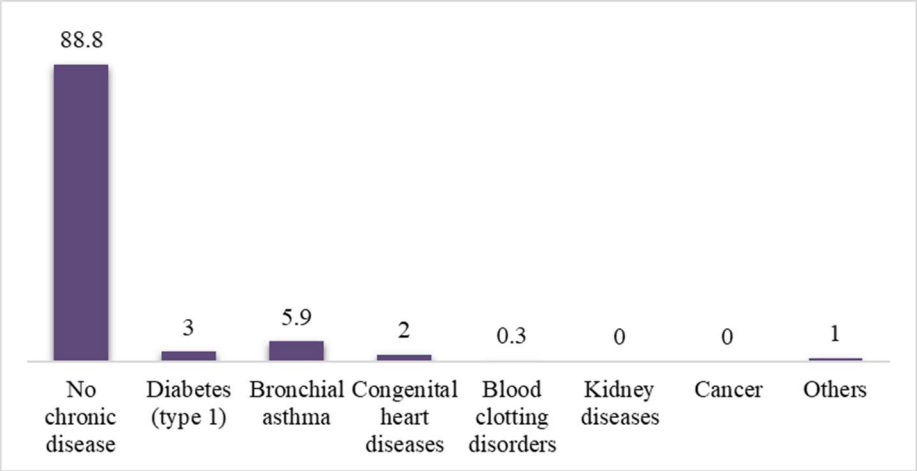

Figure 2 Percentage of chronic diseases

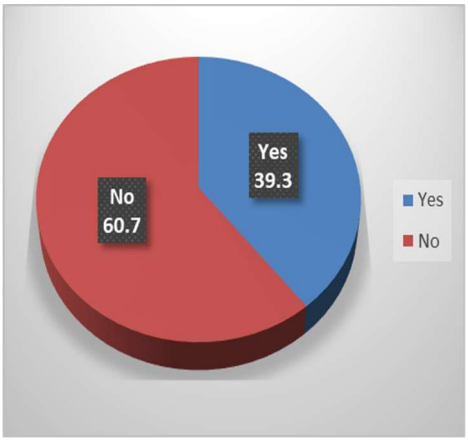

Figure 3 Percentage of side effects after the Pfizer vaccine

Adverse effects of vaccination

In this study a total of 119 children develop side effects following Covid-19 vaccination representing (39%). The most reported mild side effects were pain, redness and swelling at the site of injection (90.7%), body fatigue (88.2%), mild fever (76.5%) and mild headache (72.3%). Most of these side effects occur at the first two days after the vaccination and most of the study participants (78.2%) had received paracetamol only for the pain and the fever (Table 2).

Table 2 Mild to moderate side effects (N=119)

Variable	Answer	Frequency	Percentage
Mild to moderate fever below 39°C	No	28	23.5
	Yes, after the 1st dose	28	23.5
	Yes, after the 2nd dose	27	22.7
	Yes, after 1st and 2nd dose	36	30.3
Pain and redness	No	11	9.2
	Yes, after the 1st dose	25	21.0
	Yes, after the 2nd dose	13	10.9
	Yes, after 1st and 2nd dose	70	58.8
Mild headache (Does not affect the child's activity)	No	33	27.7
	Yes, after the 1st dose	22	18.5
	Yes, after the 2nd dose	28	23.5
	Yes, after 1st and 2nd dose	36	30.3
Body weakness, fatigue and exhaustion	No	14	11.8
	Yes, after the first dose	27	22.7
	Yes, after the second dose	30	25.2
	Yes, after first and second dose	48	40.3
Skin rash	No	111	93.3
	Yes, after the first dose	3	2.5
	Yes, after the second dose	3	2.5
	Yes, after first and second dose	2	1.7
Nausea & vomiting	No	92	77.3
	Yes, after the first dose	11	9.2
	Yes, after the second dose	6	5.0
	Yes, after first and second dose	10	8.4
Diarrhea	No	105	88.2
	Yes, after the first dose	5	4.2
	Yes, after the second dose	5	4.2
	Yes, after first and second dose	4	3.4
Timing of the side effects	First day of vaccination	53	44.5
	Second day of vaccination	53	44.5
	Third day of vaccination	8	6.7
	The fourth day of vaccination or after	5	4.2
Action needed	Paracetamol for fever and pain	93	78.2
	Warm water compresses	10	8.4
	Ibuprofen	3	2.5
	I didn't do anything	19	16.0
	Another action	5	4.2

Severe adverse effects

The most reported severe side effects were severe headache (32.8%), high fever (21.8%), chest pain (19.3%) and dyspnea (18.5%) (Table 3).

