

## Prevalence of Chronic Backpain after COVID-19 AstraZeneca and Pfizer/BioNTech Vaccines in Sultanate of Oman: A Survey-based Study

Nasir A. Hamad<sup>1</sup>, Lienda Bashier Eltayeb<sup>2</sup>,  
Senthilvel Vasudevan<sup>3</sup> and Priyanka Raj<sup>4</sup>

<sup>1</sup>Department of Biochemistry, College of Medicine and Health Sciences,  
Al-Neelain University, Sudan. National University, Oman.

<sup>2</sup>Department of Medical Laboratory Sciences, College of Applied Medical Sciences,  
Prince Sattam Bin Abdulaziz University- Al-Kharj, Riyadh, KSA.

<sup>3</sup>Department of Public Health and Biostatistics, College of Medicine and Health Sciences,  
National University, Oman.

<sup>4</sup>Department of Community Medicine, Sri Venkateshwara Medical College, India.

<https://dx.doi.org/10.13005/bpj/2751>

(Received: 01 June 2023; accepted: 23 August 2023)

COVID-19 vaccine is known to cause a variety of side effects. Low back pain has been reported to be associated with at least one of the COVID-19 vaccines. The current study investigated the prevalence of chronic back pain in individuals vaccinated with AstraZeneca and Pfizer in Sultanate of Oman. This cross-sectional observational survey-based study was conducted among COVID-19 AstraZeneca and Pfizer/BioNTech vaccinated individuals in Sultanate of Oman. Two hundred participants were involved in the study. Chi square was used to analyse the association between categorical data. Data were analysed using SPSS (29<sup>th</sup> release). The prevalence of back pain among individuals vaccinated with AstraZeneca and Pfizer, was 36%. Females were more commonly affected by the back pain, especially in the 4<sup>th</sup> decade of life. AstraZeneca and Pfizer is associated with back pain, especially in females. Possible explanations require further investigations.

**Keywords:** Frequency, Chronic backpain, COVID-19, vaccine, AstraZeneca, Pfizer.

Coronavirus belongs to the family coronaviridae which contain glycoprotein spikes in their envelope that gives the virus a crown-like shape<sup>[1]</sup>. Coronavirus contains a single RNA molecule. The late SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2) has caused the highly contagious pandemic COVID-19, which is similar to severe acute respiratory syndrome.<sup>1</sup>

There are three main types of COVID-19 vaccines introduced based on how they are designed. The first type, an inactivated vaccine;

uses the whole organism after inactivation with certain chemicals, heat or radiation. This vaccine can be widely used among people including those who are immunocompromised. The second type is a live-attenuated vaccine which weakens the virus or bacterium while still alive. This type is not usually suitable for immunocompromised people. A third type, a viral vector vaccine; only delivers the genes with the information to trigger the immune response of interest through a vector<sup>2</sup>.

Four vaccines are approved for use in Oman, these include Pfizer/BioNTech vaccine (RNA), Oxford/AstraZeneca and Gamaleya Sputnik vaccines (non-replicating viral vectors), and Sinovac corona vaccine (inactivated)<sup>3</sup>.

The Pfizer/BioNTech is a messenger RNA vaccine that contains the nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2<sup>3</sup>. Other ingredients that help stabilize the vaccine may include lipids, salts as well as sugars. Possible side effects may be localized (to the site of injection) or systemic. Pericarditis and myocarditis have also been reported but very rarely. Additional side effects that have been reported include severe allergic reactions<sup>4</sup>.

The Oxford/AstraZeneca is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike glycoprotein produced in genetically modified human embryonic kidney (HEK) cells. The vaccine contains genetically modified organisms (GMOs). Other ingredients include L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, ethanol, sucrose and sodium chloride<sup>4</sup>. Very common side effects may be localized (tenderness, pain, itching or bruising) or generalized (fatigue, chills, headache, nausea, joint pain or muscle ache). Common side effects include vomiting or diarrhea, pain in legs or arms and flu-like symptoms. Uncommon side effects include sleepiness, decreased appetite, abdominal pain, enlarged lymph nodes and excessive sweating. Very rare side effects include thrombosis (brain, liver, spleen and intestine) and Guillain-Barré syndrome (GBS).<sup>5,6</sup>

### **Back pain and COVID-19**

The neurological effects of COVID-19 infection were thoroughly investigated and established<sup>7,8</sup>. A study by Morgan *et al* (2021) reported back pain after COVID-19 infection and concluded that it may be attributable to the virus but rather a transient condition<sup>9</sup>. Another study by Mohammad Ali *et al* (2022) found that 24.4% of COVID-19 survivors reported lower back pain, compared to 15.7% of people who hadn't been infected. Possible explanations were the dysregulated immune response and Spinal muscle weakness<sup>10</sup>. Some of the common side effects of different COVID-19 vaccines have also been reported. Among these side effects were

joint/muscle pain with Pfizer<sup>11</sup> and myalgia with AstraZeneca<sup>12</sup>.

