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Original Article

Outcomes of single dose COVID-19 vaccines: Eight month follow-up of a large cohort in Saudi Arabia

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ABSTRACT

Background: Two vaccines for COVID-19 have been approved and administered in the Kingdom of Saudi Arabia (KSA); Pfizer-BioNtech BNT162b2 and AstraZeneca-Oxford AZD1222 vaccines. The purpose of this study was to describe the real-world data on the outcome of single dose of these COVID-19 vaccines in a large cohort in KSA and to analyse demographics and co-morbidities as risk factors for infection post one-dose vaccination.

Methods: In this prospective cohort study, a total of 18,543 subjects received one dose of either of the vaccines at a vaccination centre in KSA, and were followed up for three to eight months. Data were collected from three sources; clinical data from medical records, adverse events (AEs) from a self-reporting system, and COVID-19 infection data from the national databases. The study was conducted during the pandemic restrictions on travel, mobility, and social interactions.

Results: The median age of participants was 33 years with an average body mass index of 27.3. The majority were males (60.1%). Results showed that 92.17% of the subjects had no COVID-19 infection post-vaccination as infection post-vaccination was documented for 1452 (7.83%). Diabetes mellitus 03), organ transplantation ($p = 0.02$), and obesity ($p < 0.01$) were associated with infection post-vaccination. Unlike vaccine type, being Saudi, male, or obese was associated with the occurrence breakthrough infections more than other parameters. AEs included injection site pain, fatigue, fever, myalgia, headache and was reported by 5.8% of the subjects.

Conclusion: Single dose COVID-19 vaccines showed a protection rate of 92.17% up to eight months follow-up in this cohort. This rate in AZD1222 was higher than what have been previously reported in effectiveness studies and clinical trials. Obese, male, and Saudi were at higher risk of contracting the infection post-vaccination, Saudi and male might have more social interaction with the public when mobility and social interactions were limited during the pandemic. Side effects and AEs were within what has been reported in clinical trials.

Background

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2) causes coronavirus infectious disease 2019 (COVID-19), which was

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declared as a global pandemic [1–3]. SARS-CoV-2 is highly contagious and transmitted through human-to-human contact [4]. Most COVID-19 cases (81%) are asymptomatic or present with mild to moderate symptoms [5]. However, other cases are severe (14%) to critical (5%); with a case fatality rate of 2–3% [6]. As of September 2021, more than 222 million confirmed cases of COVID-19 and 4.5 million deaths were reported globally [5]. To reduce the risk of SARS-CoV-2 transmission, preventive strategies have been implemented, including the use of face masks, hand washing/hygiene, contact tracing, travel bans, and government-led cancellation of unnecessary activities [5,6].

Importantly, prophylactic vaccines are sought as the ultimate intervention to bring the pandemic under control. Over 200 vaccine candidates for COVID-19 were at various stages of clinical development [7]. Of these, at least 50 candidate vaccines have been evaluated in clinical trials and several vaccines have been approved by regulatory authorities, based on demonstrated safety profile and acceptable efficacy rates [7]. COVID-19 vaccine efficacy, in phase III clinical trials, were 95% for the Pfizer-BioNtech BNT162b2 vaccine, 92% for the Gamaleya Sputnik V vaccine, 94.5% for Moderna mRNA-1273 vaccine, 70% for the AstraZeneca-Oxford AZD1222 vaccine, and 97% for Sinopharm BIBP COVID-19 vaccine [7–9].

Three of these vaccines were approved for emergency use by a number of international regulators, including the Saudi FDA, at the end of 2020. Accordingly, Kingdom of Saudi Arabia (KSA) was among the first countries to launch an accelerated programme for COVID-19 vaccination [10,11]. For each vaccine, there were a number of vaccine controlled randomised clinical trials focusing on evaluating safety, immunogenicity, and efficacy [7,12], which were the basis for regulatory approvals. However, to gain a better understanding of how COVID-19 vaccines would perform in various populations, it is essential to gather real-world data and analysis post-vaccination, particularly in different ethnic populations and other sub-populations. These sub-populations can be defined based on differences in gender, age, nationality, occupation, and comorbidities.

Therefore, this study was conducted to evaluate the outcome of Pfizer-BioNtech BNT162b2 and AstraZeneca-Oxford AZD1222 COVID-19 vaccines in protecting from COVID-19 in KSA, including national and expatriate subjects from different countries. It also analyses demographics and clinical characteristics of subjects as well as adverse events (AE) post-vaccination. Unlike the recommended regimen of two doses, all subjects in the study received only a single dose of either BNT162b2 or AZD1222 vaccines between 19th December 2020 and 14th April 2021. This was because at the early phase of the vaccination programme, KSA has decided to postpone the second dose of COVID-19 vaccines due to vaccine supply issues as well as to achieve a quick rollout of COVID-19 vaccines.