Table 3 Severe and serious side effects (N=119)

Variable	Answer	Frequency	Percentage
High grade over 39°C?	No	93	78.2
	Yes, after the 1st dose	7	5.9
	Yes, after the 2nd dose	9	7.6
	Yes, after 1st and 2nd dose	10	8.4
Chest pain	No	96	80.7
	Yes, after the 1st dose	7	5.9
	Yes, after the 2nd dose	8	6.7
	Yes, after 1st and 2nd dose	8	6.7
Dyspnea	No	97	81.5
	Yes, after the 1st dose	4	3.4
	Yes, after the 2nd dose	7	5.9
	Yes, after 1st and 2nd dose	11	9.2
Severe headache affecting the child's activity	No	80	67.2
	Yes, after the 1st dose	9	7.6
	Yes, after the 2nd dose	13	10.9
	Yes, after 1st and 2nd dose	17	14.3
Anxiety or depression	No	96	80.7
	Yes, after the 1st dose	6	5.0
	Yes, after the 2nd dose	11	9.2
	Yes, after 1st and 2nd dose	6	5.0
Seizures	No	109	91.6
	Yes, after the 1st dose	5	4.2
	Yes, after the 2nd dose	4	3.4
	Yes, after first and 2nd dose	1	.80
Severe allergic reaction	No	112	94.1
	Yes, after the 1st dose	2	1.7
	Yes, after the 2nd dose	3	2.5
	Yes, after 1st and 2nd dose	2	1.7
Blood clots	No	116	97.5
	Yes, after the 1st dose	2	1.7
	Yes, after the 2nd dose	1	.80
	Yes, after first and 2nd dose	0	0.0
Lymph node enlargement	No	109	91.6
	Yes, after the 1st dose	5	4.2
	Yes, after the 2nd dose	1	.80
	Yes, after 1st and 2nd dose	4	3.4
Dizziness or fainting	No	101	84.9
	Yes, after the 1st dose	9	7.6
	Yes, after the 2nd dose	5	4.2
	Yes, after 1st and 2nd dose	4	3.4
Appendicitis	No	114	95.8
	Yes, after the 1st dose	3	2.5
	Yes, after the 2nd dose	1	.80
	Yes, after1st and 2nd dose	1	.80

Health impacts of the adverse effects of Pfizer Covid-19 vaccine

More than half of the study participants who reported side effects can perform their daily activity (52.9%). The children can attend their schools regularly (40%) and who need paracetamol to help treat these side effects were (40%). Most of the side effects relieved without seeing a doctor in (85%) and did not need hospital admission in (95.8%) of the study participants and only five children (4.2%) need hospital admission for 1-3 days with complete cure (Table 4).

Table 4 Health impact and action needed (N=119)

Variable	Answer	Frequency	Percentage
The Child can perform his usual daily activities	Yes	63	52.9
	No	56	47.1
School attendance	Yes	47	39.5
	No	72	60.5
Medication needed	Yes	53	44.5
	No	66	55.5
Physician consultation	Yes	18	15.1
	No	101	84.9
Hospital admission	Yes	5	4.2
	No	114	95.8
Length of hospital stay	1 day	3	60.0
	2 days	1	20.0
	3 days	1	20.0
Ultimate impact	Full recovery of the child	109	91.6
	Another effect	10	8.4

4. DISCUSSION

COVID-19 infection can be prevented most effectively with vaccination. The Pfizer-BioNTech COVID-19 vaccine is advised for children aged 5 to 11 years old as a means of preventing COVID-19, according to the Advisory Committee on Immunization Practices (ACIP). The findings on safety are identical to those reported in clinical trials. Pfizer-BioNTech COVID-19 vaccine recipients aged five to eleven years should be informed that local and systemic responses are common following vaccination (Woodworth et al., 2021).

