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ORIGINAL ARTICLE

Neurological complications of covid_19 vaccination in Egyptian population, A multi-center study

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Abstract

Background: ***A pulmonary-systemic coronavirus illness (COVID-19) caused by the novel SARS-CoV-2 was initially reported in Wuhan, China, in December 2019. COVID-19 quickly gained international attention as a health issue, and in March 2020, it was classified as a pandemic.***

Aim and objectives: ***Assessment of the incidence of neurological complications after COVID-19 vaccination in the Egyptian population.***

Subjects and methods: ***This prospective cohort study was conducted on a group of 300 Individuals who received the COVID-19 vaccine at Al Hussein Hospital and Kobry El Kobba Medical Complex. The recruitment cycle spanned between February 2022 and October 2022.***

Result: ***Regarding different types of vaccine and onset of neurological symptoms, most cases had (1-7 days) onset by 7.5%, 3.2%, 2.8%, 2.3%, and 1.8% for AstraZeneca, sputnik, Sinofarm, Moderna and Pfizer respectively. The most frequent neurological symptom reported was headache, followed by sensory affection. Limb weakness was the least frequent symptom reported. Among the comorbidities assessed in this study, Hypertension (HTN) was the most common, with diabetes mellitus (DM) following closely behind cardiac disease, renal disease, and hepatic disease.***

Conclusion: ***The most frequent age group was 18-30 years, and the study population was predominantly male. The most prevalent comorbidity among patients was hypertension, although smoking rates were relatively low. Sinofarm was the most common vaccine type administered. Neurological symptoms were reported by a small proportion of participants, with headache being the most frequent symptom.***

Keywords: Neurological complications; COVID-19 vaccination

1. Introduction

By the end of 2021, COVID-19 vaccinations were approved in multiple countries for human use, offering a promising solution in the fight against the virus.[1]

Since December 31, 2020, four main vaccine kinds have been widely distributed globally: Ad26.COV-2. S (Janssen), ChAdOx1 nCov-19 (Oxford-AstraZeneca), mRNA1273 (Moderna), and BNT162b2 (Pfizer–BioNTech).[2]

The first two are COVID-19 mRNA-based vaccines that encode the SARS-COV-2 spike protein antigen; the remaining two are recombinant adenoviral vectors. The efficacy of the four vaccines included in the 2021 trials ranged from 66.6% to 95% in preventing COVID-19 infections. The most common side effects were injection-site injury, pain and reactions, axillary lymphadenopathy, fatigue, myalgia, arthralgia, and headache.[2]

Vaccine reluctance, primarily because of safety concerns, has been an issue since the start of the worldwide vaccination effort, even though the safety records in the clinical studies were satisfactory. Concerns are expressed because adenovirus-vectored vaccines have been linked to significant or even deadly effects such as allergies, myocarditis, and thrombotic events.[3]

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Nonetheless, the European and UK Medicines and Healthcare Products Regulatory Agency later revised their reports. They found that there was no statistically significant difference in the rate of fatal thrombotic events between the vaccinated group and the general population, indicating a favorable risk/benefit ratio for the vaccination.[4].4Vaccines against SARS-CoV-2 frequently cause neurological side effects, most of which are mild.[5]

The current study aims to evaluate the frequency of neurological side effects in the Egyptian population following COVID-19 vaccination.

2. Patients and methods

A prospective cohort research was conducted on 300 individuals vaccinated against COVID-19 at Kobry El Kobba Medical Complex and Al Hussein Hospital. The hiring window was open from February 2022 until October 2022. The ethical committee of Al-Azhar University's Faculty of Medicine approved. The patients were enrolled after providing written informed permission at the time of enrollment. The ethical committee of Al-Azhar University's Faculty of Medicine approved. Patients were enrolled after providing written informed permission at the time of enrollment.

Inclusion criteria: Every participant must be older than eighteen and have had the COVID-19 vaccination. The study covers the following vaccination types: Sinovac, Astra-Zeneca, Johnson & Johnson Sputnik, Moderna, Pfizer-BioNTech, and Astra-Zeneca.

