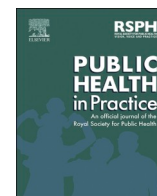




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## A study of SARS-CoV-2 delta variant breakthrough infections and side effects of the Oxford-AstraZeneca vaccine

Nawfal R. Hussein<sup>a</sup>, Bizav Naji Rasheed<sup>b</sup>, Ibrahim A. Naqid<sup>a,\*</sup>, Arshed Mustafa Dirbaz<sup>c</sup>, Zana Sidiq M. Saleem<sup>d</sup>, Nashwan Ibrahim<sup>d</sup>, Dildar H. Musa<sup>d</sup>, Sulav Muslih Mohammed<sup>c</sup>

<sup>a</sup> Department of Biomedical Sciences, College of Medicine, University of Zakho, Kurdistan Region, Iraq

<sup>b</sup> Department of Medical Laboratory Technology, College of Health and Medical Techniques, Shikhan, Duhok Polytechnic University, Duhok, Kurdistan Region, Iraq

<sup>c</sup> Nizarke Primary Health Center, Directorate of Health, Duhok, Kurdistan Region, Iraq

<sup>d</sup> Department of Internal Medicine and Surgery, College of Medicine, University of Duhok, Kurdistan Region, Iraq

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### ABSTRACT

**Objective:** This study aimed to investigate the breakthrough infection rate and safety profile of the AstraZeneca vaccine.

**Methods:** The breakthrough COVID-19 infection rate was defined as a positive polymerase chain reaction test 14 days after the vaccine dose. Safety was assessed as local reactions and systemic events that occurred within 14 days of receiving vaccine doses.

**Results:** The average age of the 265 participants was 43.85 years and 169 (63.77%) were male. After the second dose, 18 (6.71%) participants contracted the infection. The SARS-CoV-2 delta variant was responsible for all infections but no participants required hospitalisation. We found significant correlations between post-vaccination IgG levels and post-vaccination infection ( $P = 0.001$ ; odds ratio [OR] = 0.959; 95% Confidence interval [CI]: 0.944–0.974), and between a history of previous infection and post-vaccination infection rates ( $P = 0.005$ ; OR = 0.1; 95%CI:0.009–0.6). IgG levels were significantly higher in women than in men ( $P = 0.006$ ) and in patients who developed side effects after vaccination than in those without side effects ( $P = 0.04$ ). A significant association was found between a history of COVID-19 infection prior to vaccination and IgG levels ( $P = 0.001$ ).

**Conclusions:** The vaccine is effective in preventing severe disease, with few side effects.

### 1. Introduction

In December 2020, a cluster of patients with pneumonia of unknown aetiology was reported in China [1]. Initial investigations identified a novel coronavirus, designated as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as the cause. In March 2021, the World Health Organization declared the coronavirus disease 2019 (COVID-19) pandemic which was spreading worldwide [1]. With more than 270 million infections and more than 5 million confirmed deaths attributed to COVID-19 as at November 2021, this pandemic is considered one of the deadliest in recent years. This deadly pandemic has stimulated the development of vaccines against the virus. Different vaccines have been developed with varying efficacy and safety. Among these, the Oxford-AstraZeneca partnership has developed the ChAdOx1 nCov-19

(AZD1222) vaccine. The AstraZeneca vaccine uses a chimpanzee adenovirus vector [2]. Adenovirus is genetically modified so that it cannot infect humans [2]. The efficacy and safety of AstraZeneca vaccines have been studied in many countries worldwide, including the UK, Brazil, and South Africa [2]. The vaccine has been administered to adults older than 18 years with an acceptable efficacy and safety profile. It has been shown that two doses of the AstraZeneca vaccine have 70% efficacy against COVID-19 with serious side effects occurring in less than 1% of recipients [2].

In the Kurdistan region of Iraq, the first case of COVID-19 was reported in March 2021 [3–5]. Since then, the region has experienced three devastating waves with >350000 registered infections and a death toll of >7000 [4,5]. These waves have a negative impact on an already weak health system [6–8]. The re-infection rate in the region is low [9–11]. Different clinical presentations of the disease have been

\* Corresponding author. Microbiology and immunology (UK) Head of Biomedical Science Department College of Medicine, University of Zakho, Kurdistan Region, Iraq.

