

Eustachian Tube Dysfunctions due to Mask Among Quarantined Healthcare Professionals During COVID-19 Pandemic: A Cross-sectional Study from Nuh, Haryana (India)

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Abstract

Background: Hand hygiene and personal protective equipment (PPE) are the key factors to prevent COVID-19 disease among healthcare workers. The documented side effects of continuous use of mask or PPE are dermatitis, but its effects on eustachian tube seems to be neglected. **Objectives:** So, we conducted this study by keeping our main objective as to investigate the eustachian tube dysfunctions (ETDs) due to continuous use of mask among healthcare professionals (HCPs) in district Nuh, Haryana. **Materials and Methods:** This cross-sectional study was conducted among 217 eligible HCPs. The sample size was calculated as 97 considering unknown prevalence of ETDs among HCPs (50%), so all HCPs were included in the study. We developed a structured questionnaire in which responses were close-ended and it attempted to capture the responses of the study participants and an association between variables was considered significant if the *P*-value was <0.05 . **Results:** Out of the 217 subjects, only 207 subjects provided their written consent after understanding the study objectives and 206 were included in the analysis as one subject has pre-existing ear disease. The daily hours of mask usage among 52.4% of participants was between 4 and 8 h; 2.6% of doctors experienced severe pain and pressure in the ear. The Eustachian Tube Dysfunction Patient Questionnaire-7 (ETDQ-7) score was significantly higher among females and mask usage of four or more hours ($P < 0.05$). **Conclusion:** The present study revealed that 42.3% of the participants had ETDs. The results will facilitate hospital-level administration to provide practical recommendations to medical workers such as head-supported mask instead of ear-supported masks and use of ear protectors.

Keywords: COVID-19 pandemic, eustachian tube dysfunctions, healthcare professionals, mask

INTRODUCTION

The COVID-19 has risen up out of Wuhan region of China and appeared as pandemic influencing everyone of the landmasses including the majority of the nations.^[1] Currently on March 22, 2021, worldwide documented confirmed cases are 126,308,812 and mortality due to it is around 2,777,746 and similarly count in India is rising exponentially with documented confirmed cases as 11,599,130 and mortality due to it is 159,755.^[2,3] The mode of spread of COVID-19 is basically droplet-based, and infection is acquired after getting into contact with

the droplets either present in the surrounding or settled on the objects.^[4]

In spite of the fact that the case fatality rate of COVID-19 (2.3%) is lower when contrasted with severe acute respiratory syndrome (9.5%) and Middle East respiratory

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syndrome (34.4%), when it comes to rate of transmission it is quite high in contrast to those illnesses.^[5] As the transmission rates are higher, the healthcare workers (HCWs) dispensing duties in vicinity of COVID-19-infected or suspects are vulnerable to acquire the infection very easily and will act as potential source of infection to transmit it to other patients of same or other wards or to the other colleagues. The recent literature has shown that high transmission rates have raised concern among HCWs and they are sometimes over conscious while providing care to patients or suspects.^[6]

Hand hygiene and personal protective equipment (PPE) are the key factors to prevent COVID-19 disease among HCWs. Furthermore, the Ministry of Health and Family Welfare (MoHFW), India, has currently published regulations and guidance over the use of masks and PPE for health workers.^[7] There is no doubt that every content of PPE is necessary for preventing infection from COVID-19, but among them the facial mask is the only content which is used for the most of hours.^[8] The most frequently occurring side effects of wearing face mask continuously for longer duration are facial skin complications which include mild erythema, rashes, swelling, severe inflammatory pustules, maceration, and lichenification of the nasal bridge, forehead, and post-auricle areas that come into contact with the mask.^[9]

The side effect of continuous use of mask on Eustachian tube is untouched area, and no literatures (whether recent or past) were found after rigorous search over Google Scholar.^[10] The eustachian tube dysfunction (ETD) ranges from aural fullness or popping to pain which results in discomfort and affects the effective use of face mask.^[11] Moreover, recently, Government of India (GoI) has issued guidelines for use of mask in public places.^[12] As this global COVID-19 crisis provides a unique opportunity to work upon this untouched area, the present study was conducted with an aim to investigate the eustachian tube disorders among quarantined healthcare professionals (HCPs) due to continuous use of masks during COVID-19 pandemic, which will be overall the first step in identifying such side effects and will complement other upcoming future studies.

