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A Comparative Study about post-vaccination symptoms with Coronavirus (COVID-19) vaccines among people in Saudi Arabia and Egypt

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Background: Coronavirus (COVID-19) a new member of the human coronavirus's family, was identified in 2019 as the causative agent of a new disease outbreak in China associated with severe medical complications and even death in some cases. The unavailability of a vaccine or other efficacious therapeutic option has required all the nations worldwide to combat the pandemic's spread. Several precautionary strategies, which include lockdown, social distancing, wearing facemasks, and travel limitations, have been applied to stop this pandemic. On December 11, 2020, the US Food and Drug Administration (FDA) authorized the emergency use of the Pfizer-BioNTech (BNT162b2) COVID-19 vaccine and on February 15, 2021, the adenoviral vector vaccines ChAdOx1 nCoV-19 (AstraZeneca-Ox- ford) were granted emergency use. To assess and compare the short-term side-effects of Pfizer/BioNTech and AstraZeneca vaccines among participants in Saudi Arabia and Egypt. It was conducted among people vaccinated with Pfizer or Astra- Zeneca. The respondents were asked about the signs and symptoms after the first and second doses of the vaccines. Data will be collected through the questionnaire that distributed among people in KSA, and Egypt. It was noticed that most of participants were vaccinated with (Pfizer/BioNTech) in KSA (77.4%) which is more than Egypt (45.7%). More symptoms were appeared after the first dose of Oxford-AstraZeneca vaccine (ChAdOx1 nCoV-19) vaccine and after the second dose of (Pfizer/BioNTech) vaccine in participants either from Egypt or KSA. Severe symptoms were observed in Egypt (31.8%) compared to Saudi Arabia (18.1%), while more than 60% of participants suffering from moderate symptoms that can treated with rest and few medications. Moreover, only a few patients needed to be admitted to the hospital due to vaccines' side effects on respiratory system. Fatigue and fever were significantly associated with Pfizer-BioNTech, compared to the Oxford-AstraZeneca vaccine. Headache (47.4% & 38.7%) is the most common symptoms that appeared after vaccination.We can conclude that only a few patients needed to be admitted to the hospital due to vaccines' side effects on respiratory system. Fatigue and fever were significantly associated with Pfizer-BioNTech, compared to the Oxford-AstraZeneca vaccine. These side effects such as pain at the site of the injection, fever, and headache, and they are more common in those after the second dose of the vaccines. A follow-up study is needed to evaluate the effectiveness of the vaccines in controlling COVID infection and assessment of long-term side effects.

Keywords: ***Coronavirus (COVID-19), Pfizer-BioNTech vaccine (BNT162b2), AstraZeneca-Ox- ford (ChAdOx1 nCoV-19) vaccine, Symptoms, Egypt, Saudi Arabia.***

INTRODUCTION

Human coronaviruses constitute a large family of viruses that usually cause mild to moderate upper respiratory illnesses in people such as the common cold. [Kahn JS et al 2005]. In Wuhan, China in December 2019, the infection started and spread rapidly throughout the world quickly and In March 2020, the World Health Organization (WHO) announced the novel disease outbreak as a pandemic (El-Shitany et al. 2021,]. Despite the effort to stop the transmission of COVID-19, the infection spread throughout mainland China, and in January 2020, cases were reported in Thailand, Japan,

