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Single Center Study of Vaccination Breakthrough Infection with SARS-CoV-2 Among Erbil Population in August 2021

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Abstract

Objectives: This is a first study to determine the incidence of COVID-19 infection in the post-vaccinated in Erbil City population.

Methods: This prospective study was conducted in the Central Health Laboratory in Erbil City over a period from 1st to 31st of August 2021. All vaccinated & non vaccinated persons (18 years of age and above) who had symptoms suggestive of COVID-19 were engaged in the study. Nasopharyngeal swabs were collected and examined for SARS-CoV-2 by real-time RT-PCR implemented to all attendance according to World Health Organization guidelines.

Results: A total of 2934 persons had attended the Central Laboratory for checking during the study period. From this total number, 551 (18.8%) were vaccinated while 2383 were nonvaccinated (81.2%). Sixty one persons (61, 11.1%) of the vaccinated group showed a positive PCR. The highest incidence of PCR positivity according to age range, gender and vaccine dose, were as follows: male (42; 68.9%), 33–47 years (36; 59%), second dose (36; 59%) respectively. Statistically, the differences of distribution of the PCR positivity concerning the these factors were: non-significant. The higher incidence of PCR positivity was among the nonvaccinated group (449, 18.8%) and statistically, the differences of distribution of the PCR positivity between both groups of vaccinated and the nonvaccinated was significant ($P \leq 0.05$).

Conclusion: Primarily the present study conclude that SARS-CoV-2 incidence among vaccinated persons was 11.1%. Overall the present data provides further assurances of the effectiveness of the vaccines even when the vaccine was not able to prevent completely the infection. Further studies are needed to explore this topic.

Keywords: SARS-CoV-2, vaccines, polymerase chain reaction, post-vaccination, breakthrough, Erbil

Introduction

COVID-19 is a novel infectious malady caused by a SARS-CoV-2 virus, which is demonstrated mostly as an acute respiratory disease with an interstitial alveolar pneumonia. Yet, it can involve different organs encompassing the heart, kidneys, nervous system, blood and the digestive tract[1].

COVID-19 vaccines are efficient and pivotal weapons to boost the control of this pandemic[2]. Vaccination against COVID-19 has been considered as the most influential mean to halt the dispersal of the virus, beside the protective measures utilized by each individual[3].

The COVID-19 mRNA vaccines (from Biontech/Pfizer and Moderna) have been authorized in different countries (including the USA and the EU) after successful clinical trials and are already in prevalent use[4]. The two products contain a nucleoside-modified mRNA, encoding the sequence of the full-length S protein with two stabilizing proline mutations in S2 to preserve the native prefusion conformation. Both vaccines use lipid nanoparticles for delivery[5]. In the real-world settings, the Pfizer-BNT162b2 vaccine is approximately 90% effective in preventing SARS-CoV-2 infection and 94–100% effective in preventing severe or fatal disease[6].

Meanwhile, several vaccines based on different non-replicating adenovirus vectors and the full-length S protein are used for vaccination campaigns in many countries after approval by national and international authorities[3]. These vaccines include products of the Gamaleya Institute in Moscow (Sputnik V), University of Oxford/AstraZeneca (AstraZeneca, Cambridge, UK) (ChAdOx1-S/AZD1222), the Beijing Institute of Biotechnology/CanSino (CanSino Biologics, Tianjin, China) and Janssen Pharmaceutica (Janssen Pharmaceutica, Beerse, Belgium)[7]. In these vaccines different adenoviruses are used as vectors but the basic principle of production platforms and mechanism of action is the same[8]. The gene for the SARS-CoV-2 S protein is synthesized as a DNA and engineered into the DNA genome of adenoviruses, replacing an adenovirus gene (E1) that is essential for virus replication[9]. Through this manipulation, the adenovirus can no longer replicate and cannot give rise to a full infectious cycle (it is therefore referred to as non-replicating viral vector), but it can still enter cells and express the inserted foreign gene to produce the coronavirus S protein[10,11].

However, early studies propose that COVID-19 vaccines shelter against severe illness; however, postvaccination SARS-CoV-2 infections (i.e., breakthrough infections) can occur because COVID-19 vaccines do not offer 100% protection[12]. More recently, postvaccination infections in fully vaccinated persons have been mentioned though little is known about the risk factors, clinical presentation and outcomes for breakthrough infections compared with demographically and clinically similar controls[13]. Thus, the objectives of this study were to report any postvaccination infections among fully or partially vaccinated persons, and to determine some factors like: age, gender, and vaccine dose which may have an association with infections in the vaccinated persons. Our aim was not to determine specific vaccine efficacy or effectiveness.