A few studies focused on the association between back pain and COVID-19 vaccines. A study by Nagla *et al.* (2021) showed that the frequency of back pain among Saudi residents after the first Pfizer dose was 0.8% compared to 2.4% after the second dose. The duration of the pain, however, was not reported<sup>13</sup>. Another study by Balsam *et al.* (2021) concluded that back pain occurred in 2.8% of participants aged less than 49 years and 8.5% in those aged more than 49 years after the first dose of Sinopharm, compared to 2.4% and 5.1% after the second dose, respectively. Females were more commonly affected than males in both groups<sup>14</sup>.

Many Omani citizens, as well as expatriates residing in Sultanate of Oman, have increasingly reported back pain with variable intensity after one or both doses of the vaccine. There is no data regarding the pathophysiology of the back pain following Covid-19 vaccine. Erum Khan *et al.* (2022) reported one case of acute transverse myelitis as a vaccine-related case. It appeared within one week following the first dose of Moderna vaccine<sup>[15]</sup>. Many studies has also established an association between the vaccine and transverse myelitis<sup>16,17,18</sup>.

COVID-19 vaccine was also reported to trigger sciatica<sup>19</sup>. COVID-10 vaccines are also suspected to cause axial spondylarthritis<sup>20</sup>. Hence the current study aimed to measure the prevalence of back pain in individuals vaccinated with COVID-19 vaccines AstraZeneca and Pfizer/BioNTech in Sultanate of Oman. Moreover, the study has assessed the effects of various demographic as well as vaccine-related parameters on the correlation between the back pain and the vaccine.

## **MATERIALS AND METHODS**

This survey-based cross-sectional observational study was conducted in the period from April to November 2021 measure the frequency of back pain in individuals vaccinated with COVID-19 AstraZeneca and Pfizer in Sultanate of Oman. Sample size was taken from Omani individuals and expatriates residing in Sohar Province, Oman, vaccinated with Pfizer

or AstraZeneca during the period from April to November 2021. Exclusion criteria included history of medical or traumatic conditions that cause back pain (osteoarthritis, spondylarthritis, scoliosis, accident, compression fractures and herniated disc) and age extremities.

Two hundred participants were enrolled in the study, sample size was calculated based on a 95% confidence level, a 3% margin of error, a 2.4% proportion and around 222,000 population size. A structured questionnaire (online and hard copy) was used for collection of baseline and demographic data. The questionnaire was piloted prior to the study by using a representative group of 10 individuals. Responders filled up the questionnaire and offered their feedback. Accordingly, the questionnaire was refined and retested. The questionnaire was divided into two major domains, domain I covered variables related to demographic data (age and gender) and vaccine received (AstraZeneca/Pfizer). Domain II covered variables related to back pain (onset, intensity, character, location, temporal pattern, and duration). Chi square was used to analyse the association between categorical data. Data were analysed with the SPSS (28<sup>th</sup> version). All individuals signed an informed consent. Ethical approval was obtained from College of Medicine and Health Sciences, National University, Oman (registration ID: NU/COMHS/EBC0012).

**RESULTS**

**Socio-demographic data**

The study included Two hundred individuals. One hundred individuals were vaccinated with AstraZeneca and another hundred individuals were vaccinated with Pfizer. There was no control group as this is a cross-sectional study. Distribution of sociodemographic variables among participants is shown in table-1.

**Prevalence of back pain**

The study found that about 36% (72) of participants have developed back pain after being vaccinated. Six characteristics of pain were addressed including onset, intensity, character, location, temporal pattern and duration. Pain was graded using the 0-10 numeric pain rating scale<sup>21</sup>. It has been shown that pain was of sudden onset in 25% (18) individuals and gradual onset in 75%

(54) individuals (table-2). The study revealed that pain was severe in 9.7% (7) individuals, moderate in 61.6% (44) individuals, and mild in 29.1% (21)

**Table 1.** Distribution of socio-demographic variables among study subjects

Variable	No. of participants	Percentage (%)
Age group (in years)		
<20	29	14.5
20-30	36	18
30-40	85	42.5
40-50	33	16.5
>50	17	8.5
Total	200	100
Gender		
Male	90	45
Females	110	55
Total	200	100