E-mail address: [ibrahim.naqid@uoz.edu.krd](mailto:ibrahim.naqid@uoz.edu.krd) (I.A. Naqid).

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### List of abbreviations

<b>SARS-CoV-2</b>	severe acute respiratory syndrome coronavirus 2
<b>COVID19</b>	coronavirus disease 2019
<b>AZ</b>	AstraZeneca vaccine
<b>PCR</b>	polymerase chain reaction
<b>RTPCR</b>	Real time polymerase chain reaction
<b>RdRP</b>	RNA-dependent RNA polymerase

reported in the region [10,12–14]. Real-world experience has shown different efficacy and safety profiles for vaccines [15]. Therefore, we aimed to study the COVID-19 breakthrough infection rate and the safety profile of the AstraZeneca vaccine.

## 2. Methods

### 2.1. Outcomes

The primary outcome of our study was to determine the rate of COVID-19 breakthrough infection, defined as the development of signs and symptoms as well as positive polymerase chain reaction (PCR) test results 14 days after receiving the second dose of the vaccine. In addition, the incidence of hospitalisation, severity of infection, and case fatalities were studied.

The participants of who contracted the infection in our study were classified into groups of mild, moderate, and severe cases. Patients without any symptoms or signs of pneumonia and negative normal imaging were classified as mild cases. Cases were classified as moderate when there were symptoms and signs of pneumonia plus positive imaging for pneumonia but with normal respiratory rates and oxygen saturation of 95–93% at rest. Cases were defined as severe when patients had radiological evidence of pneumonia plus respiratory distress, oxygen saturation of  $\leq 93\%$  at rest, or arterial partial pressure of oxygen (PaO<sub>2</sub>)/fraction of inspired oxygen (FiO<sub>2</sub>)  $\leq 300$  mmHg (1 mmHg = 0.133 kPa).

The safety outcome was the recording of local reactions and systemic events that occurred within 14 days of receiving vaccine doses. Participants were asked to report any side effects by phone. In addition, participants were asked about side effects at each visit to the primary healthcare centre and, finally, through phone calls at the end of the study.

### 2.2. Participants

Volunteers aged 19–76 years who were already registered to receive the vaccine and agreed to participate were included in the study which was conducted in Duhok City, Kurdistan Region of Iraq between April to October 2021. Exclusion criteria included individuals who had a recent history of COVID-19 infection in the last 6 months, signs and symptoms of infection, pregnancy, recent coagulopathy, and any confirmed or suspected autoimmune or immunodeficiency disease. During the first visit to the healthcare centre, participants completed a questionnaire which included questions regarding sex, age, and symptoms of infection. In the following visits, participants completed a questionnaire which included questions on post-vaccination side effects. The participants were followed up for 104 days (including 14 days for the vaccine to work plus 90 days) after receiving the second dose.

### 2.3. RNA extraction and RTPCR

When symptoms developed, participants were tested using a PCR test. According to the manufacturer's instructions, RNA was extracted from nasopharyngeal samples using a QIAamp Viral RNA Mini RNA,

eluted in 50  $\mu$ L of RNase-free water, and stored at  $-80$  °C until use. In this study, two reactions were involved in RT-PCR testing. The first reaction targeted a conserved region of a 76 bp long fragment from the E gene (LightMix). In the second reaction, a 100 bp fragment from a conserved region of the RNA-dependent RNA polymerase (RdRP) gene was targeted (LightMix). The test was considered positive if both the reactions were positive. The test was considered negative if both reactions were negative. If one reaction was positive and the other negative, the test result was considered indeterminate. The SARS-CoV-2 delta variant was determined using the PowerCheck SARS-CoV-2 S-Gene mutation detection kit ver.1.0.

### 2.4. Immunoglobulin G (IgG) testing levels

IgG levels were measured at 30th day after the second dose of vaccination. MAGLUMI 2019-nCoV IgG was used to measure IgG levels. The measurements were calibrated against an internal standard. To quantify the results, a six-point standard curve was used. After quantification, results were expressed as arbitrary units/mL (AU/mL). The results were considered negative if the concentration was  $<1.0$  AU/mL.

### 2.5. Statistics

Statistical analyses were performed using the GraphPad Prism version 8. Statistical significance was set at  $p < 0.05$ . The relationship between the studied variables and IgG levels was reported as mean  $\pm$  standard deviation (SD). The *t*-test was used to analyse the numerical data, while the chi-squared test and Fisher's exact tests were used to analyse categorical data. Pearson's correlation coefficient was used to study the relationship between age and IgG levels. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated.