and South Korea [Gralinski LE et al. 2020, Kim JY et al. 2020]. now is causing a global pandemic at the beginning of 2021. Saudi health officials have taken early preventive measures, such as complete lockdown of the country to reduce the spread of (COVID-19) [Alhazmi A et al.2021]. Some health authorities developed various vaccines, such as Pfizer-BioNTech vaccine (BNT162b2) which is based on the mRNA technology to express the SARS-CoV-2 spike (S) gene. The vaccine utilized for people ages 16 years and older [FDA Briefing Document.2020]. Pfizer-BioNTech, an ARN vaccine, was the first recommended in France for over-50-years-old-healthcare-workers, or with high risk of severe COVID-19 and for patients over 75 years of age. In phase 1/2/3 of the studies conducted by Pfizer-BioNTech, in vaccine recipients, reactogenicity symptoms were frequent, mostly mild to moderate, commonly reported after the second dose However, patients with a previous clinical or microbiologic diagnosis of Covid-19 were excluded [Mehta NS et al.2020]. The vaccination requires two shots given at least 21 days apart. Pfizer-BioNTech vaccine (BNT162b2) is based on the mRNA technology to express the SARS-CoV-2 spike (S) gene and has shown a high efficacy rate against SARS-CoV-2 infection. Specifically, phase III trials showed that BNT162b2 has about 95% efficacy against laboratory-confirmed SARS-CoV-2 symptomatic infection, at least seven days after the second dose in the individual of 16 years and older without current or previous history of COVID-19. mRNA vaccines are a new type of vaccine that has been recently utilized. BNT162b2 mRNA vaccine has been developed to stimulate immune response against SARS-CoV-2 using mRNA coding SARS-CoV-2 spike protein [Singer SR et al.2021, Goshen-Lago et al.2021]. This vaccine was approved by the U.S. food and drug administration (FDA) on the 11th of December 2020 for EUA in individuals older than 16 years of age. Consequently, the Saudi food and drug administration (SFDA) approved BNT162b2 to be used in Saudi Arabia. [Alhazmi A et al.2020]

Second approved vaccine in KSA is Oxford-AstraZeneca vaccine (ChAdOx1 nCoV-19). Vaccines are now regarded as one of the effective preventive measures that can reduce the spread and the progression of such infectious diseases [Orenstein WA et al.2017]. Authors found that two doses of Oxford-AstraZeneca adenovirus-vectored vaccine (ChAdOx1 nCoV-19) showed an overall 63% efficacy against symptomatic SARS-CoV-2 infection. This vaccine was authorized to be used in the age group of 18 years and older. Unlike BNT162b2, ChAdOx1 nCoV-19 uses replication-deficient chimpanzees adenovirus as a viral vector to express the SARS-COV-2 spike protein [[Alhazmi A et al.2020]]. The aim of the ministry of health in Saudi Arabia is to vaccinate 70% of the population [Mohamed NA et al.2021]. Some mild to moderate side effects were shown due to the immune response of both vaccines such as pain, redness or swelling at the site of injection, tiredness, headaches, chills, muscle, and joint aches, and fever [El-Shitany et al. 2021, Polack Fet al.2020, Voysey M et al.2021].

This study will play an important role in vaccine safety by reporting and recognizing post-vaccination symptoms. It will also be beneficial for clinicians and healthcare professionals who must be aware of potential long-term complications and enrich their knowledge about the presence of these possible complications. So, we aim to compare between the side effects after getting the vaccine either Pfizer-BioNTech mRNA (BNT162b2) or Oxford-AstraZeneca (ChAdOx1nCoV-19) vaccines among Saudis and Egyptians.

MATERIALS AND METHODS

2. Subjects and Methods:

2.1 Study Design and sample collection

This cross-sectional study was conducted through well designed questionnaire among people receiving vaccines either Pfizer-BioNTech vaccine (BNT162b2) or Oxford-AstraZeneca vaccine (ChAdOx1 nCoV-19) or both in Saudi Arabia & Egypt (on google Drive) for 2 months starting from October 2021, the questionnaire was pre-tested for validity. It consists of 20 questions about Scio-demographic, the adverse effect after receiving vaccines against COVID-19 Virus infection. This study was approved by the Research Ethics Committee, University of Hail, Hail, Saudi Arabia (No H-2021-226, dated 6/12/2021). Data was collected from individuals who received COVID-19 vaccines in Saudi Arabia and Egypt, either Oxford-AstraZeneca or Pfizer- BioNTech vaccines.

2.2 Inclusion Criteria

Both genders of population who got one or two doses of covid-19 vaccine, between the age of 18 and above 65 years.

2.3 Exclusion Criteria

Population who didn't get covid-19 vaccine (children underage of 18 years old).

Statistical Analysis:

The Statistical analysis will be done with Statistical Package for Social Sciences (version 25 SPSS Inc, Chicago, IL, USA). Descriptive analysis was performed by prescribing frequency distribution and percentages for study variables, including participants personal data, history of COVID-19 infection, vaccination data, and post-vaccination side-effects.