Materials and Methods

Study Protocol

This prospective study was carried out in the Molecular diagnostic department at the Central Public Health Laboratory

(CPHL) in Erbil City through a period from August 1 2021 to August 31 2021. This study was achieved with the cooperation of Department of Microbiology, College of Medicine, Hawler Medical University, Erbil, Iraq.

Moral Considerations

This study was confirmed by the: Ethics Committee of Hawler Medical University, Erbil and approved by Erbil director health for collecting samples and data from referred patients at CPHL-Erbil. Acquainted endorsement was possessed from each patient. The patients were aware of study's goals and they could regress thereof if they wished so to do.

Study Population

The study population included all suspected cases of Covid-19 attending CPHL for PCR screening of SARS-CoV 2 infection during study period. Inclusion criteria were: 18 year old and above, and inhabitants of Erbil governorate. All the attendance who conferred agreement for SARS-2 PCR testing and to share in this study were involved in the study. Relevant clinical information, including patients' vaccination status (type and dose number) age, gender, date of birth, was collected upon recruitment. Non-consenting or unwilling patients were excluded from this study.

SARS-CoV-2 Testing by Real-time RT-PCR

Nasopharyngeal and/or throat swab samples were collected in viral transport medium from the enrolled patients by a trained laboratory technician and examined for SARS-CoV-2 by real-time RT-PCR following World Health Organization guidelines.

Viral RNA was extracted using SphaeraMag DNA/RNA Isolation Kit on automate Phoenix-Pure96 system (procomcure com.) following manufacture's instruction. Real-time RT-PCR was done using DIAGNOVITAL®SARS-CoV-2 Real-Time PCR Kit (RTA Laboratories Biological Products Pharmaceutical and Machinery Industry) on Rotor-Gene Q (QIAGEN) Real-Time PCR Detection System. DIAGNOVITAL®SARS-CoV-2 detects the presence of 2 different and highly specific gene sequences of SARS-CoV-2: E gene and RdRp gene. All 2 assays must be tested positive to confirm the sample as SARS-CoV-2-positive.

Statistical Analysis

The data analysis was performed using descriptive statistics, including frequency, and frequency percentage. Comparisons were made using chi2 test by using standard equations. The results were announced with $P \leq 0.05$ or $P \leq 0.01$ as the acceptable level of significance.

Results

A total of 2934 persons had attended the Central Laboratory for checking during the study period. Of this total number, 551 (18.8%) were vaccinated while 2383 were nonvaccinated (81.2%).

Table 1 delineates the incidence of PCR positivity among vaccinated persons according to age, gender and number of dose. It is noted that sixty one persons (11.1%) of the vaccinated group showed a positive PCR. The highest incidence of PCR positivity according to age range, gender and dose, were as follows: male (42; 68.9%), 33–47 years (36; 59%), second dose (36; 59%) respectively. Statistically, the differences of distribution of the PCR positivity concerning the abovementioned factors were: non-significant.

Table 1. **Incidence of PCR positivity among vaccinated persons in relation to age, gender, number of dose**

Parameter	N	PCR (+)	%	PCR (–)	%
Age					
18–32	171	18	29.5	153	31.2
33–47	301	36	59	265	54.1
48–62	54	3	4.9	51	10.4
63–82	25	4	6.6	21	4.3
Total	551	61	100	490	100
		df = 3 NS			
Gender					
Male	421	42	68.9	379	77.3
Female	130	19	31.4	111	22.7
Total	551	61	100	490	100
		df = 1 NS			
Dose					
First	179	25	41	154	31.4
Second	372	36	59	336	68.6
Total	551	61	100	490	100
		df = 1 NS			

Table 2. **Incidence of PCR positivity among vaccinated and nonvaccinated persons**

Parameter	Vaccinated	%	Nonvaccinated	%	Total
PCR(+)	61	11.1	449	18.8	510
PCR (–)	490	88.9	1934	81.2	2424
Total	551	100	2383	100	2934

$\chi^2 = 18.8187$ df = 1 Significant ($P \leq 0.05$)

Table 2 clarified the incidence of PCR positivity among vaccinated persons in comparison to the nonvaccinated persons (control). The higher incidence of PCR positivity was among the nonvaccinated group (449, 18.8%) and statistically, the differences of distribution of the PCR positivity between both groups of vaccinated and the nonvaccinated was significant ($P \leq 0.05$).