**Table 2.** Frequency of back pain related variables among study subjects

Variable	No. of participants	Percentage (%)
Onset		
Sudden	18	25
Gradual	54	75
Total	72	100
Intensity		
Mild	21	29.1
Moderate	44	61.6
Severe	7	9.7
Total	72	100
Character		
Dull aching	36	50
Sharp	5	7
unspecified	31	43
Total	72	100
Location		
Lower half	55	72.2
Upper half	17	27.8
Total	72	100
Temporal pattern		
Intermittent	64	88.9
Continuous	8	11.1
Total	72	100
Duration		
< 1 week	15	20.8
1-2 weeks	12	16.7
2-4 weeks	18	25
> 4 weeks	27	37.5
Total	72	100

individuals (table-2). Regarding character, 50% (36) of individuals said that the pain was dull aching, 43% (31) said it was unspecified, and 7% (5) of individuals described it as sharp (table-2). Anatomically, the pain affected the lower half in 72.2% (55) of individuals and the upper half in 27.8% (17) of individuals (table-2).

Regarding temporal pattern, pain was intermittent in 88.9% (64) of individuals and

continuous in 11.1% (8) individuals (table-2). Lastly, the pain lasted for less than a week in 20.8% (15) of individuals, 1-2 weeks in 16.7% (12) of individuals, 2-4 weeks in 25% (18) of individuals, and more than one month in 37.5% (27) individuals (table-2).

**Back pain and age**

The current study concluded that 13.8% (10) of individuals with back pain were under

**Table 3.** Association between back pain and Age

Age	Back pain after vaccination		Total	Chi square	p value
	No n (%)	Yes n (%)			
<20 years	19 (14.8)	10 (13.8)	29	13.518	0.009
20-30 years	24 (18.7)	12 (16.7)	36		
30-40 years	55 (42.9)	30 (41.6)	85		
40-50 years	14 (10.9)	19 (26.3)	33		
>50 years	16 (12.5)	1 (1.4)	17		
Total column	128	72	200 (grand total)		

**Table 4.** Association between back pain and Gender

Gender	Back pain after vaccination		Total	Chi square	p value
	No n (%)	Yes n (%)			
Females	72 (56.2)	38 (52.8)	110	0.224	0.635
Males	56 (43.8)	34 (47.2)	90		
Total column	128	72	200 (grand total)		

**Table 5.** Association between back pain and Type of vaccine

Vaccine	Back pain after vaccination		Total raw	Chi square	p value
	No n (%)	Yes n (%)			
AstraZeneca	62 (48.5%)	38 (52.8)	100	0.347	0.555
Pfizer	66 (51.5%)	34 (47.2)	100		
Total column	128	72	200 (grand total)		

**Table 6.** Association between back pain and Dose number of vaccine

Vaccine	Back pain after vaccination		Total raw	Chi square	p value
	First dose n (%)	Second dose n (%)			
AstraZeneca	7 (19.4)	29 (80.6)	36	0.693	0.405
Pfizer	10 (27.8)	26 (72.2)	36		
Total column	17	55	72 (grand total)		

20-year-old, 16.7% (12) of individuals were in their twenties, 41.6% (30) of individuals were in their thirties, 26.3% (19) of individuals were in their forties, and 1.4% (1) were above 50-year-old (table-3).

Statistical analysis was significant at  $p < 0.05$ . Consequently, being in the age group 30-40 years is a risk factor for developing the back pain after the vaccine. On the other hand, individuals who are above 50-year-old, followed by those below 20-year-old, were the least to develop the back pain after vaccination.

#### **Back pain and gender**

The study showed that 52.8% (38) of female participants developed the back pain after whereas 47.2% (34) of male participants developed the pain. Statistical analysis was insignificant at  $p < 0.05$  (table-4).

Accordingly, gender has no effect on the association of back pain with the vaccine. In other words, being male or female did not decide whether an individual will or will not experience the pain.

#### **Back pain and vaccine type**

Regarding type of vaccine, 52.8% (38) individuals developed back pain after AstraZeneca while 47.2% (34) individuals developed the pain after Pfizer (table-5). Statistical analysis was insignificant at  $p < 0.05$ . In other words, type of vaccine did not affect whether a vaccinated individual will or will not develop the back pain.

