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Prevalence of Otorhinolaryngological Symptoms and Its Relationship with Previous Infection of Corona Virus among Post Vaccinated Individuals in Eastern region, Saudi Arabia

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Abstract— Background: Vaccination and other measureshave helped control the effects ofCOVID-19 in many countries. Many studies are being conducted to assess the side effects of different types of vaccines focusing on the general symptoms. Furthermore, there is no previous study that has investigated the prevalence of otorhinolaryngological symptoms among post-vaccinated patients in Saudi Arabia. **Aim:** This study aims to assess otorhinolaryngological symptoms post Covid-19 Vaccine and factors associated among patients with and without covid-19 infection. **Methods:** A Retrospective cross-sectional study was conducted among a sample of people at Eastern region who received at least 2 doses of covid-19vaccine. People who had otorhinolaryngological symptoms before the 2nd dose were excluded. The data collection sheet included socio economic and demographic information, covid-19infection, vaccination and post-vaccination otorhinolaryngological symptoms. **Results:** A total of 463 responses were gathered, 271 individuals fulfilling the inclusion criteria completed the study questionnaire. Participant's ages ranged from18 to 69 years with mean age of 33.5 ± 14.8 years old. Pfizer vaccine was received by 121 (44.6%) individuals, while 55 (20.3%) received AstraZeneca. The most reported were Runny nose/itching/sneezing (8.1%),Sensation of discomfort/feeling of something stuck in the throat (7%), cough (6.3%). Exact of 29.1% of persons with history of covid-19infections experienced otorhinolaryngological symptoms compared to 23.4% of others with no infection history. **Conclusion:** In conclusion, the study revealed that post-covid-19 vaccination otorhinolaryngological complications were not frequent but reported mainly nasal and respiratory complications, mostly among females. Furthermore, otorhinolaryngological symptoms were more frequent among persons who were infected with pervious covid-19virus.

Keywords: Covid-19, pandemic, vaccination, otolaryngeal, otorhinolaryngeal symptoms, population, Saudi Arabia

Introduction

COVID19 is an on-going viral pandemic which started in early December 2019 inWuhan city and has been declared as a worldwide emergency by world health organization 'WHO'. It has been identified as a novel enveloped RNA beta-corona virus [1]. It is transmitted via droplet, direct contact with oral, nasal, and eye mucous membrane. Also, it may becomeairborne through aerosol generating clinical procedure [2]. According to WHO, Globally, till 30 January 2023 there have been 753,001,888 confirmed cases of COVID-19, including 6,807,572 deaths [3].

In Saudi Arabia there were 827,737 confirmed cases of COVID-19 from 3 January 2020 to

27 January 2023, with 9,563 fatalities, As of December 3, 2022, 68,148,406 vaccination doses had been delivered [4].

The presentation of coronavirus disease can range from asymptomatic to very severe, resulting in death. The severity of the disease varies based on demographic feature, co-morbidities, and immune system response [5,6]. A multi-centers study with 1519 positive coronavirus disease across all regions of Saudi Arabia concluded the most common symptom were cough in 89,4% of cases, fever in 85,6%, sore throat in 81,6 %, runny nose in 72%. Less common symptoms were myalgia, headache, and gastrointestinal symptoms [7]. Saudi Arabia KSA was among the first countries thatmade major efforts in order to provide effective measures to prevent this pandemic disease from further spread and progression by implanting COVID-19 vaccination programs all around the country [8]. Pfizer-BioNTech mRNA vaccine (BNT162b2) and Oxford-AstraZeneca (ChAdOx1 nCoV-19) vaccine were the first vaccines that were approved and introduced to Saudi Arabia. Initially, these vaccines were attained for some high-risk people, such as healthcare workers and old age people with chronic diseases; then they became widely available for the whole population. Many studies are being conducted to assess the side effects of different types of vaccines focusing mainly on the general symptoms. The most common systemic adverse effects were myalgia, fatigue, headache, dizziness, fever, and vomiting, whereas the most common local adverse effects were pain and swelling at the site of injection and joint pain [9, 10]. The most common general vaccine-related complaints are locally in theinjection site of Pfizer vaccine in both people whose previously been infected withCovid19 and those who have not, along with other complaints like fast heartbeat, bonepain, fatigue, headaches, fever, and diarrhea. However, difficulty breathing wherehigher in previous infected participants (26.3%) compared to participants without previous infection (3.9%)(10,12). Regarding otorhinolaryngology (ORL)-related symptoms, rhino rhea (4.4%) were the most common complaints, along with sore throat (3.2%)and nasal congestion (2.9%). Flu symptoms and Bell's palsy were all reported as well[11].