MATERIALS AND METHODS

Study setting and design

The present quantitative study was cross-sectional in design, conducted at one of the medical colleges of southern Haryana (Nuh) during the third week of April 2020. Nuh was the most exceedingly abysmal-influenced area among every one of the 22 districts of Haryana state with greatest number of positive cases. Countless people were sent on quarantine and isolation, which also included HCWs.

Study population and sample size

The study participants were the HCPs (doctors and nurses) who have completed their defined period of quarantine after working in the COVID-19 wards or fever clinics. The list alongside the contact details of such participants was obtained from Medical Superintendent office and it counted to around 217 eligible participants. The study excluded the subjects who were having pre-existing ear disorders such as vestibular/inner ear pathology who may incur dizzy or vertigo symptoms as a result of increase in middle ear pressure or having severe nasal obstruction, who developed COVID-19 disease during or after discharging duties and who were seriously ill such as malaria (fever in the evening hours associated with chills), high-grade fever (temperature of 39.4°C or more), and psychological distress (a score of 3 or more on General Health Questionnaire-12).

The sample size was calculated ($n = 97$) considering the proportion of healthcare personnel having ETD as 50% (studies not found in Haryana), with confidence level of 95% and 10% absolute allowable error by using online standard sample size calculator (OpenEpi), so we decided to include all eligible participants (217) in our study.

Study tool

We developed a structured questionnaire in which responses were close-ended and it attempted to capture the domains of participant's characteristics, any pre-existing diseases, daily hours of mask usage, and symptoms related to ETD during or after mask use over past 1 month. The validity of gathered questions for the questionnaire was performed by a group of doctors counting to 15 in number from various specialties with an aim to spot the questions having maximum level of agreement among the group and questions having an Aiken's $V > 0.7$ were finalized for the study and Cronbach's alpha of the questionnaire was 0.90. According to the study's objective, every attempt was made to keep the questions clear and unambiguous. Before distributing the final questionnaire to the study participants, refinements were made as required to aid comprehension and organize the questions. Prior to moving to the ethical review, we piloted the developed questionnaire in 10 HCWs (doctors and nurses) to note the comprehensiveness of questions and average time taken by participants to complete the study questionnaire and it was found that the questionnaire was easily understood and the time required for completing the questionnaire was about 8–10 min.

The study questionnaire comprised three sections. Section 1 explored the demographic information of respondents including age, gender, and occupation (such as doctor and nurse). Section 2 collected information regarding any pre-existing disease among participants (such as any pre-existing ear disorders, asthma/chronic obstructive

pulmonary disease, sinusitis, hypertension, and diabetes mellitus) and daily hours of mask usage. Section 3 aimed to investigate the occurrence of symptoms related to ETD during or after mask use over the past 1 month using Eustachian Tube Dysfunction Patient Questionnaire (ETDQ-7).^[13] The ETDQ-7 is short and simple to use, with a low subject burden. It has been shown to be accurate and relevant for assessing ETD-related symptoms in adults for cross-sectional studies and is having high sensitivity and specificity. Particularly expressing ETDQ-7 diagnostic capability to differentiate between persons with disease and no disease is tremendous. In particular, the ability of the ETDQ-7 to discriminate between diseased and non-diseased groups is excellent. The seven statements regarding symptoms in ETDQ-7 were “Over the past 1 month, how much has each of the following been a problem for you” such as (A) pressure in the ears; (B) pain in the ears; (C) a feeling that your ears are clogged or under water; (D) ear symptoms when you have a cold or sinusitis; (E) crackling or popping sounds in the ears; (F) ringing in the ears; and (G) a feeling that your hearing is muffled. Response to statements was noted on a 7-point Likert scale format (1, 2 = no problem; 3, 4, 5 = moderate problem; and 6, 7 = severe problem).