Exclusion criteria: people who tested positive for COVID-19 one month before vaccination using either a quick antibody test (IgM or IgG) or real-time reverse transcriptase-polymerase chain reaction (rt-PCR). A month prior to immunization, individuals had a brain injury.

Data collection

demographic information such as age and sex, age above 18, and lifestyle choices. HTN (on antihypertensive drugs or documented history of Bp > 160/90 mm hg on at least two occasions) is one of the comorbidities. Diabetes Mellitus (DM): two separate readings before the onset of COVID-19 symptoms, an increased HBA1c upon admission, or use of anti-diabetic drugs. There are two types of smokers: those who have never smoked regularly or who have quit smoking regularly more than five years ago, and those who smoke frequently (regular daily cigarettes smoking > five years)

Concomitant therapies: Clinical characteristics and chest imaging (high-resolution thorax C00T).

The neurologic examination is divided into several steps: The cranial nerves (CNs), the sensory and motor systems, the cerebellum, the meninges, reflexes, and higher functions are among these processes.

Neurological imaging: If necessary, include visual evoked potentials (VEP) and brain scans (CT, MRI, MRV, MRI cervical, MRI dorsal, MRI lumbosacral). If a patient has weakness and is suspected of having acute polyneuropathy, a CSF examination may be necessary, in addition to an EEG if a seizure is anticipated.

Statistical methods

The software utilized was SPSS v. 26, the Statistical Package for the Social Sciences. Qualitative data were presented as numbers and percentages and tested for in-between groups' difference significance with the Chi-square test when its assumptions were met; otherwise, the Fisher exact test or Monte-Carlo method was performed. The means ± standard deviations were used to present quantitative data and tested for in-between groups' difference significance with a t-test assuming normality of the data distribution after confirmation of normality tests; otherwise, the nonparametric Mann-Whitney U test was used.

After ensuring model fitness, logistic regression, and discriminant analysis, models were built to predict mortality and stroke among COVID-19 patients.

The logistic regression model was evaluated for its fit using the Omnibus test; the Hosmer-Leme show goodness-of-fit test, the Nagelkerke R Square, the classification table, and Receiver operating characteristics (ROC) curves.

The discriminant analysis was a linear discriminant analysis that included continuous predictor variables with normal distribution, homoscedasticity, no auto-dependence, no outliers, and no multicollinearity. The minimal loading value of the included variables was 0.3; variables with lower values were excluded. The ROC curves were drawn for each predictive logistic regression model, and then the area under the ROC curves was tested against the area obtained by chance, which equals 0.5. All tests were carried out at a 0.05 level of significance.

3. Results

Table 1. Demographic data for the whole study group.

		N	%
AGE	18-30	56	18.7%
	31-40	34	11.3%
	41-50	53	17.7%
	51-60	53	17.7%
	61-70	54	18.0%
	71-80	35	11.7%
	> 80	15	5.0%
AGE GROUPING	18-40	90	30.0%
	41-60	106	35.3%
	> 60	104	34.7%
GENDER	Female	47	15.7%
	Male	253	84.3%

The most frequent age group was 18-30 by

18.7% followed by 61-70 by 18% and the least frequent group was > 80 years by 5%. 84.3% of patients were males and 15.7% were females.

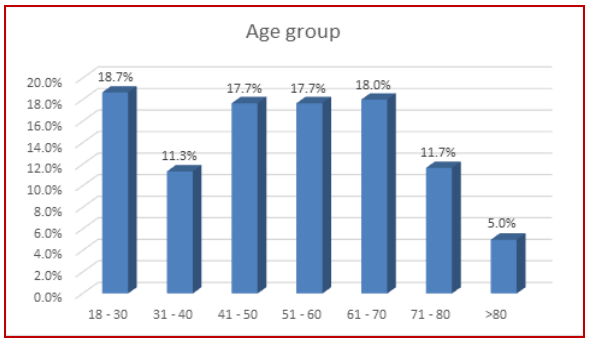

Figure 1. Demographic data for the whole study group.

