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Safety and efficiency of COVID-19 vaccine in North Africa

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ABSTRACT

Background In the absence of a specific treatment for COVID-19, preventive measures have been implemented to control this pandemic and vaccination is one of them. However, it is crucial to verify the safety and efficiency of every vaccine. The aim was to determinate the predictive factors of side effects and reinfection after COVID-19 vaccine. Methods A cross-sectional study was conducted in February 2022 among Tunisians infected with COVID-19 between March 2020 and February 2022, using an online self-administered questionnaire. We conducted univariate and multivariate analyses using binary stepwise logistic regression. Results A total of 1541 was selected from 1911 individuals. Comorbidities affected a quarter of the population (22.3%). Before the initial infection, 39.3% had received full vaccination, and 8.7% had received partial vaccination. By February 2022, the majority (82.9%) had received at least two vaccine doses. The reinfection rate was 30.6%. All vaccines prior to the first infection was identified as a protective factor against reinfection. Inactivated virus vaccinations were less likely to induce adverse effects. Conclusion ach vaccine has its own set of advantages and disadvantages: mRNA-based vaccines had a higher incidence of side effects but all vaccines provided better protection against reinfection.

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Introduction

COVID-19 was declared a global pandemic on March 11, 2020[1] and continues to persist.[2,3] From its emergence until August 31, 2023, the world health organization (WHO) has recorded more than 770 million confirmed cases of COVID-19 and 7 million deaths worldwide. In the absence of a specific treatment for COVID-19, preventive public health measures such as mask-wearing, physical distancing, good hand hygiene, isolation of confirmed cases and vaccination have been implemented to reduce COVID-19.[4,5] However, the most effective alternative to curb the virus's spread, reduce severe illness and death, and enable society to return to normalcy, is a safe and effective vaccine with minimal side effects.[6] Vaccines are a crucial tool, though none are 100% effective in controlling this pandemic.[7] Multiple vaccine has been developed worldwide using various technologies, including mRNA, viral vector, protein subunit, and inactivated virus.[7–9] The first COVID-19 vaccines were granted emergency use authorization in the United States by the end of 2020,[10,11] marking a significant turning point in the battle against the pandemic. Globally, 13 billion vaccine doses have been administered, contributing to achieving herd immunity and reducing the virus's ability to spread. Post-vaccination monitoring systems continuously track vaccine safety, and any adverse events are thoroughly investigated.[12,13] Nevertheless, it is well understood that each vaccine comes with its own set of advantages and side effects[14,15] but the benefits of vaccination far outweigh the risks. While COVID-19 vaccination is highly effective in preventing infection and reducing the severity of the disease, the possibility of reinfection exists, particularly in the context of emerging variants and waning immunity. Reinfection can occur due to an insufficient initial immune response to the virus or a decline in neutralizing antibody responses over time.[16] As of June 20, 2023, Tunisia has administered 13 million vaccine doses.[17] The Tunisian government has approved various vaccines, including Pfizer-BioNTech, Moderna, AstraZeneca, Sputnik V, Janssen, Sinopharm and Sinovac, and has made them available to the entire population.[18] Our study aims to determine the side effects and the incidence of reinfection following COVID-19 vaccination and identify their predictive factors.

Methods

Study design

A cross-sectional study was conducted in February 2022 among the Tunisians population infected with COVID-19 between March 2020 and February 2022.

Study population

All Tunisians who had been infected with COVID-19, confirmed by either a rapid test or PCR at least once, and who agree to participate in the study were included.

The sample size needed was estimated using the formula: $n=[(Z_{\alpha/2})^2 \times p \times (1-p)]/i^2$. The rate of side effects considered was 70%[19] and the prevalence of reinfection ranges from 0.3% to 31.4%.[20–24] To optimize the sample size, a proportion (p) of

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70% was selected, a precision (i) of 5% and a risk error (α) of 5% were evaluated, resulting in a necessary sample size of at least 288 individuals and a loss of 30% due to non-eligible participants (not being a Tunisian, under 18 years of age, ect.) were considered, resulting in a required sample size of at least 375 participants. We excluded individuals under the age of 18, Tunisians residing abroad, non-Tunisian residents in Tunisia, those who were unvaccinated at the time of the study, and those who had received mixed vaccines. In Tunisia, the population was vaccinated with three types of vaccines: mRNA vaccines including Pfizer and Moderna; viral vector including Sputnik, Janssen & Janssen and AstraZeneca; and inactivated virus vaccines including Sinovac Coronavac and Sinopharm.[25,26]