Our aim to evaluate the prevalence of ORL symptoms in post-vaccinatedpersons and characteristics associated with the occurrence of the symptoms. There arefew studies reporting ORL symptoms in the community, and none have been conducted in Saudi Arabia. Furthermore, we aim to assess the relationship between the prevalence of ORL symptoms and the history of Covid19 infection.

Materials&Methods

Studydesign:

A descriptive community-based cross-sectional study conducted in Saudi Arabia, Easternregion.

Study size and population:

Any resident lives in Eastern region above 18 years old who received at least two dosesof COVID 19 vaccine is included in the selection criteria. Individuals who took singledose, refused to participate, younger than 18 years old and who had ORL symptoms before the COVID19 vaccine were excluded from the study.

The sample size was determined using a single population proportion formula. A 95%

confidence level, 5% margin of error. The estimated (p)Value is 65.5% which is the proportion of vaccinated population with 2 doses in Eastern region; the calculated sample size (n) = 350. N=0.655(1-0.655) (1.96)2/0.052.

The questionnaire was distributed among eastern resident, 463 responses were receivedand 271 responses were included, 192 responses got excluded according to the stated criteria.

Datacollection:
An online questionnaire distributed to the community by a Google forms link. Thequestions were formulated based of similar studies, the ORL symptomsobtained from American academy of otolaryngology. Otorhinolaryngology consultants reviewed and approved the Arabic version of the questionnaire. The questionnaire contains two main sections; the first section covers general information about the participants such as gender, age, chronic diseases, and infection status with SARS-CoV-2.The second section focused on the COVID-19 vaccine-related data such as type and date of COVID-19 vaccine, the first or second doses, symptoms that are commonly associated with the COVID-19 vaccine, it included common general and otorhinolaryngology symptoms found in the literature (cough, nasal congestion, rhinorrhea,sore throat, hearing loss, dizziness, loss of smell, loss of taste, ear pressure, and facial paralysis. Other symptoms such as weakness, fatigue, headache, myalgia, fever, vomiting, nausea, and anaphylaxis. Further questions as on set duration, severity of side effects were assessed as well.

The questionnaire validity was assessed and reviewed in context to study objectives.All suggested modifications were applied to improve the questionnaire validity till the final format used in the current study was obtained. The questionnaire showed satisfactory level of reliability with Cranach's Alpha based on Kurder Richardson method (KR-21) co-efficient for scale data of0.70.

Ethicalapproval:
Prior to conducting the survey, ethical approval was obtained from the Institutional Research Board and the Ethics Committee of King Faisal University in Al Ahsa cityafter fulfilling all the required ethical criteria (Research Number: KFU-REC-2022-FEB-EA000428).

Data analysis
The data were collected, reviewed, and then fed to Statistical Package for Social Sciences version 21 (SPSS: An IBM Company). All statistical methods used were two tailed with alpha level of 0.05 considering significance of P value less than or equal to
0.05. Descriptive analysis was done by prescribing frequency distribution and percentage for study variables including participant's bio-demographic data, covid-19infection, and vaccination and post vaccination symptoms. ORL symptoms among vaccinated individuals were graphed. Cross tabulation for showing factors associated with ORL symptoms post Covid-19 Vaccine and to assess the association between ORL symptoms and Covid-19 Vaccine among patient with /without previous COVID 19 infection. Thus done by using Pearson chi-square test for significance and exact probability test if there were small frequency distributions.

Results

A total of 271 individuals fulfilling the inclusion criteria and completed the study questionnaire were included in the study. Participant's ages ranged from 18 to 69 years with manage of 33.5 ±14.8 years old. Exact of 152(56.1%) participants were females and 255(94.1%) were Saudi. A total of 63(23.2%) have chronic health problem which was DM among 21(33.3%), HTN (17.5%), respiratory diseases (14.3%), and hypothyroidism (6.3%). Exact of 57 (21%) have medications. Covid-19 infection was before the vaccine among 59 (44%) persons (table1).