The ETDQ-7 score ranged from a minimum of 7 to a maximum of 49 and a score of 14 or more was used as cut-off for categorizing the participants to have ETD.^[13] Also, pneumatic otoscopy was done among subjects to confirm ETD (retracted or poorly mobile tympanic membrane) and impedance audiometry (abnormal tympanogram); and subjects with moderate-to-severe disease were referred to hospital for further management.

Data collection

After receiving ethical approval from Institutional Ethical Committee (IEC), Government Medical College (GMC), Nalhar, the study was started. Participation in the present study was completely voluntary, and no compensation was offered. It was assured that prior to participation in the study, each participant gave informed consent, and the participants' anonymity and confidentiality were conserved. They were contacted over phone shortly after their 14-day quarantine period ended to ensure their availability to participate in this study. After explaining study's intent to participants, they were requested to participate. The investigator used a face-to-face interview approach to administer the questionnaire to the participants. The questionnaires filled by participants were also double-checked for completeness.

Data analysis

The gathered data were entered into an MS Excel spreadsheet, which was then coded and cleaned for any errors. IBM SPSS Statistics for Windows, Version 22.0 software (IBM Corp., Armonk, NY, USA), was used for

analyzing the study data. More variables were generated during data cleaning stage to make variable's association easier. Before applying frequency tests, clear values for different outcomes were specified. Quantitative data were presented as mean and standard deviation (SD), whereas categorical data were presented as percentages (%). For quantitative variables, an independent *T*-test was applied to assess differences among groups. The strength of the association between the categories for ETDQ-7 score and the independent variables was determined using the χ^2 test. All tests were run at a 5% level of significance; an association was considered significant if the *P*-value was less than 0.05.

Ethical consideration

The authors of this manuscript declare that this scientific work complies with reporting the quality, formatting, and reproducibility guidelines set forth by the Helsinki Declaration for the involvement of humans in research. Appropriate approval was obtained from Institutional Ethics Committee. Clinical trials registration was not done as it was an observational study.

RESULTS

Out of the 217 subjects, only 207 subjects provided their written consent after understanding the study objectives and 1 subject (0.5%) was having history of pre-existing ear disorders, so 206 subjects were included in the analysis. All study subjects were wearing the N-95 mask which was supported by ears while they were in the vicinity of COVID-19-suspected or positive patients. Female participants dominated in the study as they constituted 62.6% of the total participants. Among healthcare personnel, the doctors were 55.3% whereas nurses were 44.7%. The overall mean age $\pm$ SD of participants was

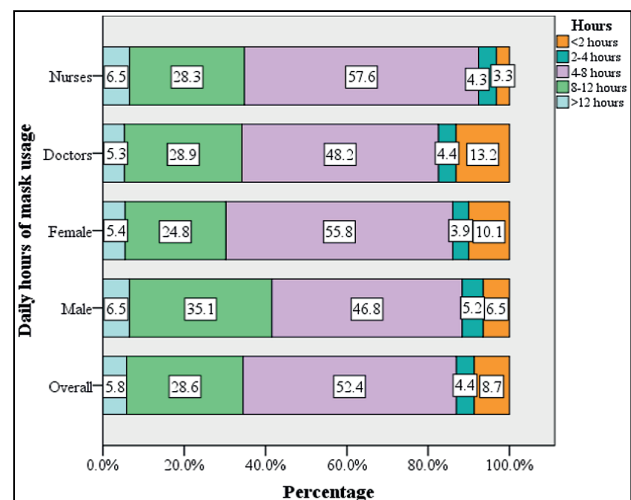


Figure 1: Daily hours of mask usage among study participants (*n* = 206)

32.05 ± 6.49, whereas the mean age for doctors and nurses was 33.82 ± 6.31 and 29.86 ± 6.04, respectively.

When asked specifically about history of previous illness, 4.9% of the participants responded as history of asthma, 2.9% responded as sinusitis, and 1.0% were hypertensives. Figure 1 shows that the daily hours of mask usage in more than half of the participants (52.4%) was between 4 and 8 h. Table 1 provides the distribution of responses to the ETDQ-7 Likert scale by the study participants, and the overall mean ETDQ-7 score was 14.71±6.83. Figure 2 shows the distribution of responses to the ETDQ-7 among doctors and nurses, and it was observed that 2.6% of the doctors responded that they had feeling of severe pain and pressure in the ear over the past 1 month after use of mask. Similarly, 2.2% of the nurses experienced severe ear symptoms during sinusitis, crackling or popping sound in the ear, and feeling of ears clogged or underwater.