### 2.6. Ethics

The study protocols, questionnaire, and consent forms were approved by the Ethics and Scientific Committee of the College of Medicine, University of Zakho, Duhok City, Kurdistan Region of Iraq. Written consent was obtained from all participants.

## 3. Results

### 3.1. Participants

A total of 265 participants were recruited for the study. The median age of the participants was 43 years (standard error of mean: 0.83; interquartile range: 33–52 years) and 169 (63.77%) were male. Ninety-three (35.09%) participants had a history of COVID-19 infection  $>6$  months prior to vaccination. The number of participants who had side effects was 205 (77.36%) after the first dose of vaccination and 33 (12.45%) after the second dose (Table 1). Among them, 31/33 (93.93%) reported side effects after the first dose (see Table 2).

Three participants (1.12%) contracted the infection after the first dose of the vaccine and were excluded from further analysis. After the second dose, 18 (6.71%) participants contracted the infection. The median age of those who contracted the infection after the second dose was 41.5 years (standard error of mean: 3.54; interquartile range: 34–62 years) and 13/18 (72.22%) were male. All participants who contracted

**Table 1**  
Number of participants with side effects after first and second doses.

	Side effects (No. %)	No side effects (No. %)	Total
After first dose of vaccine	205 (77.36)	60 (22.64)	265
After second dose of vaccine	33 (12.45)	232 (87.55)	265

**Table 2**  
Side effects after first and second doses of vaccination.

Side effect	After first dose (No.%)	After second dose (No.%)
Fever	184 (68.66)	24 (8.96)
Injection site pain	65 (24.25)	6 (2.24)
Myalgia	84 (32.34)	5 (1.87)
Headache	73 (27.24)	8 (2.99)

infection had the SARS-CoV-2 delta variant. Among those who contracted the infection, four had mild infection and the rest had moderate infection; all were treated at home and did not require hospitalisation. No deaths were reported in the patients who contracted the infection after vaccination.

We found a significant correlation between post-vaccination IgG levels and infection ( $P = 0.001$ ; OR = 0.959; 95%CI 0.944–0.974) (Table 3). Moreover, a history of previous COVID-19 infection was significantly associated with lower post-vaccination infection rates ( $P = 0.005$ ; OR = 0.1; CI = 0.009–0.6) (Table 3). No associations were found between age, sex, side effects, and post-vaccination infection rates (Table 3).

### 3.2. IgG levels

IgG levels were significantly higher in women than in men ( $p = 0.006$ ) and were significantly higher in patients who developed side effects after vaccination than in those without side effects ( $P = 0.04$ ) (Table 4). No significant association was found between age and IgG levels ( $P = 0.08$ ,  $r = -0.1054$ , R squared = 0.0111) but a significant association was found between a history of COVID-19 infection prior to vaccination and IgG levels ( $P = 0.001$ ) (Table 4).

## 4. Discussion

Our region has experienced three devastating waves of COVID-19 infection [16,17]. In this study, we investigated the rate of COVID-19 breakthrough infections in people receiving two doses of the Oxford-AstraZeneca vaccine. Of the 268 participants, only 1.12% contracted infection after the first dose of the vaccine and were excluded from further data analysis. In addition, 6.71% of patients contracted the infection after the second dose. Among those who contracted the infection, four had mild infections and the others had moderate infections; all patients were treated at home and did not require hospitalisation. Our results are in agreement with a study from Vietnam that reported an 8% breakthrough infection rate after vaccination, which were mainly mild infections [18]. Such mild-to-moderate infections that do not require hospitalisation is consistent with vaccine efficacy in

**Table 3**  
The association between various factors and post-vaccination infections.

Variable	Post-vaccination infection		Statistical analysis		
	Infected	Not infected	P value	OR	95 %CI
Age: Mean ± SD	46.28 ± 15.01	43.67 ± 13.42	0.42	1.01	0.979–1.05
Gender	Male n (%)	156 (92.31)	0.61	2	0.5–2
	Female n (%)	63 (65.62)			
Previous history of COVID-19: n (%)	1 (1.08)	92 (98.92)	0.005	0.1	0.009–0.6
Post vaccination IgG level: Mean ± SD	35.63 ± 34.85	85.68 ± 26.79	0.001	0.959	0.944–0.974
Side effects: n (%)	12 (5.85)	193 (94.15)	0.25	0.6	0.2–2

SD: Standard Deviation; OR: Odd Ratio; CI: Confidence Interval.