TABLE1. Bio-demographic data of covid-19 vaccinated individuals in Eastern region, Saudi Arabia

Bio-demographicdata	No	%
Ageinyears		
18-30	98	36.2%
31-40	78	28.8%
41-50	42	15.5%
51-60	40	14.8%
> 60	13	4.8%
Gender		
Male	119	43.9%
Female	152	56.1%
Nationality		
Saudi	255	94.1%
Non-Saudi	16	5.9%
Have chronic diseases		
Yes	63	23.2%
No	208	76.8%
What are the diseases		
DM	21	33.3%
HTN	11	17.5%
Respiratory	9	14.3%
Hypothyroidism	4	6.3%
CVD	5	7.9%
Others	13	20.6%

Do you take medications on a daily basis?		
Yes	57	21.0%
No	214	79.0%
Have you been diagnosed with Corona virus-Covid-19 previously?		
Yes	134	49.4%
No	137	50.6%
The time of infection with the Covid-19		
Beforevaccine	59	44.0%
Aftervaccine	75	56.0%

A total of 75 participants (27.7%) received two doses of covid-19 vaccine and 196(72.3%) received 3 doses. Pfizer vaccine was received by121(44.6%) individuals,
While 55 (20.3%) received Astra Zeneca, and 8 (3%) received Moderana while 87(21.1%) received more than 1 type. As for Post-vaccine symptoms, the most reportedwere local pain (37.3%), followed by tiredness (29.2%), fever (27.3%), headache (26.6%), weakness (9.2%) while 84 (31%) had no symptoms.(Table 2)

TABLE2. Covid-19 vaccination among study participants with associated symptoms

Covid-19 vaccination	No	%
Vaccine type		
Pfizervaccine	121	44.6%
AstraZeneca	55	20.3%
Moderna	8	3.0%
Morethan onetype	87	32.1%
Number of vaccine doses		
Twodoses	75	27.7%
Threedoses	196	72.3%
Post-vaccine symptoms		
None	84	31.0%
Localpain	101	37.3%
Tiredness	79	29.2%

Fever	74	27.3%
Headache	72	26.6%
Weakness	25	9.2%
Nausea & vomiting	20	7.4%
Allergy	4	1.5%
Others	3	1.1%

Otolaryngological Symptoms Among post vaccinated Individuals

The majority had no otolaryngological Symptoms (73.8%). The most reported wereRunny nose / itching / sneezing (8.1%), Sensation of discomfort/feeling of something stuck in the throat (7%), cough (6.3%), dizziness (4.8%), Sore throat (3.7%), Nasal obstruction (3%), and Anosmia (2.6%). The least reported were Change/hoarseness inthe voice (0.4%) and Loss of taste (0.4% while 73.8% of the vaccinated persons had no symptoms (Figure1).

A total of 14(19.7%) persons had the symptoms within minute after the vaccine but 42(59.2%) had the symptoms within days, 7(9.9%) within weeks and it was within month among eight persons(11.3%). Symptoms lasted for days among 48(67.6%) persons, and For weeks among 8 (11.3%), for months at 10 (14.1%) and 5 cases had the symptoms for more than 1 year. The daily activities were severely affected among 4 cases (5.6%) with symptoms, moderately affected at 25 (35.2%) cases, mildly affected among 28(39.4%) and 3 cases (4.2%) reported affected their sleep while 11(15.5%) had no effect at all. A total of 15 (21.1%) cases with symptoms needed going to hospital due to experienced symptoms.(Table 3)