Discussion

To the best of our knowledge, no published data are available on the occurrence of SARS-CoV-2 infections among vaccinated citizens in Erbil governorate, hence this study can be considered as the first study of such quality to deal with and investigate the incidence, correlated factors among these persons.

The incidence of positive PCR in the post-vaccinated group was 11.1%, which was differed significantly from the incidence in the nonvaccinated group (18.8%). It seems that from the results of the present study, factors like age, gender and dose had no impact on the high incidence of PCR positivity among vaccinated group.

Post-vaccinations infections are a matter of interest but sufficient data concerning these infections are not available in real world setting[14]. Vaccines have effectiveness in decreasing risk of getting COVID-19 infections by 70–90%, and also shield from severe infection[13]. It is possible, therefore, some people who are fully vaccinated against COVID-19 may get COVID-19 infection[4].

A recent study by Amit et al.[15] showed that the ratio of vaccinated people infected with COVID-19 after receiving the first dose vaccine was 0.5%, while a study achieved by Hatmal MM et al. in Jordan[16] declared that the incidence was 7.02% after the first dose only. This variation in ratios could be due to the fact that Amit et al.'s study involved only healthcare workers; this class of the population is assumed to be well-educated and has a furthermore strict commitment in following prevention regulations to avoid COVID-19 infection. In Amit's study, individuals infected with COVID-19 were also tested in the early post-vaccination period (1–10 days), while there was no time limit in the present study.

Anecdotal report (unpublished) from India & declared records from other part of world (refer website of Center for Disease Control, USA) deduce that these infections are existing. In addition, it seems that these breakthrough infections are either asymptomatic or mild in nature[14].

Despite the fact that the preventive efficacy of COVID-19 vaccines is argued in clinical trials, the knowledge about what happens following vaccination in the real world is still modest, especially among the general population[16]. Thus, knowing what to expect after vaccination will help with public education, dispelling myths, and lowering the apprehension about COVID-19 vaccines[15]. Fear and suspicion, as well as a lack of information about clinical trials, have all been identified as factors that may lead to hesitancy in receiving the COVID-19 vaccines[10].

The present study found a relatively high SARS-CoV-2 following receipt of the second dose. Polack et al.,[4] and Butt AA et al.[13] concluded that while the vaccine's protective effect may not be obvious during the first two weeks after vaccination so recipients may wrongly realize themselves to be at a reduced risk of SARSCoV-2 infection and become less firm to nonpharmacological preventive measures such as social distancing and face covering.

Careful education and counselling during the vaccination process could help efforts to minimize such risk-compensation behavior[17].

The concept of vaccination is dependent on triggering an adaptive immune response, B and T cells, from which memory cells will evolve and furnish a long-lasting immunity. Although an immune response can take place as early as within the first week, long-lasting immunity can take up to 4 weeks to develop[7]. The BNT162b2 vaccine was shown to elicit an effective humoral (antibody-mediated) and cellular (T-cell-mediated) responses a week after the booster dose. However, the response between the first and second doses was negligible[18].

Vaccine efficacy does not always portend vaccine effectiveness, i.e., the protection advantage related to a vaccine when administered non-randomly under field conditions. Equally, randomized controlled trials were done in a nominated age group, or geographical setting might not predict effectiveness if the vaccine is more widely prevailed. Alternative vaccine platforms or the addition of adjuvants may be required for adequate immunogenicity, as for influenza vaccines[19,20].

It is noted from the results of the present studies, old ages persons had a lower incidence of PCR positivity while the highest incidence was in the age range of 33–47 years (59%). A study by Butt AA et al.[21] in Qatar announced that increasing age was independently associated with a higher risk of severe disease or death in persons with breakthrough infection. In addition, encumbrance of comorbidities was not linked with the higher risk of severe disease or death[21, 22]. It is worthy to mention that Central Laboratory in Erbil offers its services for public and military personals so it is expected that most attendance will be males and of age ranges mostly detected in the present study.

The strengths of our study include: a national population, appropriately matched control group, it is the first step to elucidate such an important and newly arising topic in this vaccination campaign.

Limitations of the present study include small sample size, short duration, bias and shortages in collecting data regarding demography and risk factors like on obesity, smoking and co-morbid diseases which are important determinants of severity of COVID-19.

Further studies are recommended to study and investigate this vital topic taking into consideration type of the vaccine, interval between the emergence of symptoms and the last dose. In addition follow up such persons are mandatory to explore any complications associated with vaccination.

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Conflicts of Interest

There are no conflicts of interest.

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