RESULTS

Table 1. showed demographic characteristics of study population. Total response from Saudi Arabia were 2051 participants, only 758 and from Egypt 462 responses who were completing the questionnaire. Male participants were low 73 (15.8%) from Egyptians and 131(17.3%) from

Saudis. About 60% of participants either from Egypt or KSA their ages ranged from 18-25 years old, and most of participants with university degree.

Table 1:Demographic Characteristics of the Egyptians and Saudis Participants who received vaccines.

Characteristics	Egyptians [n (%)]	Saudis [n (%)]	Total Participants
Total number of responses	462 (37.9%)	758 (62.1%)	1220
Gender			
Male	73 (15.8%)	131(17.3%)	204
Female	389 (84.2%)	627 (82.7%)	1016
Age Groups (Years)			
18-25	286 (61.9%)	457 (60.3%)	743
26-35	57 (12.4%)	86 (11.3%)	143
36-45	69 (14.9%)	129 (17%)	198
46-55	38 (8.2%)	65 (8.6%)	103
56 and more	12 (2.6%)	21 (2.8%)	33
Education level			
Elementary & Middle	14 (3%)	26 (3.4%)	28
Secondary	113 (24.5%)	190 (25.1%)	297
University	326 (70.6%)	525 (69.3%)	861
Postgraduate	9 (1.9%)	17 (2.2%)	26

[Total n=1220 Participants, n=462 (Egyptians), n= 758 (Saudis)].

Table 2. More than 90% of participants either from Egypt or KSA received double doses of vaccine and 81.2% & 74.1% of participants were found to be infected with COVID-19 before receiving the vaccine either from Egypt or KSA respectively.

Majority of population received Pfizer/BioNTech vaccine (45.7% & 77.4%), followed by Oxford-AstraZeneca vaccine (39.2% & 9.7%), while the lowest percentage received both vaccines (15.1% & 12.9%) either from Egypt or KSA respectively (Figure 1).

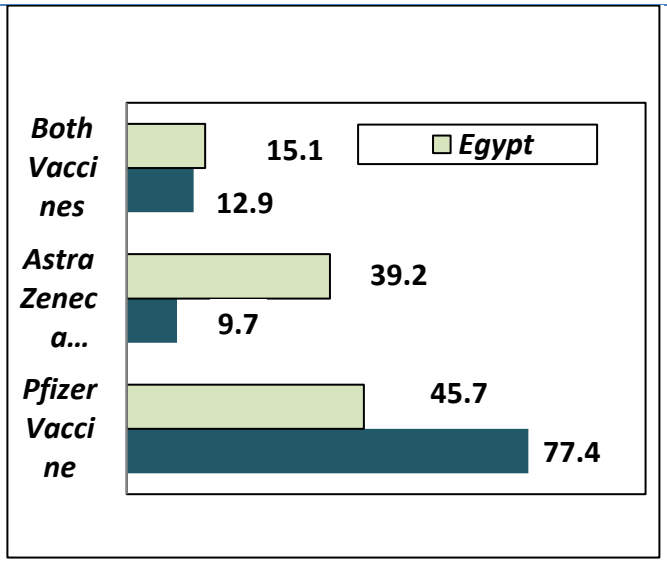

Figure1: Patients' answer about the type of Vaccine (%).

It was noticed that many symptoms were appeared after the first dose of Oxford-AstraZeneca vaccine and after the second dose of Pfizer/BioNTech in most of participants. As shown in **Table 3**, about 19.1% & 14.5% of participants without symptoms and 31.8% & 18.1% with severe symptoms while the majority with moderate symptoms (59.1% & 67.5%) after receiving vaccines either from Egypt or KSA respectively (Figure 2).