The determination of COVID-19 Variants Of Concern (VOC) typically involves genetic sequencing of the virus. This process can be more complex in certain countries, such as Tunisia, due to several challenges, including limited resources and a scarcity of national laboratories equipped for such procedures. Consequently, the sequencing efforts have focused on specific clusters or severe cases. According to the Tunisian Ministry of Health, the predominant circulation of VOCs during the study period was the Alpha variant from December 2019 to April 2021, the Delta variant from May 2021 to December 2021, and the Omicron variant starting from January 2022.[27]

Data collection

Data was collected using an online self-administered questionnaire in both French and Arabic through Google Forms. The questionnaire was shared on Facebook, which is considered as the most popular social media in Tunisia,[28] as well as on radio, and television channels for one month in February 2022, with weekly reminders. Respondents were questioned about their socio-demographic factors, COVID-19 infection history, reinfection, its impact on their health, post-COVID infection symptoms, vaccination and side effects.

Data analysis

Data entry and analysis using the Statistical Package for Social Sciences (SPSS) version 21.0. Quantitative variables were presented as mean and standard deviations if the distribution is normal and compared by the t-test Student. Qualitative variables were presented as frequencies and percentages and compared by chi-square test. Univariate after multivariate logistic regression was used. All variables with a p value less than or equal to 20% were included in the univariate analysis. The significance threshold was set at 5%, and the strength of association was estimated by calculating the odds ratio (OR) and its 95% confidence interval. The rate of menstrual disorders was calculated in the sub-population of women of childbearing age.[29]

Variables' definitions

Reinfection was defined as patients who had two positive tests confirmed by either rapid test or PCR, taken more than 90 days apart and who had recovered clinically.[30,31] Long COVID was defined as the persistence of current symptoms or the emergence of new symptoms within three months after onset, lasting at least two months, and having no differential diagnosis.[32] Safety was defined by presence or absence of post-vaccination adverse effects.[33]

Ethics approval and consent to participate

The Farhat Hached University Hospital's Ethical Committee (Institutional Review Board code:00008931) approved this study, and it was carried out in accordance with the ethical principles the Declaration of Helsinki (CER:34–2022 is the reference number for the committee's opinion). The Google form's two sections were preceded by an introductory paragraph that described the study's goals and methodology. Responses' anonymity was emphasized. The first element of the Google form required participants to indicate their agreement to participate in the study by selecting "yes" in response to the following question: "Do you agree to participate in the study?" This action was required in order for them to access the questionnaire. The user of the link was not given the questionnaire if they selected "No" as their response. Full names and e-mail addresses were not collected to ensure anonymity and confidentiality.

Results

General characteristics of the population

Among the 1911 participants, 1541 were selected. The sex ratio F/M was 3.98 with an average age of 37.27 ± 9.25 years, which serves as the population's cutoff point. The Tunis governorate had the highest participation (19.4%), followed by the Sousse governorate (16.1%), Ariana governorate (10.8%), Ben Arous governorate (8.8%), and Sfax governorate (6.4%). Regarding participants' lifestyle habits, 18.6% were active smokers and 11.8% were alcohol consumers. About 39.1% of the population was overweight and 18.8% were obese. Comorbidities affected a quarter of the population (22.3%), with respiratory problems (6%), hypertension (5.4%), thyroid disorder (5.5%), and diabetes (3.8%). A total of 937 (60.8%) people received the mRNA Pfizer-BioNTech vaccine, 221 (14.3%) received the mRNA Moderna vaccine, 180 (11.7%) received the adenovirus vector AstraZeneca vaccine, 75 (4.9%) received the adenovirus vector Janssen & Janssen vaccine, 77 (5.0%) received the inactivated Sinopharm vaccine and 51 (3.3%) received the inactivated Sinovac Coronavac vaccine. We did not identify any subjects vaccinated exclusively with Sputnik, as all of them had a mixed vaccination schedule (and were excluded from the study) because those exclusively vaccinated solely with Sputnik had not received their vaccine pass.