Methods

Subjects and data collection

In this prospective cohort study, data for 20,555 vaccinated subjects were collected from a single vaccination centre at Ministry of National Guard Health Affairs (MNG-HA) hospitals in Riyadh city, Saudi Arabia, during the first days of vaccination campaign. The subjects received either BNT162b2 or AZD1222 vaccines. Clinical data for all subjects were retrieved from the MNG-HA electronic medical records. Co-morbidities were extracted based on the ICD codes. The BMI was extracted as continuous numbers and categorised into obesity based on the CDC cut-off of BMI > 30. Confirmation of COVID-19 infections were obtained from the national databases at the Ministry of Health which covers any COVID-19 PCR testing performed in the entire country. Subjects were given access to an online portal for reporting symptoms and adverse events; in addition, vaccine safety records at the Infection Prevention and Control Department at the King Abdulaziz Medical City (KAMC), MNG-HA, were reviewed. Those who were infected prior to vaccination, had two doses of Pfizer vaccine (< 100 subjects), had COVID-19 infection within two weeks of vaccination (only 73 cases), or lack data on COVID-19 testing were excluded from the analysis. Therefore, 18,543 out of 20,555 subjects were included in the study analysis. Subjects were followed up for at least three months (last vaccination was on the 14th April 2021 and last follow up was on the 10th August, 2021).

Statistical analysis

Descriptive statistics were applied to summarise the data of subjects' demographical and clinical characteristics and the number of AEs. Comparisons between the two study groups (No infection post-vaccination versus infection post-vaccination) in terms of demographical and clinical variables, including gender, nationality, and comorbidities were evaluated using chi-2 tests.

Multivariate analysis was applied to model the likelihood of infection after vaccination using backward elimination logistic regression. An alpha level 0.5 was used to enter and to stay in the model for all demographical and clinical variables. The final model is reported in terms of odds ratios and 95% confidence intervals. The Wilcoxon rank-sum test was used to test differences in the number of days between vaccination and infection for infected individuals in terms of gender, nationality, and comorbidities. All statistical analyses were performed using SAS 9.4 (SAS Institute Inc., Cary, NC) and data visualisation using GraphPad Prism V8 software (GraphPad Software, San Diego, CA).

Results

Clinical and characteristics of the study cohort

Of the 18,543 vaccinees, 410 (2.3%) received BNT162b2 and 18,133 (97.8%) received AZD1222. Of the total number of vaccinees, 11,145 (60.1%) were males and 7398 (39.1%) were females. The participants were relatively young with a median age of 33 years (IQR: 26–42). The median body mass index (BMI) was 27.3 (IQR: 23.8–31.4).

Outcomes of single dose COVID-19 vaccines

Out of 18,543, 17,091 (92.17%) remained uninfected post-vaccination while SARS-CoV-2 infection was documented for 1452 (7.83%) vaccinated individuals (Table 1). Forty-six (11.2% of those who received BNT162b2) and 1406 (7.75% from those who received AZD1222) had the infection post two weeks of the single dose vaccination, indicating the protection rate of these vaccines, Table S1. Age was similar in the two groups of vaccinated subjects (uninfected and infected); median age was 33 (IQR: 26–43) for the uninfected group and 33 (IQR: 26–41) for the infected group. Likewise, the BMI was similar in the uninfected group (median = 27.3 (IQR: 23.8–31.3)) and the infected group (median = 28.1 (IQR: 24.5–32.3)).

To identify risk factors associated with infection post-vaccination, we analysed comorbidity data of subjects in the two groups (Table 1). Male gender and Saudi nationality appeared to be associated with infection post-vaccination than female and non- Saudi nationality ($p < 0.01$). Diabetes ($p = 0.03$), organ (mainly kidney) transplantation ($p = 0.02$), and obesity ($p = 0.0014$) were found to be associated with the risk of infection in vaccinated subjects. Remarkably, lung diseases, asthma, or cancer, for which treatment by chemotherapy predisposes patients to microbial infection due to leukocytopenia, did not affect the likelihood of infection among vaccinated subjects.

Table 1
Co-morbidities and characteristics of subjects vaccinated with either BNT162b2 or AZD1222 COVID-19 vaccines.