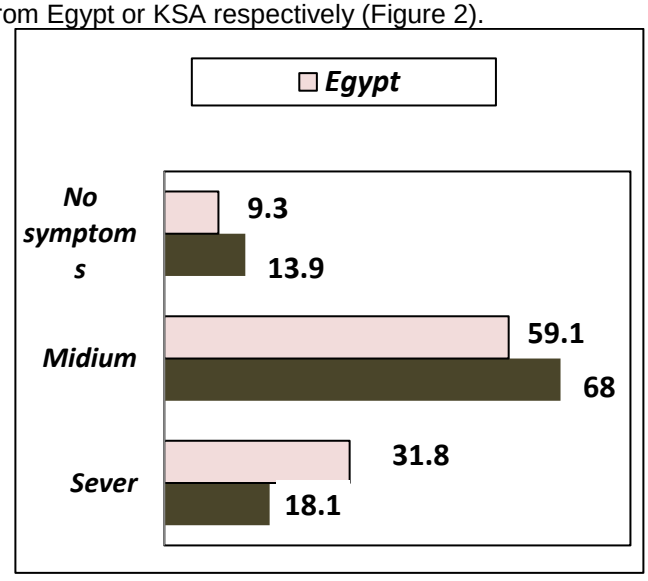

Figure 2: Pateints' answer about the severity of symptoms (%).

High percentages of participants suffered from symptoms after 4 hours from vaccination (27.1% & 34.4%) or after 12 hours (46.3% & 39.8%) either among Egypt or KSA respectively. These symptoms were varied between persons, fever (77.1% & 70.4%), pain, redness and swelling at the injection site (65.2% & 50.1%), Muscle pain

(69.3% & 45.8%), Fatigue (49.8% & 38.8%), Headache (47.4% & 38.7%), are the most common symptoms appeared either among Egypt or KSA respectively. The respiratory symptoms were severe with hospital admission for small number of participants (1.3% & 1.3%), while (22.9% & 3.6%) having severe symptoms without hospital admission either among Egypt or KSA respectively (Figure 3).

Table 3: Sign and symptoms among studying groups after receiving vaccination.

Question	Answer	Egyptians n (%)	Saudis n (%)	P value
The symptoms after vaccination.	Pain, redness and swelling at the injection site	301 (65.2)	380 (50.1)	0.034*
	Loss of smell and taste sensation	10 (2.2)	30 (4)	NO
	Fever	356 (77.1)	269 (70.4)	NO
	Deep vein thrombosis	11 (2.4)	6 (0.8)	NO
	Diarrhea, nausea, and vomiting	117 (25.3)	96 (12.6)	0.009*
	Sleep disorder	256 (55.4)	120 (15.8)	0.000*
	Muscle pain	320 (69.3)	347 (45.8)	0.008*
	Headache	219 (47.4)	293 (38.7)	0.01*
	Fatigue	230 (49.8)	294 (38.8)	0.01*
	Sweeting & Numbness	133 (28.8)	110 (14.5)	0.04*
	No Symptoms	88 (19.1)	110 (14.5)	NO
The severity of symptoms.	Severe	147 (31.8)	136 (18.1)	0.001**
	Moderate	227 (49.1)	512 (67.5)	0.001*
	No symptoms	88 (19.1)	110 (14.5)	NO
The time of symptoms appearance after vaccination.	Four hours	125 (27.1)	261 (34.4)	0.038*
	12 hours	214 (46.3)	301 (39.8)	0.044*
	24 hours after receiving the vaccine	30 (6.4)	64 (8.4)	NO
	After > 20 hours	12 (2.6)	22 (2.9)	NO
	No symptoms	81 (17.5)	110 (14.5)	NO
The duration of symptoms after vaccination.	Less than one day	158 (34.2)	144 (19)	0.006*
	1-3 days	180 (38.9)	435 (57.4)	0.015*
	4-7 days	36 (7.8)	69 (9.1)	NO
	No symptoms	88 (19.1)	110 (14.5)	0.043*
Receiving medications to relieve symptoms.	Yes	371 (80.3)	503 (66.7)	0.013*
	No	91 (19.7)	251 (33.3)	0.014*
The severity of respiratory symptoms and hospital admission.	No symptoms	241 (52.2)	590 (79)	0.019*
	Severe, without hospital admission.	106 (22.9)	27 (3.6)	0.001*
	Severe, with hospital admission.	6 (1.3)	10 (1.3)	NO
	Simple, without hospital admission.	109 (23.6)	120 (16.1)	0.033*
The respiratory symptoms appeared.	Breath Difficulties, Chest Pain & Cough	119 (25.8)	206 (27.2)	NO
	High Temperature	356 (77.1)	269 (70.4)	NO
	Nasal & throat Congestion	96 (20.8)	74 (19.4)	NO
	Nausea & dizziness	87 (18.8)	97 (25.4)	NO
Receiving medications to relieve the respiratory symptoms.	Yes	293 (63.4)	318 (41.9)	0.004*
	No	169 (36.6)	440 (58.1)	0.006*
Death after vaccination.	Yes	7 (1.5)	9 (1.2)	NO
	No	354 (76.6)	538 (71)	NO
	Do not Know	101 (21.9)	211 (27.8)	0.049*