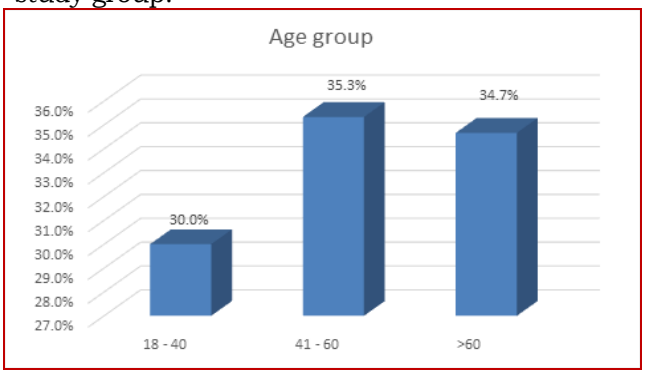

Figure 2. Demographic data for the whole study group.

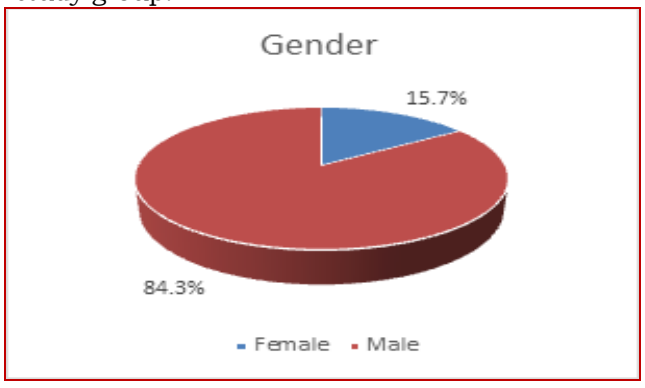

Figure 3. Gender distribution for the whole study group.

Table 2. Comorbidities for the whole study group.

		N	%
DM	No	249	83.0%
	Yes	51	17.0%
HTN	No	227	75.9%
	Yes	72	24.1%
CARDIAC DISEASE	No	285	95.0%
	Yes	15	5.0%
HEPATIC DISEASE	No	295	98.3%
	Yes	5	1.7%
RENAL DISEASE	No	291	97.0%
	Yes	9	3.0%
C.V.S DISEASE	No	287	95.7%
	Yes	13	4.3%

The most frequent comorbidity is HTN by 24.1%, while the least frequent one is hepatic disease by 1.7%.

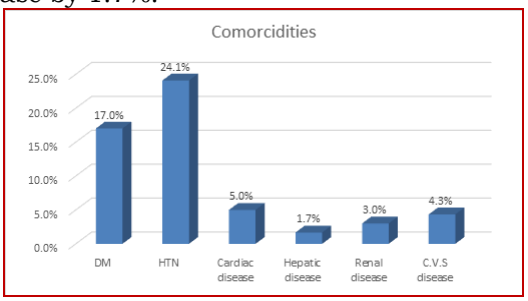

Figure 4. Comorbidities for the whole study group.

Table 3. A unique behavior that is critical to health for the entire research group.

		N	%
SMOKER	No	263	87.7%
	Yes	37	12.3%

Table 3 demonstrates that while smoking was not the most common behavior among the study group as a whole, 87.7% of the patients did not smoke.

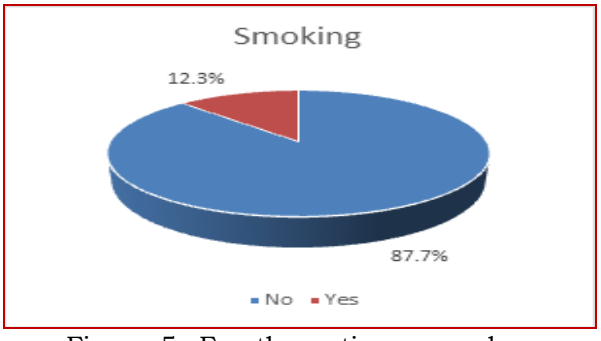

Figure 5. For the entire research group, a particular behavior of medical importance.