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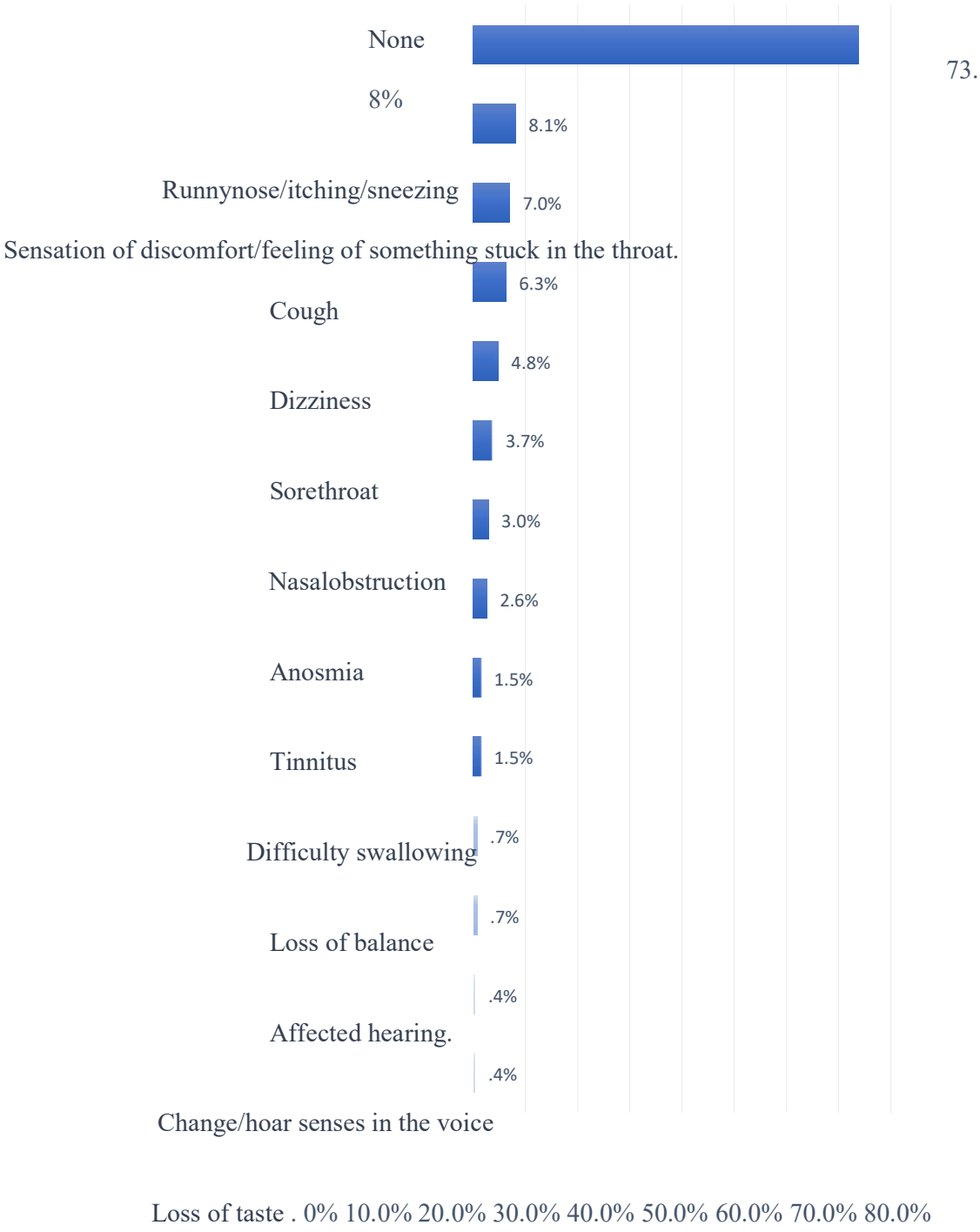

FIGURE 1. Otolaryngological symptoms among vaccinated individuals in Eastern region, Saudi Arabia

TABLE3. Otolaryngological Symptoms features among vaccinated individuals in Eastern region, Saudi Arabia

Otolaryngological Symptoms features	No	%
Duration till having the symptoms		
Minutes	14	19.7%
Days	42	59.2%
Weeks	7	9.9%
Months	8	11.3%
Duration of their symptoms		
Days	48	67.6%
Weeks	8	11.3%
Months	10	14.1%
>1year	5	7.0%
How do symptoms affect your daily activity?		
Noeffect	11	15.5%
Mildeffect	28	39.4%
Moderateeffect	25	35.2%
Severeeffect	4	5.6%
Verysevereaffectingsleep	3	4.2%
Did any of the above symptoms necessitate going to the hospital?		
Yes	15	21.1%
No	56	78.9%

The association between ORL symptoms and Covid-19 Vaccine among patient with /without previous COVID 19 infections. Exact of 29.1% of persons with history of covid-19 infections experienced ORL symptoms compared to 23.4% ofothers with no infection history. The most reports symptoms among covid-19 infectedcases were Runny nose / itching / sneezing (9% vs. 7.3%), followed by cough (9% vs.3.6%), Sensation of discomfort/feeling of something stuck in the throat (7.5% vs.6.6%).