[Total n=1220 Participants, n=462 (Egyptians), n= 758 (Saudis)]…

The most common respiratory symptoms that appeared was fever (77.1% & 70.4%), while breath

difficulties, chest pain & cough (25.8% & 27.2&) among Egypt or KSA respectively (Figure 4). About 63% (Egyptians) and 41% (Saudis) received medication to treat these respiratory symptoms. Also, this study reported that 1.5% (Egyptians) and 1.2% (Saudis) were died after vaccination.

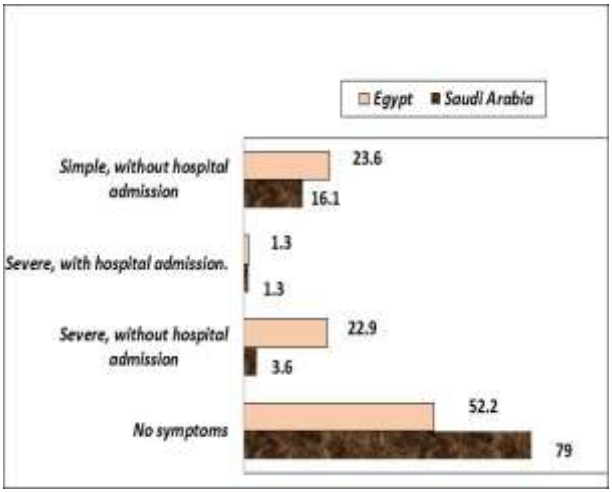

Figure 3: Pateints' answer about the respiratory symptoms severity with hospital admission (%).

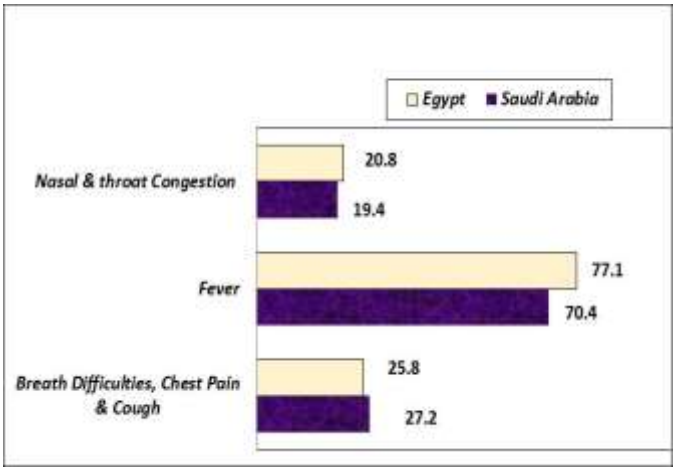

Figure 4: Pateints' answer about the respiratory symptoms after vaccination (%).

DISCUSSION

Since the beginning of the COVID-19 pandemic in January 2020, most countries have taken precautionary measures to control SARS-CoV-2 transmission with the hope of rapid production of safe and effective vaccines [Algaissi AA et al. 2020]. In response, different vaccine candidates have been simultaneously developed and only a few of them were authorized for Emergency Use Authorization (EUA) [Dal-Ré R et al. 2021]. Saudi Arabia is one of the countries that have started an early vaccination campaign as a continuum for its early unprecedented efforts and actions to combat SARS-CoV-2 spread [Algaissi AA et al.2020, Larson HJ et al.2021]. Despite the availability of the vaccine for the population in Saudi Arabia, there is a variation in people's acceptance to take the vaccine and this is probably due to the fact that these vaccines were developed in a short time compared to the previously approved vaccines which usually take years before approval. Another reason for this variation could be related to the usage of a newly emerging technique for some of the COVID-19 vaccines, mRNA vaccines [Larson HJ et at.2017 Dubé, E et al.2013, Bono SA et al.2021, Al-Qahtani WS et al.2021, Alfageeh EI et al.2021]. These two major factors may raise the concern among some individuals about potential severe post-vaccination side effects, although several reports describing the expected side effects have been issued recently [Dal-Ré R ET AL.2021]. Thus, in this study, we aimed to evaluate and compare the short-term side effects associated with the COVID-19 vaccines which are currently used in Saudi Arabia and Egypt. We collected data from individuals who received COVID-19 vaccines in Saudi Arabia and Egypt, either Oxford-AstraZeneca or Pfizer- BioNTech vaccines.