Table 4. Type of vaccination for the whole study group.

		N	%
VACCINATION TABLE	Astrazenica	67	22.3%
	Pfizer	56	18.7%
	Moderna	44	14.7%
	Sputnik	62	20.7%
	Sinofarm	71	23.7%

Table 4 shows that 23.7% of patients had Sinopharm, 22.3% had Astrazenica, 20.7% had sputnik, 18.7% had Pfizer and 14.7% had Moderna vaccine.

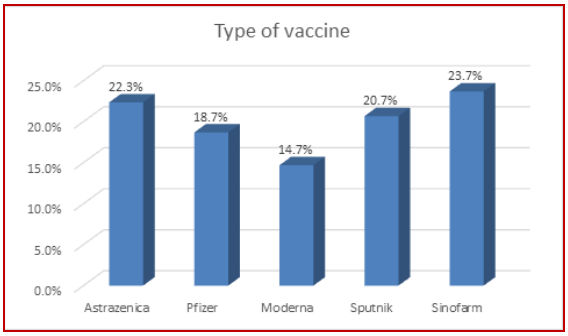

Figure 6. Type of vaccination for the whole study group.

Table 5. Onset of presenting symptom for the whole study group.

		N	%
ONSET	No	285	95.0%
	1 - 7	11	3.7%
	8 - 15	2	0.7%
	16 - 21	1	0.3%
	22 - 30	1	0.3%

Table 5 shows that, 3.7% of patients had acute onset (1-7 days), 1.3% of patients had onset more than one week till one month.

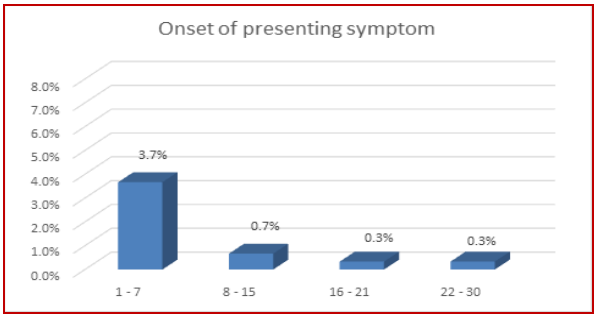

Figure 7. Onset of presenting symptom for the whole study group.

Table 6. Neurological symptoms for the whole study group.

		N	%
HEADACHE	No	291	97.0%
	Yes	9	3.0%
LIMB WEAKNESS	No	299	99.7%
	Yes	1	0.3%
6TH CRANIAL NERVE PALSY	No	299	99.7%
	Yes	1	0.3%
SENSORY AFFECTION	No	296	98.7%
	Yes	4	1.3%
MUSCLE PAIN	No	297	99.0%
	Yes	3	1.0%

Table 6 demonstrates how the research group's neurological complaints were distributed, the most frequent symptom is headache by 3% followed by sensory affection by 1.3%, while the least frequent symptoms are limb weakness by 0.3%.

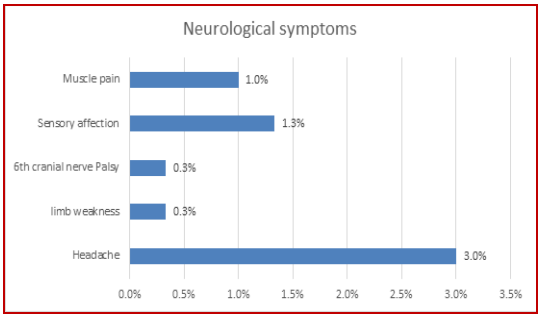

Figure 8. Neurological symptoms for the whole study group.

4. Discussion

In our study, the distribution of vaccine types among participants showed that Sinofarm was the most common vaccine received, followed by AstraZeneca, Sputnik, Pfizer, and Moderna. These findings reflect the availability and distribution of different vaccines in the study setting. It is important to remember that the study was conducted in a specific area and at a particular time. Therefore, the vaccine distribution might not represent other regions or periods.

In our study, the onset of presenting neurological symptoms was 3.7% acute (1 - 7 days) and 1.3% more than one week until one month.