TABLE4. The association between otolaryngological symptoms and Covid-19 Vaccine among patient with/without previous COVID19 infection

Otolaryngological Symptoms	Have you been diagnosed with Corona virus-Covid-19 previously?				p-value
	Yes		No		
	N	%	N	%	
None	95	70.9%	105	76.6%	
Dizziness	6	4.5%	7	5.1%	
Runny nose/itching/sneezing	12	9.0%	10	7.3%	
Sore throat	9	6.7%	1	.7%	
Difficulty swallowing	4	3.0%	0	0.0%	
Tinnitus	2	1.5%	2	1.5%	
Cough	12	9.0%	5	3.6%	
Nasal obstruction	5	3.7%	3	2.2%	.044*
Anosmia	6	4.5%	1	.7%	
Loss of taste	1	.7%	0	0.0%	
Sensation of discomfort/feeling of something stuck in the throat	10	7.5%	9	6.6%	
Affected hearing	2	1.5%	0	0.0%	
Change/hoar senses in the voice	0	0.0%	1	.7%	
Loss of balance	1	.7%	1	.7%	

P:Exactprobabilitytest
** P< 0.05(significant)*

Regarding the factors associated with ORL symptoms post Covid-19 Vaccine exact 31.6% of female participants had post vaccine ORL symptoms versus 19.3% of males (P=.023). All other factors were in significantly associated with having post-vaccine ORL symptoms.

TABLE 5. Factors associated with otolaryngological symptoms post Covid-19 Vaccine among study participants.

Bio-demographicdata	Post-vaccine otolaryngological symptoms				p-value
	Yes		No		
	N	%	N	%	
Ageinyears					
18-30	26	26.5%	72	73.5%	
31-40	14	17.9%	64	82.1%	.115
41-50	16	38.1%	26	61.9%	
51-60	13	32.5%	27	67.5%	
> 60	2	15.4%	11	84.6%	
Gender					
Male	23	19.3%	96	80.7%	.023*
Female	48	31.6%	104	68.4%	
Nationality					
Saudi	67	26.3%	188	73.7%	.910$
Non-Saudi	4	25.0%	12	75.0%	
Havechronicdiseases					
Yes	21	33.3%	42	66.7%	.142
No	50	24.0%	158	76.0%	
Doyoutakemedicationsona Dailybasis?					
Yes	18	31.6%	39	68.4%	.299
No	53	24.8%	161	75.2%	
Vaccinetype					
Pfizervaccine	32	26.4%	89	73.6%	
AstraZeneca	14	25.5%	41	74.5%	.999
Moderna	2	25.0%	6	75.0%	
Morethan onetype	23	26.4%	64	73.6%	
Numberofvaccinedoses					
Twodoses	19	25.3%	56	74.7%	.841

Threedoses	52	26.5%	144	73.5%

P:Pearson X^2test *$:Exact probability test*
** P< 0.05(significant)*

Discussion

Vaccination is one of the most successful public health interventions in controlling and preventing the spread of infectious diseases[12]. Saudi Arabia provide defective measures to control the disease spread by promptly implementing vaccination programs throughout the country[8]. Two doses of BNT162b2 were tested in the third phase of a randomized experiment, and the results showed high efficacy in protection against COVID-19, with only temporary, mild to moderate pain at the injection site, weariness, and headache. The frequency of severe adverse events (AE) was minimal and comparable across the place and vaccination groups [13].The safety of the ChAdOx1 nCoV-19 vaccine (AZD1222) was based onan interim analysis of data from four clinical trials completed in the United Kingdom, Brazil,and South Africa; nearly two-thirds of vaccinated persons experienced mild sideeffects. No causally related serious adverse effects were reported among thestudyparticipants [14].

The current study aimed to assess post-vaccination ORL symptoms and associated factors among patients with and without COVID-19 infection who received a COVID-19 vaccine. The study showed that nearly one-fourth of the persons who received at least two doses of the COVID-19 vaccine developed ORL symptoms. The most reported symptoms included runny nose, itching, and sneezing; a sensation of discomfort or feeling of something stuck inthe throat; cough; dizziness; sore throat; nasal obstruction; and anosmia. The least-reported symptoms were change/hoarseness in the voice and loss of taste.