	No infection post-vaccination	Infection post-vaccination	P value
	(n = 17,091)	(n = 1452)	
Male	10,188 (59.62%)	957 (65.91%)	< 0.0001
Female	6903 (40.38%)	495 (34.09%)	
Nationality: Saudi	12,026 (70.36%)	1189 (81.89%)	< 0.0001
Nationality: Non-Saudi	5065 (29.64%)	263 (18.11%)	
Diabetes mellitus	1602 (9.37%)	161 (11.09%)	0.0325
Hypertension	1916 (11.21%)	62 (11.16%)	0.9505
Hyperlipidemia	1009 (5.90%)	77 (5.30%)	0.3494
Chronic kidney disease	213 (1.25%)	18 (1.24%)	0.9826
Chronic lung disease	604 (3.53%)	61 (4.20%)	0.1894
Asthma	578 (3.38%)	58 (3.99%)	0.2182
Malignancy	183 (1.07%)	16 (1.10%)	0.9118
Obesity	603 (3.53%)	75 (5.17%)	0.0014
Haemodialysis	93 (0.54%)	8 (0.55%)	0.973
Organ Transplant	11 (0.06%)	4 (0.28%)	0.0254

Regression analyses showed that being Saudi, male, or obese is associated with contracting the infection post a single dose of COVID-19 vaccines (Table 2). The data showed that the time between vaccination and infection was between 15 and 146 days (median = 82 days), Fig. 1. These periods of time were similar with no significant differences in either of the vaccine type; however, the number of BNT162b2 vaccinees was small (n = 410) with a smaller number of COVID-19 cases post BNT162b2 vaccine (only 46 cases). In addition, these times were not different with regard to subject co-morbidities (Table S2).

Adverse events to COVID-19 vaccines

Only 1084 subjects utilised the online reporting portal or contacted the hospitals to report AEs, 5.8% (Table 3). Injection site pain was the most frequently reported AE (800 cases). Other common AEs include fatigue (732 cases), fever (714 cases), myalgia (678), headache (657 cases), joint pain and malaise (399 cases). In contrast, AEs, such as skin rash, cough, abdominal pain and tachycardia were only reported by single individuals among vaccinated subjects.

Discussion

This cohort study is the largest study, up to date, from KSA to evaluate SARS-CoV-2 infection rate in individuals vaccinated with a single dose of either BNT162b2 or AZD1222 vaccines. It showed that 92% of the vaccinees remained uninfected in a follow-up period of three to eight months post-vaccination. In a previous small study from KSA, the effectiveness of the AZD1222 vaccine was 99.5% within 3 weeks of the first dose [13]. In clinical trials, the efficacy rates, in preventing symptomatic SARS-CoV-2 infections, were 52% (95% CI: 30–86%) after one dose and 95% (95% CI: 90–98%) after two doses of BNT162b2 [8]; and 70% (95% CI: 55–81%) after two doses of the AZD1222 vaccine [9]. Furthermore, real-world data showed that two doses of BNT162b2 vaccine reduced the risk of SARS-CoV-2 infection by 90% between Dec. 2020 and Mar. 2021 in the USA [14]. It

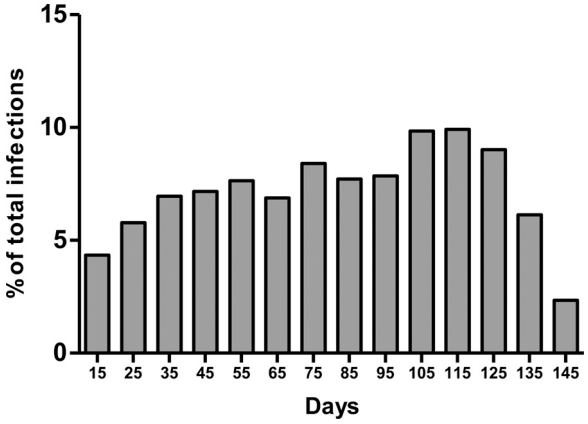

Fig. 1. Days between COVID-19 vaccination and breakthrough infections shown as percentage of the infected subjects.

was also found that most breakthrough infections (that occur post-vaccination) were either asymptomatic or mildly symptomatic [15].

In previous studies, the rate of breakthrough infections was not different among vaccinees by age group, gender, or type of vaccine, but it was lower among those without comorbidities (0.44 [95% CI 0.25, 0.62]) compared with those with 1–3 comorbidities [16]. Diabetic patients are generally at higher risk of severe COVID-19 and increased mortality [17]. In the current study, infections were significantly higher in subjects with diabetes mellitus, obesity, or organ transplantation. The contribution of underlying diseases to breakthrough infections is important as additional boosting doses are being recommended by regulators and health officials globally. The immune responses after COVID-19 vaccine were lower among those with underlying comorbidities such as diabetes mellitus, hypertension and renal disease [18], which could partially explain the occurrence of breakthrough infections. It should also be considered that the rate of COVID-19 cases varies across time, which would certainly influence our findings and any effectiveness study. The coverage of vaccines against different variants is also variable; therefore, the rate of breakthrough infections might be different in different times and location according to case rate and circulating variants. Therefore, long-term follow-up on the vaccinees is needed to estimate the longevity of the single dose vaccine effectiveness.

Furthermore, a regression analysis of the present data showed that Saudis, males, and obese subjects were associated with contracting the infection post-vaccination more than other groups. It is possible that Saudi males are at a higher rate of infections in general due to social norms, occupations, and behavioural interactions; thus, further social-epidemiological studies are warranted as differences in infections across nationalities or ethnicities have been reported previously [16,19,20].