In our study, the onset of symptoms within the group with neurological symptoms was 73.3% in most cases with acute onset (1 - 7 days), while 26.7% of cases had an onset of more than one week to one month.

In our study, regarding different types of vaccine and onset of neurological symptoms, most cases had (1 - 7 days) onset by 7.5%, 3.2%, 2.8%, 2.3%, and 1.8% for AstraZeneca, sputnik, Sino farm, Moderna and Pfizer respectively.

In an Egyptian Case Series by Salama et al.[6] it was stated that the individuals' ages ranged from 24 to 60 years old, with five females and three males. Their symptoms appeared three days to four weeks following the first (n = 3) or second (n = 5) vaccination dose.[6]

In an observational cohort study spanning multiple centers, Göbel et al.[7] headache was a clinically noted side effect following mRNA BNT162b2 mRNA COVID-19 immunization. Typically, headaches occurred at 18.0 ± 27.0 h and lasted 14.2 ± 21.3 h following immunization. The majority of patients experienced moderate to severe bifrontal or temporal throbbing headaches. Muscle aches, weariness, and exhaustion were the most frequent side effects.[7]

In our study, a small proportion of participants reported experiencing neurological symptoms following vaccination. The most frequent neurological symptom reported was headache, followed by sensory affection. Limb weakness was the least frequent symptom reported. These findings suggest that neurological symptoms post-vaccination are relatively rare but should not be disregarded entirely.

Saad et al.[8] revealed that the most prevalent symptom experienced by 16.5% of patients was a headache, followed by taste impairment (8.2%), trigeminal neuralgia (2.3%), seizures (4.9%), cranial nerve affection (8.7%), speech problems (6.8%), and cerebrovascular disease (CVD) (9.7%). Four of those patients were evaluated as hemorrhagic CVD (1.5%) and two as venous infarction (0.8%). Guillain-Barre syndrome was present in 1.5%, and CNS infection in 4.5% (6 were evaluated as viral infection in 2.1%, 1% patients with bacterial infection, and 1.4% with fungal infection).[8]

However, in the study of Yassin et al.[9] There were 22.2% with myalgia, 19.6% with taste problems, 18.3% with odor problems, 12.1% with headaches, 11.3% with dizziness, 9.4% with encephalopathy or cognitive dysfunction, and

2.1% with ataxia or abnormal gait. Acute CVD, such as ischemic stroke (IS), intracranial hemorrhage (ICH), and cerebral venous sinus thrombosis (CVT), affected over 2.5% of COVID-19 patients.[9]

In the study of Essmat [10], The most frequent central nervous system (CNS) manifestation was headache, while the most common peripheral nervous system (PNS) indications were taste and smell impairment.[10]

Nassar et al.[11] found that the most often reported general adverse effects of the COVID-19 vaccination were headache, exhaustion, and weakness.[11]

The majority of possibly systemic neurologic symptoms (such as headaches) were mild and could have been a result of the alleged illness behavior Vald'es-Ferrer et al.,[12] or as a result of vaccination reactogenicity Herv'e et al.,[13] neither linked to persistent nervous system dysfunction; instead, they are both connected to systemic inflammation.[12,13]

Optic neuritis (0.3%), GBS, and MS (1%) are the most common diseases in our analysis. García-Grimshaw et al.[5] found just three cases of GBS, all of which had confirmation from clinical, laboratory, and electrophysiological methods. Interestingly, all three had acute gastrointestinal infections that were suspected or verified to have started after getting the vaccine. This suggests that concurrent illnesses may raise the risk of peripheral nerve damage if they are not totally to blame.[5]

During the presentation of GBS, none of the three cases tested positive for SARS-CoV-2, despite the epidemiological link between GBS and COVID-.[14,15,19]

The reported rate of 0.43/100,000 doses, however, falls within the predicted all-cause incidence of GBS (1.1–1.8/100,000 persons/year), indicating that there is no mechanistic connection between mRNA vaccines and GBS.[16]