According to Avcı, the most common ORL symptoms in post-vaccinated individuals were rhino rhea (4.4%), sore throat(3.2%), and nasal congestion (2.9%) [11]. Colizza et al. found that the most frequently described adverse effect following COVID-19vaccination in the literature are audio-vestibular symptoms, such as tinnitus, sudden sensor neural hearing loss (SNHL), vertigo, and dizziness. Other side effects, such as facial nerve palsy, epitasis, and oral manifestations, have also been reported [15].

Regarding tinnitus and hearing loss, only four participants in our study reported havingtinnitus after being immunized, while three experienced moderate effects on their daily activity. Two people reported decreased hearing but without concomitant tinnitus.Tinnitus and air fullness were found together in two people. Parrino et al. reported that after receiving a BNT162b2 mRNA-vaccine injection, three patients experienced tinnitus with normal hearingaccording to pure tone audiometry and no abnormalities in their brain MRIs [16]. In addition, Jeong et al. described three cases of Sudden SNHL after vaccination with Pfizer-Bio N tech and Oxford-AstraZeneca[17].

Yaniretal. Reported that a number of cases of SNHL occurred in the follow-up of individuals who had received the BNT162b2mRNA COVID-19 vaccine. However, other factors, particularly diabetes and cardiovascular disease, may have contributed to the emergence of SNHLintheir communities[18].

The Italian Drug Agency and the UK Medicines and Healthcare ProductsRegulatory Agency databases reported tinnitus, vertigo, and dizziness with an overall frequency of 0.15% and 0.41%, respectively [19]. Additionally, the CDC Vaccine adverse effect Reporting System (VAERS) in the United States reported SNHL at an incidence rate of 0.000046% in week three of vaccination [20].
13 person in our study complained of dizziness. Di Mauroetal. Reported 30 patients with acute vertigo and 3 patients with dizziness 48 hours post COVID-19 vaccination. Exact of 9 cases experienced benign paroxysmal positional vertigo and while 7 cases had no clinical evidence of vestibular or central impairment [21]. Another study reported for vertigo-like symptoms in 20 cases and tinnitus in 16 cases [22].

Contrary to literature, no reported symptoms of facial palsy were detected in our study.In Moderna vaccine phase 3 trials a blinded, placebo-controlled demonstrated Bell's palsy in 3 cases of vaccine group while the placebo group 1 case[23]. Ozonof A, stated the frequency of Bell's palsy found in the vaccine group is between 3.5 times and 7 times greater than what would be anticipated in the normal population[24]. Some studies suggested activation of latent virus infection of covid19 having a role as influenza vaccine does [25].

The study revealed that ORL symptoms were more frequent among persons who were infected with covid-19 virus. The study results are similar to the finding of Avcı H study. Avcı H suggested the higher incidence of ORL symptoms inpreviously infected persons might be explained by the theory of chronic olfactorydysfunction. Additionally, covid-19 vaccination can act as trigger with those with previous Covid-19 infection causing these ORL symptoms [11].
Our study showed the ORL symptoms appeared and resolved within dayswith mild to moderate effects on their daily life activities. Sleep was affected in3 cases and only one-fifth of thecases needed to visit a hospital.

Conclusions and recommendations
In conclusion, the study showed thatORL symptoms following covid-19 vaccination were uncommon, with the majority of respondents reporting no ORL-related symptoms. The most prevalent reported adverse effects concerned the nasal and respiratory systems, with rhinorrhea, itching, and sneezing being the most common. The majority of people only have their symptoms for a short time. The mechanism of these adverse effects is currently unclear. More research is needed to fully assess these adverse effects.
Overall, most adverse effect reports were from females. Additionally, those who had the covid-19 viral infection experienced higher ORL symptoms. Therefore, we recommend informing Covid 19 vaccine recipients about possible otolaryngologyadverseeffect. Continuous studies are necessary to acknowledge more about the post-vaccine symptoms in larger populations.

Limitation of study:
The data collection was done by self-administrated questionnaire to reach larger platform through social media. The study gathered small number of responses, was done in eastern region only.

Consenttoparticipate:
Electronic informed consent was obtained from all the participants in the beginning of the questionnaire.

Conflictofinterest
The authors declare that there is no conflict of interest regarding the publication of this article.

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