Of the vaccinated subjects, only 5.8% reported AEs post-vaccination unlike a previous study from KSA where 34.7% reported AEs [13]. However, lack of reporting does not indicate lack of AE occurrence; and the difference in AE rate might be related to the methodology. The current study was based on self-reporting while the previous study utilised an active method by calling subjects and recording AEs. In the current study, the most reported AEs were injection site pain, fatigue, fever, myalgia, and headache. Injection

Table 2
Odd ratios from a multivariate logistic regression analysis modelling the probability of COVID-19 infection post-vaccination.

Variable	Crude-odd ratio	95% CI	P value	Adjusted odd ratio	95% CI	P value
Gender: Male	1.309	1.169–1.465	< 0.0001	1.167	1.039–1.311	0.0091
Nationality: Saudi	1.902	1.658–2.183	< 0.0001	1.805	1.567–2.079	< 0.0001
Obese	1.454	1.134–1.866	0.0032	1.327	1.033–1.705	0.0271

Table 3
Reported adverse events post COVID-19 vaccination.

AE	Number of cases	AE	Number of cases
Injection site pain	800	Cardiac (Chest pain, palpitation, dyspnoea)	12
Injection site swelling (and redness)	216	Dizziness	11
Fatigue	732	Gastrointestinal (Abdominal pain, vomiting, diarrhoea)	8
Fever	714	Lymphadenopathy	7
Myalgia	678	Skin rash	4
Headache	657	CNS (Syncope, numbness)	3
Joint pain	399	Blurred Vision	2
Malaise	399	Cough	1
Chills	312	Profuse sweat	1
Nausea	164		

site pain was the most common AE post AZD1222 (30.5%) vaccination in the previous local study [13] while it was not possible to establish a rate for this AE in the current study due to the used method. Injection-site pain was reported by 48.6% [13] in phase III clinical trials; however, it varied depends on the vaccine type [21]. Fever was the most frequently reported adverse effects after COVID-19 vaccination in this study. It was reported in 18.5% after the first dose, 1.3% after the second dose of BNT162b2 vaccine in KSA [22]. This rate was 31% after the AZD1222 vaccine [13], but was 66% after either AZD1222 or BNT162b2 vaccine in another study [23]. In clinical trials, fever was reported in 22% of participants receiving BNT162b2 vaccine [24].

The current study showed that seven vaccinees had lymphadenopathy after COVID-19 vaccination. The incidence of ipsilateral axillary reactive lymphadenopathy following mRNA vaccine was 13% among 68 patients who had CT-scan [25]. The estimated occurrence of lymphadenopathy was 1% and 10% after the after BNT162b2 and mRNA-1273 vaccines, respectively [26]. Nevertheless, lymphadenopathy is usually documented following other intramuscular vaccines such as influenza and human papillomavirus vaccines [27,28].

The current study is based on a single centre, which may limit its generalisability. It did not include AEs from all those who were vaccinated, which does not allow for establishing an accurate incidence rate of AEs post-vaccination. The included vaccinees only received one dose, making it impossible to extrapolate the findings to the recommended two-dose regimen, which has now been completed in many individuals in KSA. Despite these limitations, the study provides an early and significant finding of the outcomes of a single dose COVID-19 vaccination that might be sought where vaccine supply is short. The study also provokes the need for further studies on risk factors for post-COVID-19 vaccination breakthrough infections such as gender and obesity.

Conclusion

This study is the first to investigate the safety and protection outcomes of two main vaccines in a large cohort in Saudi Arabia including national and expatriate subjects from different countries. Single dose COVID-19 vaccines showed a protection rate of 92% with no major side effects during the three to eight months observational period. Obese, male, and Saudi were at higher risk of contracting the infection post-vaccination, Saudi and male might have more social interaction with the public when mobility and social interactions were limited during the pandemic. Side effects and AEs were within what has been reported in clinical trials.

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Ethical approval

The study was approved by the Institutional Review Board (IRB) at King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia for Project no. NRC21R-120-03 with IRB approval reference no.: IRBC/0862/21 and project no. RC20/180 with IRB approval reference no.: IRBC/0714/20. Informed consent was waived by the IRB due to the anonymous retrospective collection of data.

CRediT authorship contribution statement

Data acquisition: **NKA, AA (Amal), SA, FA, FF, MB, AMA**. Formal analysis: **NKA, SAA, OA, FF**. Resources: **MA, AA (Ahmed)**. Writing – original draft, Writing – review & editing: **NKA, JAA, AA (Abrar), SAA**. All authors have reviewed and approved the manuscript.

Competing interests

The authors declare no conflict of interest or competing interest.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jiph.2022.04.001.

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