#### **Back pain and dose number**

It was also shown that 19.4% of individuals vaccinated with AstraZeneca developed the pain after the first dose and 80.6% developed the pain after the second dose. Regarding Pfizer, around 27.8% of vaccinated individuals developed the pain after the first dose and 72.2% developed the pain after the second dose (table-6). Statistical analysis was insignificant at  $p < 0.05$ . As a result, there was no correlation between the dosage number and the prevalence of back pain.

## **DISCUSSION**

COVID-19 vaccine is known to cause several local and systemic side effects some of these are short-term and others occur as long-term complications. Low back pain was clearly and increasingly stated by a number of vaccinated individuals as a side effect<sup>1</sup>. In the current study, we

analyzed the prevalence of back pain in individuals vaccinated with AstraZeneca and Pfizer in Sultanate of Oman. Two hundred individuals were enrolled in the study, vaccinated with AstraZeneca and Pfizer. The study revealed frequency of back pain among vaccinated subjects was 36%. In my point of view, this percentage cannot be ignored as it represents more than one third of participants. By comparing this frequency to the frequency of back pain caused by the infection itself in the study done by Mohammad Ali *et al*<sup>12</sup>, which was 24.4%, we found that back pain was more frequent among vaccinated subjects. We concluded that the back pain was more related to the vaccine rather than to the infection. Moreover, this can support our theory that the vaccine is associated with back pain because the vaccine that is responsible for the back pain may be produced on a genetically modified basis that involves the virus that causes the infection itself<sup>6</sup>. Possible explanations for back pain after vaccination with these vaccines is the dysregulated immune response due to the infection caused by the vaccine and so-called vaccine-induced myalgia, transverse myelitis, spondylarthritis, or sciatica.

Our finding suggested that the low back pain was mostly intermittent, chronic dull aching in nature. As a result we can conclude that back pain that occurs after COVID-19 vaccination is a long-term rather than a temporal side effect, pointing to a possible etiological factor of long-standing nature which may or may not be dose-related.

The study also showed that the majority of individuals with back pain were in their thirties while those who were above 50-year-old were the least affected with the pain. Accordingly, it did not agree with Balsam *et al.* (2021) findings the back pain frequency was higher in participants aged more than 49 years<sup>15</sup>. Accordingly, our findings support the theory that these vaccines cause back pain as it affect individuals at a relatively younger age. This fact can make the vaccine a genuine contributor to the back pain because of the lesser probability of having the pain at a younger age due to other factors. The result that females were more affected than males was in agreement with Balsam *et al.* findings in both groups of age. There was no data regarding the pathophysiology behind women being more affected than males. Estrogen levels may play a role in the pathogenesis of low

back pain as it increases pain sensitivity among menopausal women<sup>22</sup>.

The study concluded that type of vaccine did not affect whether an individual will or will not develop the back pain. This is quite acceptable as both vaccine share some structural similarities and some common ingredients that help stabilize the vaccine. Most individuals developed the back pain after the second dose of both vaccines. This conclusion, though statistically insignificant, was in agreement with Nagla et al. (2021) study which found that the frequency was higher after the second dose<sup>1</sup>. The study, however, did not agree with the Balsam et al. findings which stated that around 10% of cases developed the back pain after the first dose, compared to around 7% after the second dose<sup>[15]</sup>. Our finding could be explained on the basis that the effect of the vaccine is of the dose-dependent type. Subsequently, the development of back pain can be classified as an “adverse effect” rather than a “side effect”.

There is no data regarding the pathophysiology of back pain following COVID-19 vaccine. Many studies reported transverse myelitis<sup>16,17,18</sup>, sciatica<sup>19</sup> and axial spondylarthritis<sup>20</sup> as possible complications of the vaccine. The possible causes of chronic back pain after vaccination was beyond the scope of the study.

There were several limitations to this study. As a cross-sectional study, the temporal link between the back pain and the vaccination cannot be determined because both are examined at the same time. Another limitation is that the study cannot support conclusions on the risk of disease, nor on causal relationships. This is because such studies offer a snapshot of a single moment in time; they do not consider what happens before or after the snapshot is taken. Other limitations included recall and selection bias, and limited time-points which do not allow for causal conclusions.

We recommend further longitudinal studies that conduct several observations over a longer period of time with an emphasis on the etiological background of the back pain after COVID-19 vaccination.

## CONCLUSION

The current study has investigated the frequency of back pain among individuals

vaccinated with COVID-19 AstraZeneca and Pfizer vaccines. The prevalence of chronic low back pain among vaccinated individuals was 36%. Females were more affected than males. The most commonly affected age group was especially the 4<sup>th</sup> decade of life. Possibilities of long-standing background like transverse myelitis, sciatica or axial spondylarthritis should always be put into consideration.

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