Figure 3 shows the comparison of ETDQ-7 scores between doctors and nurses using the independent *T*-test analysis, and difference in the ETDQ-7 scores was not significant ($P > 0.05$).

Out of the 206 study participants, 87 participants (42.3%) had ETDQ-7 score of 14 or more, which means that 42.3% were having ETD during COVID-19 pandemic due to longer duration of mask usage. The otoscopy and tympanometry among those 87 participants with ETDQ-7 score of 14 or more showed that 61 participants (70.1%) had retracted or poorly mobile tympanic membrane and abnormal tympanogram, whereas subjects with ETDQ-7 of less than 14 had normal tympanic membrane and normal tympanogram. The χ^2 test analysis in Table 2 revealed that the ETD was significantly higher among females and participants having daily mask usage of ≥ 4 h ($P < 0.05$).

DISCUSSION

At present, COVID-19 is worldwide at the forefront in the media and most of the public, specifically among HCWs and patients; given that substantial and standard public health measures are essential for timely infection prevention and control, positive perceptions and practices among HCWs regarding COVID-19 prevention and control measures are crucial, and no research is currently being undertaken to explore the physical discomfort induced by PPE, particularly facial masks. The present study provided us a better understanding of the problems associated with ETD caused by wearing a facial mask, which is a vital practice for infection prevention.

The present study revealed that more than half of healthcare personnel (86.9%) were using mask for four or more hours. A study by Nepal *et al.*^[14] showed that there was good practice of wearing mask among more than 80% of the study participants. Similarly, studies done by Asaad *et al.*^[15] and Alsahafi *et al.*^[16] have shown positive attitude toward usage of mask/PPE among more than 70% of HCWs.

Studies conducted by Brainard *et al.*^[17] and Leung *et al.*^[18] have shown that triple-layer surgical facial masks are capable of significantly reducing the load of influenza virus RNA in respiratory droplets and coronavirus RNA in aerosols and respiratory droplets. However, although experimental models support the possible impact of hand hygiene or face masks, evidence from multiple randomized controlled trials (RCTs) of such interventions did not endorse a significant effect on spread of laboratory-confirmed influenza, according to a research by Xiao *et al.*^[19] and Jefferson *et al.*^[20]

Table 1: Distribution of responses to ETDQ-7 Likert scale among study participants ($n = 206$)

Eustachian tube dysfunction questionnaire (ETDQ-7)	Number (%) or mean+ SD						
	No problem		Moderate problem			Severe problem	
	1	2	3	4	5	6	7
Variables/Likert scale score							
Over the past 1 month, have you felt any "pressure" in the ears?	64 (31.1)	30 (14.6)	51 (24.8)	37 (18.0)	17 (8.3)	1 (0.5)	6 (2.9)
Over the past 1 month, have you felt any "pain" in the ears?	82 (39.8)	51 (24.8)	40 (19.4)	21 (10.2)	9 (4.4)	3 (1.5)	0 (0.0)
Over the past 1 month, do you have the feeling that your "ears are clogged" or "under water"?	106 (51.5)	33 (16.0)	24 (11.7)	33 (16.0)	8 (3.9)	0 (0.0)	2 (1.0)
Over the past 1 month, do you have the feeling of "crackling" or "popping" sounds in ear?	102 (49.5)	42 (20.4)	22 (10.7)	25 (12.1)	13 (6.3)	2 (1.0)	0 (0.0)
Over the past 1 month, do you have the feeling of "ringing" in ear?	121 (58.7)	44 (21.4)	12 (5.8)	19 (9.2)	10 (4.9)	0 (0.0)	0 (0.0)
Over the past 1 month, do you have the feeling that your hearing "muffled"?	107 (51.9)	29 (14.1)	28 (13.6)	25 (12.1)	14 (6.8)	2 (1.0)	1 (0.5)
Over the past 1 month, do you have the ear symptoms when you have a cold or sinusitis?	119 (57.8)	51 (24.8)	23 (11.2)	4 (1.9)	7 (3.4)	2 (1.0)	0 (0.0)
ETDQ-7 score	14.71±6.83						