Both vaccines have reported severe (31.8% & 18.1%) and moderate (59.1% & 67.5%) symptoms after receiving vaccines either from Egypt or KSA respectively. It has been reported, either from the trial results or the real-world data, that the side effects associated with the COVID-19 vaccine are mild to moderate [Larson HJ et al.2011, Dubé, E et al.2013, Bono SA et al.2021, Voysey M et al.2013 Al-Qahtani et al.2021]. These effects associated with the vaccine and this variation due to the age/gender of the individual, type, and the dose.

In our study, most of the participants reported some side effects such as fever, pain, redness and swelling at the injection site, muscle pain, fatigue, headache among Egyptian or Saudis and these symptoms that appeared after 4 hours from vaccination (27.1% & 34.4%) or after 12 hours (46.3% & 39.8%) either among Egypt or KSA respectively. These findings are highly consistent with the reported results in phase III clinical trials and fact sheets of the vaccines, and it's mostly reported for those who received the second dose [Alfageeh EI et al. 2021, Voysey M et al.2020]. Similar data were also reported in a recent study conducted by Menni and his group, they found that tenderness and local pain around the injection site are the most reported side effects, and it occurred on the same day after the injection and lasted for about one day [Ramasamy MN et al.2021]. Furthermore, in a study conducted on participants receiving Pfizer-BioNTech in Saudi Arabia, it was found that 70% to 80% of the study participants have reported pain at the site of injection [El-Shitany et al. 2021]. Unlike other studies, most of the participants in our study reported having tiredness and high temperature, and this is mainly explained by the younger age of our participants (18-25 years old), compared to others' findings [El-Shitany et al. 2021 Ramasamy MN et al. 2021]. As it's also evidenced in

several studies that younger individuals reported a higher frequency of side effects compared to older individuals [Menni C et al.2021,Funk CD et al.2021].For the same reason, i.e., younger age of the participants, neither age nor gender was significantly associated with side effects. For example, in Menni et al. study the mean age of the participants was 50 years, and the majority of them were older than 55 years, where they reported less frequency of tiredness, from 8% to 21% of the participants, and women experienced more side effects than men [Funk CD et al.2021]. It's known that individuals who were vaccinated with the Oxford-AstraZeneca vaccine are more likely to have systemic side effects, such as fatigue and fever, compared to those who received Pfizer-BioNTech vaccine [Funk CD et al.2021]. It's noteworthy that our study was conducted at the time when the Saudi ministry of health has decided to postpone the second dose [Ministry of Health Announcemant.2021]. In the current report, we found that the respiratory symptoms were not mild to moderate, and only 1.3% need hospital admission, while (22.9% & 3.6%) having sever symptoms but without hospital admission either among Egypt or KSA respectively, also 63% (Egyptians) and 41% (Saudis) of our participants received medications to relieve these symptoms and these results revealed the safety of theses vaccines [Larson HJ et al.2011, Voysey M et al.2021].

CONCLUSION

We can conclude that only a few patients needed to be admitted to the hospital due to vaccines' side effects on respiratory system. Fatigue and fever were significantly associated with Pfizer-BioNTech, compared to the Oxford-AstraZeneca vaccine. These side effects such as pain at the site of the injection, fever, and headache, and they are more common in those after the second dose of the vaccines. A follow-up study is needed to evaluate the effectiveness of the vaccines in controlling COVID infection and assessment of long-term side effects.

CONFLICT OF INTEREST

The authors declared that present study was performed in absence of any conflict of interest.

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Research ethical approval number was (H-2021-226) that was reviewed and approved by the Research Ethical Committee (REC) at the University of Hail dated: 06/12/2021.

AUTHOR CONTRIBUTIONS

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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