**Table 4**  
The association between various factors and IgG levels.

Variables	Relationship between factors and IgG levels		P value
Gender	Male: 78.53 ± 33.04	Female: 88.88 ± 22.78	0.006
Side effect	Yes: 84.29 ± 28.59	No: 75.39 ± 34.16	0.04
Previous history of COVID-19	Yes: 95.71 ± 14.63	No: 75.02 ± 33.66	0.001

preventing severe infection and hospitalisation. It seems that the vaccine is very effective in the first three months after receiving the second dose. Further studies are needed to investigate the efficacy of such a vaccine beyond three months and to determine the best time for receiving boosters. The first case of infection with the SARS-CoV-2 delta variant was diagnosed in the Kurdistan region on the 15th of July 2021. By mid-August, the SARS-CoV-2 delta variant was the dominant variant in this region. All recorded breakthrough infections in our study were associated with the SARS-CoV-2 delta variant. The efficacy of the vaccine against other variants is unclear because no study has been conducted in this region before the arrival of the delta variant.

In our study, side effects were more common after the first dose, with rates of 77.36% and 12.45% after the first and second doses, respectively. This is in contrast to the UK, where side effects have been reported in 11.7% and 22% of patients after the first and second doses, respectively [19]. In our study, fever was reported in 68.66% and 8.96% of participants after the first and second doses, respectively. This is much higher than that reported by Jordanian health authorities and Polish health workers, where fever was reported by 35% and 13.3% of participants, respectively [20,21]. In our study, myalgia and headache were reported in 32.34% and 27.24% of participants, respectively. Injection site symptoms were reported in 24.25% and 2.24% of patients after the first and second doses, respectively. These figures are much lower than those reported in Jordan, Ethiopia, and the UK [19,20,22]. In contrast to other studies [23,24], no thromboembolic side effects were reported in our study. The discrepancies among the reported side effects can be explained by the genetic makeup of the studied population, sample size, and study design.

In agreement with a study conducted in Israel [25], we found that lower levels of neutralising antibodies were associated with breakthrough infections. Similar results were reported in a study conducted in Vietnam [18]. In addition, we found that the development of side effects was associated with higher IgG levels. This may be explained in part by the fact that the development of side effects may reflect a better immune response and, hence, more protection. Furthermore, a previous history of COVID-19 infection, 6 months prior to vaccination was associated with higher IgG levels. This can be explained by prior experience of the immune system with the virus. In a study conducted in Romania, IgG levels showed a 12-fold increase in men and an 11-fold increase in women. However, the IgG levels were homogenised after the second dose [26]. In agreement with another study [27], we found that the IgG levels were higher in women than in men. This is difficult to explain, and further studies are needed to understand this difference. The same study reported that IgG levels are higher in younger participants, although there was no statistically significant association [27]. In contrast, no significant association was found between IgG levels and age in our study which may possibly be due to the difference in study design and the genetic makeup of the participants.

Our study has limitations. Firstly, the sample size of our study was small. Measuring IgG levels was expensive and there was no enough budget to increase the sample size. Secondly, participants of this study were not randomized. To avoid bias, all participants who attended the primary healthcare and agreed to participate were included. Thirdly, self-reporting side effect might have decreased reporting. However, the participants were asked about side effects frequently with each

subsequent visit and in the final interview.

## 5. Conclusions

The vaccine was effective in preventing severe infection and hospitalisation in the first three months after vaccination. Post-vaccination IgG levels seemed to affect the post-vaccination infection rate, as we found a significant correlation between post-vaccination IgG levels and post-vaccination infections. A significant association was found between sex, history of post-vaccination side effects, previous history of COVID-19 and IgG levels. More studies recruiting a larger sample size for a longer duration are needed to investigate the efficacy of this vaccine.

## Author contributions

All the authors were involved in designing the research, conducted research, extracted data and wrote the manuscript. All authors had primary responsibility for the final content of the manuscript and all authors read and approved the final manuscript.

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## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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