Side effects following COVID-19 vaccination

Side effects were reported by 76.8% of participants (n = 1184) at the time of the study. Regarding local side effects, redness was the most frequent (34.1%). Fatigue (47.6%), headache

Table 1. Side effects of vaccine.

	Side effect	*N* = 1184%)
Local	Redness	526 (34.10)
	Pain	4 (0.25)
Systemic	Intermittent fever	495 (32.10)
	Fatigue	734 (47.60)
	Arthralgia	470 (30.50)
	Muscle pains	368 (23.90)
	Headaches	535 (34.70)
	Dizziness	5 (0.32)
	Epigastralgy	5 (0.32)
	Vomiting	7 (0.45)
	Nausea	7 (0.45)
	Chest pain	14 (0.90)
	Cough	9 (0.58)
	Tachycardia	7 (0.45)
	Menstrual disorder	11 (1.05)

(45.5%), fever (32.1%), and arthralgia (30.5%) were the most common systemic adverse symptoms (Table 1).

In the univariate analysis, females were more susceptible to developing side effects ($p = .003$; OR = 1.51[1.14–2.00]). The use of mRNA-based and adenovirus vector vaccines significantly increased the likelihood of experiencing side effects compared to inactivated virus vaccine ($p = .002$, OR = 1.51 [1.16–1.96]). For individuals aged 37 and above, who were smokers, alcohol consumers, obese, and had at least one comorbidity, the difference was statistically insignificant. Respiratory comorbidities ($p = .102$), hypertension ($p = .742$), diabetes ($p = .600$), and thyroid disorder ($p = .236$) also showed no statistical significance (Table 2).

Reinfection

More than half (52%) had been infected with the virus prior to vaccination. Before the initial infection, 39.3% had received full vaccination and 8.7% had received partial vaccination against COVID-19. A total of 528 (34.2%) received mRNA vaccine, 141 (9.1%) received adenovirus vector vaccine and 71 (4.6%) received inactivated vaccine. The rate of reinfection was 30.6%. Among the 472 participants who underwent a second infection, the majority (82.4%) were not reinfected by the same VOC. A small percentage reported a third infection (5.1%), with 88.6% of these cases associated with a different VOC compared to their initial infection.

In the univariate analysis, vaccination with two doses prior to the first infection was a protective factor against reinfection ($p = .001$; OR = 0.49 [0.31–0.76]), all types of vaccine were protective against reinfection. Obesity (BMI ≥ 30) was also

Table 2. Univariate analysis of the side effect.

	Side effect			
Variable	Yes n (%)	No n (%)	*p*	OR [CI 95%]
Gender				
Female	966 (78.4)	266 (21.6)	**.003**	1.51 [1.14–2.00]
Male	218 (70.6)	91 (29.4)		Reference
Vaccine categories				
mRNA	912 (78.8)	246 (21.2)	**.002**	1.51 [1.16–1.96]
Viral vector/Inactivated virus	272 (71.0)	111 (29.0)		Reference
Types of vaccine				
Inactivated virus	68 (53.1)	60 (46.9)		Reference
Viral vector	204 (80.0)	51 (20.0)	**≤ 10−3**	3.52 [2.22–5.60]
mRNA	912 (78.8)	246 (21.2)	**≤ 10−3**	3.27 [2.24–4.75]
Comorbidities				
Yes	264 (77.0)	79 (23.0)	.947	-
No	920 (76.8)	278 (23.2)		
Age range (years old)				
≤37	634 (76.8)	192 (23.2)	.930	
>37	550 (76.9)	165 (23.1)		-
Tabacco				
Yes	216 (75.5)	70 (24.5)	.560	-
No	968 (77.1)	287 (22.9)		
Alcohol				
Yes	135 (74.2)	47 (25.8)	.366	-
No	1049 (77.2)	310 (22.8)		
Obesity				
Yes	226 (78.2)	63 (21.8)	.540	-
No	958 (76.5)	294 (23.5)		

The multivariate analysis showed that females ($p = .003$, OR = 1.54 [1.16–2.05]), mRNA-based vaccines and adenovirus vector were more predictive of side effects than inactivated vaccine (Table 3).