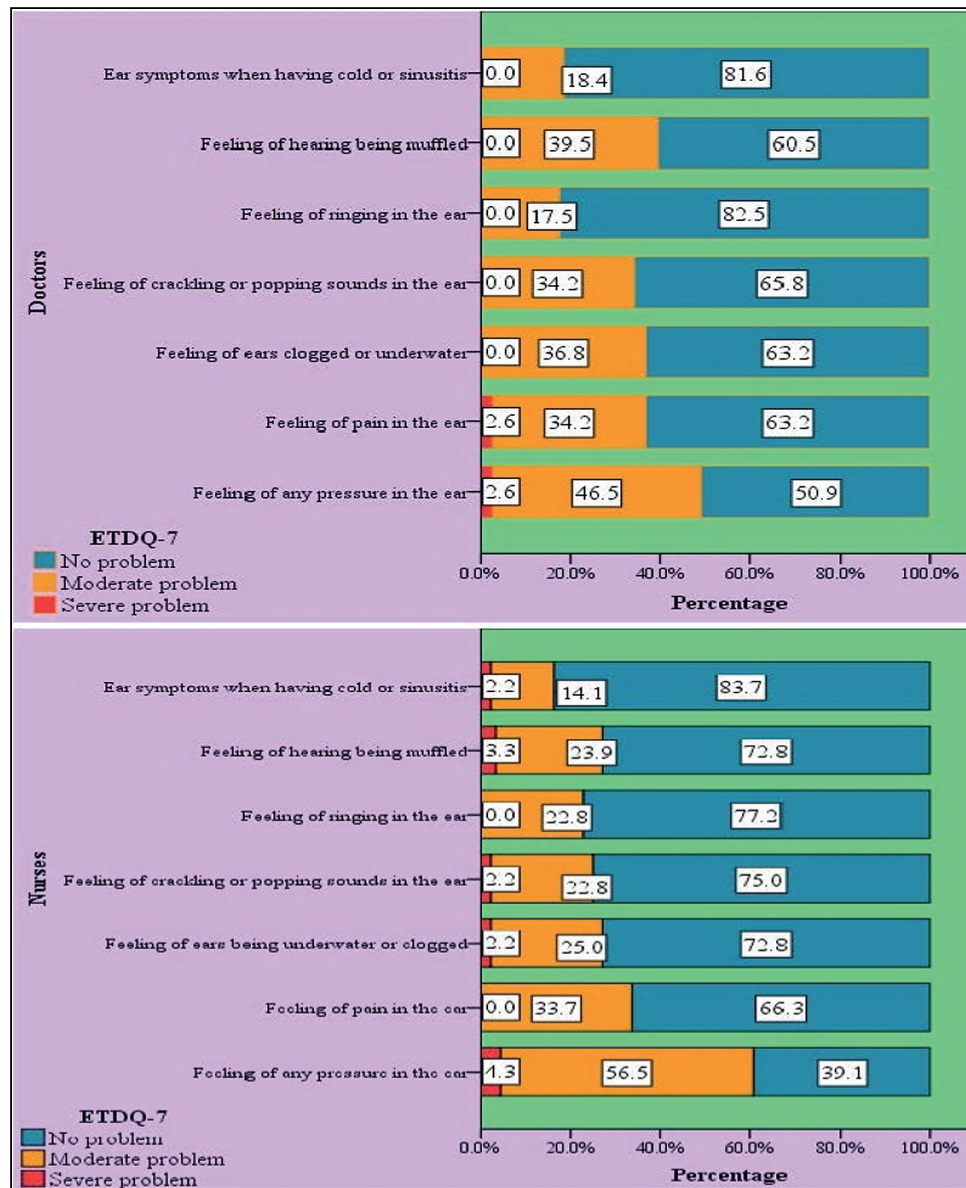


Figure 2: Distribution of responses to the ETDQ-7 among HCPs (doctors and nurses) ($n = 206$)