In order to achieve herd immunity, the KSA was one of the first countries to authorize the Covid-19 Pfizer vaccine in children aged 5 years and above after the sufficient data on vaccine efficacy and safety in this age range became available. We observed that 119 children (39%) developed one or more adverse effects after receiving the Pfizer Covid-19 vaccination, whereas 184 children (61%) did not. This is consistent with a prior study on the negative effects of the Pfizer vaccine in adults, which revealed the same results (40 %) (Alhazmi et al., 2021).

We observed that pain, redness and edema at the injection site were the most common reported side effects (90.7%) for the children in our study, followed by body fatigue (88.2%), mild fever (76.5%) and mild headache (72.3%). These findings are consistent with the FDA (Food and Drug Administration) guidelines established following the vaccination trial (Meo et al., 2021). Most adverse effects appeared within the first two days and were mild to moderate in severity. These findings are like those of CDC and FDA clinical trials. Severe headache (32.8 %), high fever (21.8 %), chest pain (19.3 %) and dyspnea (18.5 %) were the most reported severe side effects; these findings are consistent with the CDC (Centers for Disease Control) prevention, which found that among 100 reports of severe serious effects, fever was the most common (29 %) (Kadali et al., 2021).

Our findings revealed a high prevalence of neurological side effects such as anxiety and depression (19.3%), dizziness (15.1%), and seizures (8.4%), which contrasts with a previous study, less than 1% prevalence of neurological symptoms such as depression. This could be due to over diagnosis of symptoms and sometimes, shivering can be misdiagnosed as a seizure. We also discovered that after receiving the Pfizer vaccination, 10 children (8.4%) developed lymphadenopathy, 5 children (4.2%) developed appendicitis and 3 children (2.5%) developed blood clots and thrombosis.

We gave our research participants the option of reporting any other adverse effects not specified in the questionnaire and we found that 6 female teenagers (5%) reported menstrual abnormalities such as delayed periods and menorrhagia after receiving the Pfizer vaccination. More than half of our study participants who experienced negative effects were able to continue with their daily activities (52.9%). The children can go to school on a regular basis (40%) and who require paracetamol to deal with the adverse effects were (40%). Most of the side effects were alleviated without seeing a doctor (85%) and did not require hospitalization (95.8%) of the study participants, with only five children (4.2%) requiring hospitalization for 1-3 days with complete cure.

Many studies have found that most adverse effects are low to moderate in severity and resolve within a few days of immunization (Ramasamy et al., 2020). Our study has one limitation: It only recorded the vaccine's short-term side effects. In our study, the vaccine's long-term adverse effects still unknown and future research is needed to investigate other unusual long-term

side effects after COVID-19 vaccination, such as thrombosis, lymphadenopathy and other gynecological disorders in adolescent girls.

5. CONCLUSION

The vaccine of Pfizer BioNTech Covid-19 is safe, with a minimal risk of major adverse effects that can be well treated. The most frequent mild and severe side effects with Pfizer Covid-19 were pain, redness, swelling and weariness at the injection site. Most of the symptoms were not severe enough to require hospitalization when the vaccine was administered and the symptoms only lasted a few days following immunization. The symptoms were generally well tolerated, but more experiments are needed to determine the long-term effects and safety profiles.

Recommendation

All children aged 5 to 18 years old should be recommended to get vaccinated and warned that systemic and local reactions may happened after immunization with the Pfizer-BioNTech COVID-19 vaccine, but that these side effects can be controlled well. Future research will investigate other rare long-term side effects of COVID-19 vaccine, such as thrombosis and lymphadenopathy.

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Authors' Contributions

All authors contributed to the research and/or preparation of the manuscript. Abbas Elbakry A Elsayed, Naif Alrudian and Hussein Koura participated in the study design and wrote the first draft of the manuscript. Abdulmajeed Adel Al sharif and Saif Fahad Alkathiri collected and processed the samples. Abdullah Abdulrahman Alotaibi, Abdulmohsen Khalid Alghamdi, Nasser Saeed ALdosari and Ali Hassan A Ali participated in the study design and performed the statistical analyses. All of the authors read and approved the final manuscript.

Ethics Approval

All series of steps that were implemented in this study were in compliance with Ethics Committee of Prince Sattam Bin Abdulaziz University Institutional Review Board (SCBR-07-2022).

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Conflict of interest

The authors declare that there is no conflict of interests.

Data and materials availability

All data sets collected during this study are available upon reasonable request from the corresponding author.

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