Table 3. Multivariate analysis of the side effect.

	Side effect			
Variable	Yes n (%)	No n (%)	*p*	OR [CI 95%]
Gender				
Female	966 (78.4)	266 (21.6)	**.003**	1.54 [1.16–2.05]
Male	218 (70.6)	91 (29.4)		Reference
Types of vaccine				
Inactivated virus	68 (53.1)	60 (46.9)	**≤ 10−3**	Reference
Viral vector	204 (80.0)	51 (20.0)	**≤ 10−3**	3.60 [2.26–5.73]
mRNA	912 (78.8)	246 (21.2)	**≤ 10−3**	3.30 [2.26–4.80]

a predictive factor of reinfection ($p = 0.020$; OR = 1.37 [1.05–1.80]). Among individuals aged 37 and older who were smokers, alcohol consumers, obese, and had at least one comorbidity, there was no statistically significant difference. Respiratory comorbidities ($p = .905$), hypertension ($p = .728$), diabetes ($p = .758$), and thyroid disorder ($p = .199$) similarly exhibited no statistical significance (Table 4).

Long COVID

Complete vaccination protects against long COVID ($p \leq 10^{-3}$; OR = 0.49[0.31–0.76]). Reinfection is considered a risk factor for long COVID ($p = .002$; OR = 1.32[1.04–1.66].

Discussion

While COVID-19 vaccines have demonstrated a high level of safety in clinical trials, there is less statistical data comparing their safety in real world usage.[13] To our knowledge, few studies worldwide such as in the Middle East (Iraq, Jordan, Bahrain) and India[19,34–39] have compared the side effects among the three types of COVID-19 vaccines in the general population and none of them have been conducted in North Africa except for one study that focused on Algerian athletes.[40] However, side effects are considered reactogenicity symptoms which are a consequence of the expected immune response to immunization. In fact, the extent of reactogenicity, whether local or systemic, is influenced by a multitude of factors, including host characteristics (such as age and gender), vaccine features and various other elements.[41] In this study we found that 76.8% of participants reported side effects regardless of the type of vaccine. Fatigue (47.6%), headache (45.5%), fever (32.1%), and arthralgia (30.5%) were the most common systemic adverse symptoms. These findings align with those reported in numerous other studies regarding the

Table 4. Univariate analysis of the reinfection.

	Reinfection			
Variable	Yes n (%)	No n (%)	*p*	OR [CI 95%]
Gender				
Female	375 (30.4)	857 (69.6)	.740	-
Male	97 (31.4)	212 (68.6)		
Types of vaccine				
Non-vaccinated	340 (42.4)	461 (57.6)	**≤ 10−3**	Reference
mRNA	80 (15.2)	448 (84.8)	**≤ 10−3**	0.24 [0.18–0.31]
Viral vector	39 (27.7)	102 (72.3)	**0.001**	0.51 [0.34–0.76]
Inactivated virus	13 (18.3)	58 (81.7)	**≤ 10−3**	0.30 [0.16–0.56]
Complete vaccination before first infection				
Yes	95 (15.7)	510 (84.3)	**≤ 10−3**	0.49 [0.31–0.76]
No	37 (27.4)	98 (72.6)		Reference
Comorbidities				
Yes	105 (30.6)	238 (69.4)	.990	-
No	367 (30.6)	831 (69.4)		
Age range (years old)				
≤37	249 (30.1)	577 (69.9)	.650	-
>37	223 (31.2)	492 (68.8)		
Tabacco				
Yes	88 (30.8)	198 (69.2)	.950	-
No	384 (30.6)	871 (69.4)		
Alcohol				
Yes	61 (33.5)	121 (66.5)	.360	-
No	411 (30.2)	948 (69.8)		
Obesity				
Yes	105 (36.3)	184 (63.7)	**.020**	1.37 [1.05–1.80]
No	367 (29.3)	885 (70.7)		Reference

The multivariate analysis revealed that an incomplete vaccination schedule before the first infection ($p \leq 10^{-3}$; OR = 0.48 [0.30–0.75]) was protective factor of reinfection. However, obesity ($p = .028$; OR = 1.67 [1.05–2.64]), adenovirus vector vaccine ($p \leq 10^{-3}$; OR = 2.14 [1.37–3.34]) were more predictive of reinfection (Table 5).