In the present study, the ETDQ-7 score of 14 or more was observed among nearly two-fifths of study participants (42.3%). The reliability and validity of ETDQ-7 in screening for ETD is well established. A validation study by Teixeira *et al.*^[21] has shown that ETDQ-7 score had a higher correlation with the ETD (AUC: 0.64, 95% CI: 0.50–0.77). Also, Menezes *et al.*^[22] showed that ETDQ-7 score had a higher correlation with the ETD (Pearson's correlation coefficient between 0.724 and 0.897; $P < 0.01$).

The χ^2 test analysis in the present study showed that ETD was significantly higher among females and there was longer duration of mask usage. Apart from ear problems, a recent study by Zuo *et al.*^[23] has shown that nearly half of the participants (49.0%) reported mask-related skin reactions such as acne, seborrheic dermatitis, rosacea exacerbation;

around two-fifths (17.1%) reported respiratory tract problems; and less than one-tenth (6.2%) had eye symptoms. Similarly, a study by Jiang *et al.*^[24] revealed that more than two-fifths of medical staff (42.8%) had skin injuries caused by PPE, with three distinct types reported such as device-related pressure ulcer, moist-associated skin damage, and skin tears. Furthermore, logistic regression indicated that daily wearing time [95% confidence interval (CI) for odds ratio (OR) 1.61–3.21] and being male (95% CI for OR 1.11–2.13) were associated with these skin injuries.

Other side effects include a significant reduction in the consistency and volume of voice among people who wear masks, as well as an unintentional closeness. While people wear a mask, the exhaled air gets into the eyes, causing them to feel compelled to touch the eyes.^[25]