In our study, when analyzing the relationship between demographic data and neurological symptoms, our findings indicated that younger age groups had a higher prevalence of neurological symptoms than older age groups. This observation aligns with previous studies that have reported a higher incidence of adverse events following vaccination in younger individuals.[17]

In disagreement with the study of Essmat [10], research has demonstrated that individuals with neurological affection tend to be older.[10]

In the study of Romagnolo et al.,[18] They observed that COVID-19 individuals with neurological conditions tend to be somewhat older than those without such conditions.[18]

Additionally, in our study, the percentage of females who experienced neurological symptoms was higher than that of those who did not. This gender difference in symptom presentation warrants further investigation to understand potential underlying factors.

In harmony, García-Grimshaw et al.[5] found that female beneficiaries disproportionately felt the impact of unfavorable events. In the current analysis, women received just 26.8% of the immunizations but experienced 76.3% of the adverse events. To put this in perspective, the AEFI among women increased tenfold (1.7% vs. 0.19%).[5]

Saad et al.[8] found that there was a significant correlation between the presence of neurological problems and female gender (25.8 vs 15.9%).[8]

This pattern has been seen with other vaccines, and although it is undoubtedly complex, it is most likely the result of the immune system's sexual dimorphism Cook,[19]. Variations influence response to exogenous and self-antigens in hormone and genetic makeup. Although women have a lower infection incidence and a more excellent antibody response to vaccinations than men, they are more prone to autoimmune diseases.[20] Moreover, women routinely report higher adverse effects linked to vaccinations.[21]

Beyond biological factors, however, it is also possible that external pressures, such as social (such as the perception in the community that symptoms are a sign of weakness), psychological, and cultural (such as the perception of toughness and resilience in society) may result in a decrease in the amount of self-reporting by Latinx males.[22]

In our study, among the comorbidities assessed, individuals with neurological symptoms had a higher prevalence of DM, HTN, and cardiac disease than those without. This suggests that following vaccination, individuals with pre-existing health conditions might be more susceptible to neurological symptoms. However, the small sample size of individuals with neurological symptoms in our study limits the generalizability of these findings.

Saad et al.[8] found that the presence of comorbidities (40.2 vs. 9.2%), hypertension (53.6 vs. 20.5%), diabetic mellitus (DM) (44.3 vs. 11.3%), HCV (7.2 vs. 0.5%), and a history of cerebrovascular stroke (CVS) (7 vs. 0%) were all substantially correlated with the existence of neurological sequelae.[8]

In our study, regarding different types of vaccines and neurological symptoms, Pfizer and Sinofarm vaccines cause only headaches. In contrast, Moderna causes limb weakness and muscle pain in only one case for each symptom. Sputink causes headaches in 2 cases and sensory affection, sixth cranial nerve palsy, and muscle pain in only one case for each symptom. AstraZeneca causes headache in 4 cases, sensory

affection in 3 cases, and MS in 3 cases, while in 1 case, it causes muscle pain.

In our study, no clear patterns were observed in the distribution of vaccine types between individuals with and without neurological symptoms.

An estimated 6536 adverse events were reported in Mexico (data available as a preprint) among the 704 003 individuals who got the first doses of the Pfizer-BioNTech mRNA COVID-19 vaccine. At least one neurologic symptom was present in 4258 (65%) of them, with the majority (99.6%) being mild and temporary. Headache (62·2%), temporary sensory problems (3·5%), and weakness (1%) were among these occurrences that occurred. Only 17 major adverse events were reported in this trial, including seven seizures, four functional syndromes, 3 cases of Guillain-Barré syndrome, and 2 cases of transverse myelitis.[5]

4. Conclusion

The most frequent age group was 18-30 years, with males constituting the majority among the population under investigation. Hypertension was the most typical combination, and smoking was relatively low among participants. Sinofarm was the most common vaccine type administered. Neurological symptoms were reported by a small proportion of participants, with headache being the most frequent symptom. This study highlights the importance of considering age, gender, pre-existing health conditions, and vaccine type when assessing post-vaccination symptoms.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

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Conflicts of interest

There are no conflicts of interest.

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