Table 5. Multivariate analysis of the reinfection.

	Reinfection			
Variable	Yes n (%)	No n (%)	*p*	OR [CI 95%]
Types of vaccine				
Non-vaccinated	340 (42.4)	461 (57.6)	**≤10−3**	Reference
mRNA	80 (15.2)	448 (84.8)	**≤10−3**	0.24 [0.18–0.31]
Viral vector	39 (27.7)	102 (72.3)	**.001**	0.51 [0.34–0.76]
Inactivated virus	13 (18.3)	58 (81.7)	**≤10−3**	0.29 [0.15–0.54]
Complete vaccination before first infection				
Yes	95 (15.7)	510 (84.3)	**.002**	0.49 [0.31–0.76]
No	37 (27.4)	98 (72.6)		Reference
Obesity				
Yes	105 (36.3)	184 (63.7)	**.017**	1.40 [1.06–1.86]
No	367 (29.3)	885 (70.7)		Reference

most prevalent side effects.[13,15,42–46] Initially, mRNA vaccines were believed to carry no risk of reactivation and were thought to be safer than inactivated vaccines.[46,47] However, the findings of our study revealed that side effects were more common among mRNA vaccines than adenovirus vector vaccines and inactivated vaccines. Other studies support our results when comparing mRNA and inactivated vaccines[35,36,43] or mRNA and adenovirus vector vaccine[13,35,37,42] or adenovirus vector and inactivated vaccine,[19,35,48,49] but no study has compared all three types of vaccine. For most vaccines, these reactions are mild to moderate and temporary,[26,43,44] with no serious adverse event.[50–52] Another noteworthy finding is the considerable variation in side effects based on gender, with a higher prevalence of events in females compared to male as reported in the majority of the studies worldwide,[34,39–42,43,53–56] which is consistent with our results. Additionally, other predictive factors for side effects have been reported in previous studies, such as age,[34,55] comorbidities as diabetes, hypertension, asthma, thyroid disorder,[34,43] or weight status,[45] but no significant association were found in our study. The lack of statistical significance regarding the age variable in our sample may be attributed to older subjects having limited access to the internet compared to younger subjects. At the present, the precise reason for the presence or the absence of association between chronic diseases and side effects is still unclear. Nonetheless, it is suggested that additional forward-looking studies with a larger sample size are needed to confirm or infirm this correlation. It is well established that vaccines do not provide immunity to all vaccinated individuals.[57] The reasons for this variability are numerous, ranging from genetic and immunological factors to the quality of the vaccines themselves and their administration.[26] Despite significant disparities in the prevalence and severity of side effects among these vaccinations, statistical analysis suggested that vaccines may offer similar protection against severe forms of COVID-19.[19] Hence, the importance of studying these factors in the Tunisian population and identifying their specific characteristics. Indeed, the reinfection rate found in our study was 30.6% falling within the range reported in the literature (which ranges from 0.3% to 31.4%).[20–24] This variation can be attributed to various factors, including the absence of a consensus definition of reinfection,[58] the presence of different virus variants (such as Omicron, which is the most active[59]), vaccination rates, population herd immunity level, infection prevention strategies and recipient characteristics.[60–62] In our survey, receiving two vaccine doses prior to the first infection was a protective factor against reinfection. This finding is supported by several studies that have demonstrated that full vaccination provides additional protection against reinfection.[63–67] While full vaccination does not completely eliminate the risk of reinfection, it contributes significantly to controlling the pandemic by reducing the incidence symptomatic cases, critical cases, and fatalities.[68] Researchers have reported high vaccine efficacy levels, with Pfizer, Moderna and Sputnik V exceeding 90%, AstraZeneca and Janssen & Janssen above 70% and Sinopharm reaching an efficacy of 79%.[34,44,69,70] When comparing the three types of COVID-19 vaccine, mRNA-based vaccination showed a more significant decrease in the risk of reinfection compared to adenovirus vector. This observation is consistent with findings in the literature, which confirm that individuals vaccinated with Pfizer or Moderna are less likely to develop severe symptoms upon reinfection, experience fewer hospitalizations, and have lower mortality rates.[66,67,71–73] Another notable finding in this study was that obese individuals were more susceptible to reinfection. Vaccine effectiveness appears to be reduced in individuals with obesity[74–78] due to the inappropriate immune response. Prioritizing strategies to achieve and maintain a healthy weight could potentially increase vaccine efficacy and reduce the risk of severe COVID-19 infections in this population.[74,79] Encouraging healthy eating habits, physical activity, and weight reduction should be emphasized.[80] The low rate of reinfection among vaccinated individuals in our study indicates that immunity produced by vaccination remains effective despite the ongoing mutation of the COVID-19 virus and the emergence of new VOCs. While there is controversy, one meta-analysis reported that certain variants (Beta, Gamma and Delta) may have the ability to evade immunity induced by vaccination.[81] Nevertheless, overall, study results indicate that vaccination conferred immunity is likely to protect against severe forms of the disease, and that the vaccine remains effective against the majority of VOCs.[81] This survey also revealed that individuals suffering from long-COVID syndrome were more vulnerable to reinfection. However, studies have primarily explored the other aspect of this relationship between long COVID and reinfection to ascertain that reinfection could have significant consequences in terms of morbidity and could be further complicated by long COVID.[82–86]