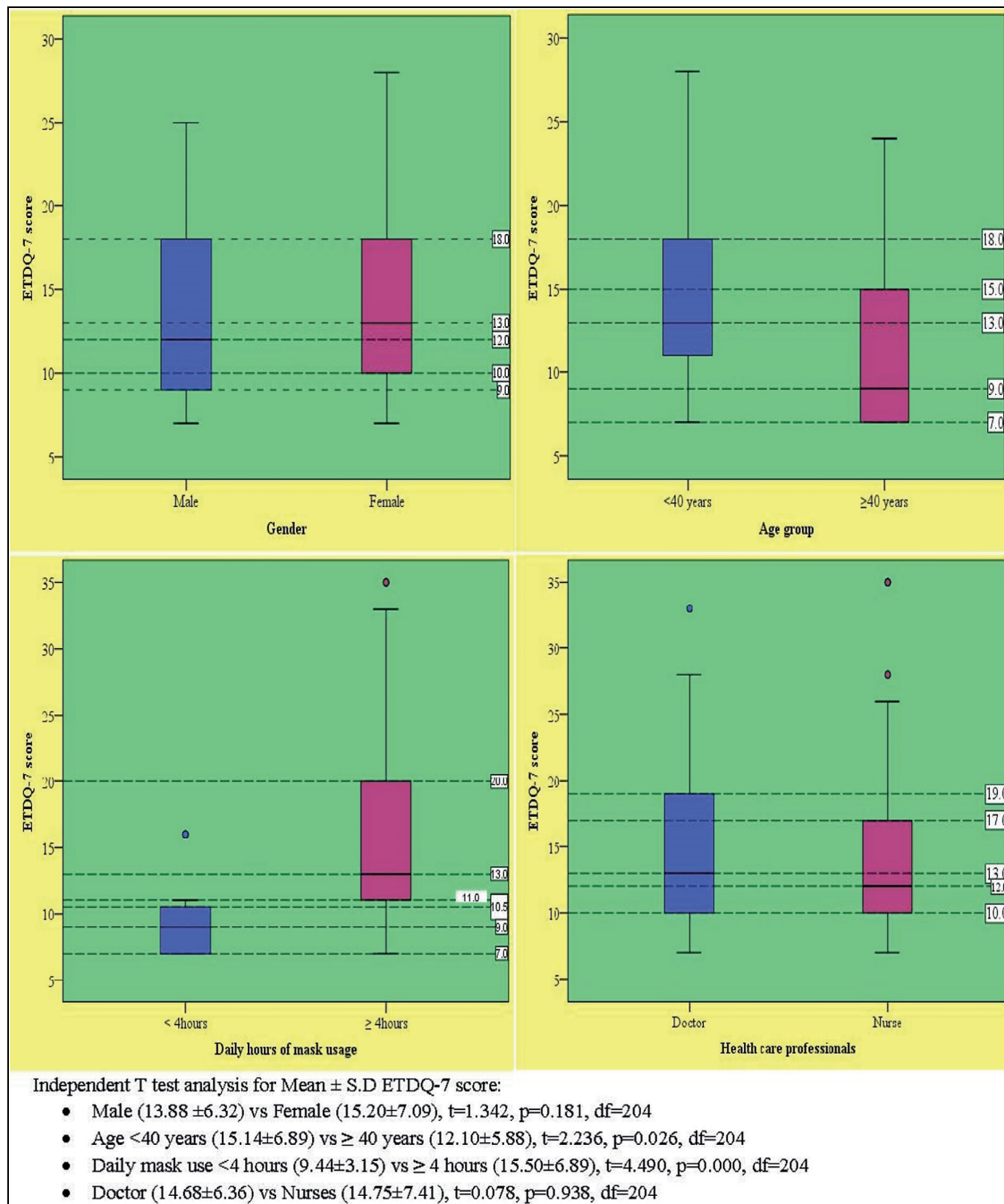


Figure 3: Independent T-test analysis for ETDQ-7 score among study variables ($n = 206$)

Furthermore, the Ministry of Health and Family Welfare (MoHFW), India, has currently published regulations and guidance over the use of masks in public locations, and Christopher *et al.*^[26] and Feng *et al.*^[27] have urged for the appropriate and rationale use of masks or PPE, but discomfort caused due to wearing facial masks will demotivate HCWs and general population.^[12] As World Health Organization has also expressed concerns about a global shortage of PPE, which puts health workers at risk, so to meet the demand, retailers have switched manufacturing to PPE for HCWs in the hour of this pandemic of coronavirus.^[28,29]

CONCLUSION

So, the present study made an attempt to find out the facial mask-related ETDs among healthcare personnel, and it was observed that 42.3% of the participants suffered from it. The results will facilitate the hospital-level administration to provide practical recommendations and solutions to medical workers such as head-supported masks (N-95 or triple-layer surgical mask) instead of ear-supported masks and use of ear protectors; the mask use shall be intermittent instead of continuous to avoid ETD. Prior to postings into COVID-19 wards or fever clinics,

Table 2: Independent association of variables and ETDQ-7 score among study participants (n = 206)

Variables	Frequency (%)		Test of significance
	ETDQ-7 score ≥ 14 (n=87)	ETDQ-7 score < 14 (n=119)	
Age group			
< 40 years (177)	79 (44.6%)	98 (55.4%)	$\chi^2=2.968$, df=1, P=0.085
≥ 40 years (29)	8 (27.6%)	21 (72.4%)	
Gender			
Male (77)	23 (29.9%)	54 (70.1%)	$\chi^2=7.703$, df=1, P=0.006
Female (129)	64 (49.6%)	65 (50.4%)	
Daily hours of mask usage ≥ 4 h			
No (27)	4 (14.8%)	23 (85.2%)	$\chi^2=9.575$, df=1, P=0.002
Yes (179)	83 (46.4%)	96 (53.6%)	
Occupation			
Doctors (114)	48 (42.1%)	66 (57.9%)	$\chi^2=0.002$, df=1, P=0.967
Nurses (92)	39 (42.4%)	53 (57.6%)	

a regular ear examination is needed, as well as guidance on how to reduce the risk of ETD. The person with moderate-to-severe ETD shall be referred to ear, nose, and throat (ENT) (outpatient departments) OPDs for further management.

While this research was novel in principle and tried to demonstrate the facial mask-associated ETD among HCWs, it has limitations and as similar previous studies were not available due to the novelty of the study, the ETDQ-7 score comparison was not illustrated to the same degree.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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