Limits of the study

While online questionnaires are convenient tools with benefits such as access to a diverse population and rapid responses, certain issues may arise during the completion of the questionnaire. Additionally, we relied on self-reported data for weight and height, the reliability and validity of which have been found to be inconsistent in previous investigations. Moreover, given the anxiety associated with this emerging pandemic, the side effects experienced by each individual, regardless of gender and age, are a highly individualized experience with specific psychological implications for each person. Therefore, the findings should be evaluated and analyzed while considering all the factors mentioned above.

Strengths of the study

This study can be considered representative of the general Tunisian population, particularly because the participants were from all 24 governorates of Tunisia. Furthermore, to the best of our knowledge, this is the first North African study that has compared the rates of side effects and reinfection and their predictive factors for the three types of vaccines

(mRNA, adenovirus vector, and inactivated vaccines) in the same general population, with a large sample size.

Identifying factors predictive of side effects and reinfection after vaccination with COVID-19 is imperative for improving the vaccine's safety and efficacy. It also helps to strengthen public confidence in vaccination. Vaccination recommendations based on individual characteristics reinforce safety measures and promote personalized vaccination strategies. Large-scale population studies on side effects are essential for effective communication, promoting transparency and trust in vaccination programs, and increasing adherence to vaccination campaigns. Analysis of viral reinfection also provides important information for decisions on booster injections and long-term efficacy. The vaccine also protects against long COVID. Taking population-specific factors into account is essential for tailoring vaccination strategies, and contributes to global health equity.

Conclusion

Although the rapid development of vaccinations represents an exceptional scientific achievement, it has raised significant concerns regarding safety and efficacy, contributing to vaccine hesitancy. Our study revealed that each vaccine has its own set of advantages and disadvantages: mRNA-based vaccines were associated with more side effects but offered greater protection against reinfection. Nevertheless, all vaccines appear to be effective in preventing severe reinfection and are generally considered safe.

Declaration

Ethical approval and consent to participate

The Farhat Hached University Hospital's Ethical Committee (Institutional Review Board code:00008931) approved this study, and it was carried out in accordance with the ethical principles the Declaration of Helsinki (CER:34-2022 is the reference number for the committee's opinion). Participants gave informed consent via an online form at the beginning of the survey, which was approved by the ethics committee.

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Authors' contributions

The authors SC and SJ designed the work. SC, MT, SS and SJ participated in data analysis and interpretation. SC, SJ, AA, OE and MM drafted the work. SC and ND revised it. SC, MM and MN supervised all the steps of the manuscript editing. All authors approved the final version of the manuscript, agreed to be personally accountable for their own contributions and ensure that questions related to the accuracy or integrity of any part of the work, are appropriately investigated and resolved. All authors read and approved the final manuscript.

Data availability statement

The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

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