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EFFECT OF USE OF SURGICAL FACEMASKS AND FFP2 FACEPIECE RESPIRATORS WITH OR WITHOUT EXHALATION VALVES ON BREATHING AIR QUALITY AND PHYSIOLOGICAL OUTCOMES IN HEALTH WORKERS: A QUASI-EXPERIMENTAL MODEL

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ABSTRACT

After the COVID-19 pandemic, facemasks are widely used and it seems that they will be still with us for a longer time all over the world. There is an ongoing discussion about whether facemasks can be harmful to human health. Therefore, a series of quasi-experimental studies were planned to investigate the effect of masks both on breathing air quality and on physiological outcomes. This second step of the series aimed to investigate the effect of three mask types, commonly used in the community and by healthcare professionals, on breathing air quality, peripheral blood oxygen saturation and heart rate. This study included 30 healthy health workers and compared three types of facemasks: surgical facemasks, FFP2 facepiece respirators with and without exhalation valves. The measurements were made at rest and in room conditions. Oxygen, carbon monoxide, sulphur dioxide, nitrogen oxides, volatile organic compounds concentrations, humidity and temperature were measured in the room area, in the mouth-nose area before the mask was worn and in the same area inside the mask after the mask was worn, while simultaneous blood oxygen concentrations and heart rates were recorded. Significant alterations were observed in in-mask oxygen, volatile organic compounds, humidity and temperature parameters, but never causing inhaled oxygen concentrations to fall below 19.5%, which is the hazardous atmospheric environment oxygen level. The most prominent differences between atmospheric and in-mask values were observed in humidity and temperature ($p<0.001$). Measured blood oxygen saturations and heart rates were found not to be significantly different between three types of masks, being minimum and maximum values of both within physiological limits. It can be concluded that wearing surgical facemasks, FFP2 facepiece respirators with and without exhalation valves were found not to differ significantly by their physiological effect at rest, but the humidity and temperature in inhaled in-mask air to be above tolerable levels. Working to increase mask comfort can be recommended in order to increase the tolerance to wearing a mask.

KEYWORDS:
COVID-19, heart rate, N95, oxygen saturation, pandemic, surgical facemask

INTRODUCTION

A pandemic is described as an infectious disease affecting a large portion of the World, spreading rapidly among people and causing deaths. The number of affected people, rate of spread and the duration of the outbreak are dependent on regions affected, processes of the protective measures and vaccinations. The World Health Organization advises personal precautions against this pandemic such as washing hands frequently, maintaining social distance, avoiding contact with eyes, nose and mouth, and practising respiratory hygiene. Additionally some further measures have been taken in many countries such as limiting public transportation, closing schools, and curfews [1]. Before the introduction of vaccines to combat the COVID-19 epidemic caused by SARS-CoV-2, humanity had to rely on non-pharmacological methods such as wearing facemasks, maintaining physical distance and ensuring hand hygiene. As one of the most promising pharmacological methods to control the epidemic and to reduce the spread of the infection, vaccines strengthened our hand in combating the epidemic. Unfortunately, considering the time needed to vaccinate the whole society, the inequalities in the supply of vaccines, the weaknesses in the protectivity of vaccines and the social resistance to get vaccinated, it appears that non-pharmacological methods will remain on the agenda for some more time until the social immunity will be achieved. Raebel et al. reported that a focused preventive approach would ensure social immunity in a period of three to six months and then it could allow the vulnerable people to return to their normal life [2]. The question is “when” and “how

long" the community would be immune. While most experts estimate this date not to be before the second half of 2021, the debate on how to act in the meantime looks likely to continue. What scientifically and rationally is clear is that everybody should continue to use facemasks and other non-pharmacological methods until the social immunity threshold is reached. Allowing the virus to circulate freely without prevention strategies such as wearing a facemask means that the health system will be overloaded, resulting possibly in an inability to cope with other health problems in the community according to Randolph and Bareiro [3] and Aschwanden [4]. Some people think that wearing facemasks for long periods impairs the inhaling air quality and may negatively affect health. This may be the main source of the resistance to the use of facemasks. The health workers are the most vulnerable group, as they are obliged to use not only surgical masks, but also different types of filtered facepiece respirators (FFP2 with or without exhalation valves), or even both surgical and FFP2 masks together (mostly for economic concerns like prolonging the usability of FFP2 masks) for hours a day. There is an urgent need for finding evidence-based support for eliminating the worries about possible physiological harmful effects of facemask use by health workers and followed by a secondary benefit regarding the use by the general public.

This study aimed primarily to investigate the effect on the inhaled air quality and the physiological effects (blood oxygen saturation and heart rate) of surgical facemasks (SM) and FFP2 facepiece respirators with (vFFP2) and without (FFP2) exhalation valves among healthy healthcare professionals. The secondary benefit is expected as providing evidence-based data to healthcare professionals and educators, so that the compliance to be increased.

MATERIALS AND METHODS

Sampling and type of the study. This study is the second phase of a quasi-experimental research conducted in the Department of Public Health, Faculty of Medicine, Çukurova University, Adana, Turkey in January-March 2021. The minimum sampling size was calculated to include 30 participants, based on 80% of power and 95% of confidence interval. The number of participants composed of healthy healthcare workers was 30 in the study and with a total of 180 measurements, among them 30 were ambiental. All health workers from the Departments of Public Health and Work Health and Safety were invited to participate as volunteers and the first applying 30 were included in the study. The inclusion criterion was being healthy. Applicants with obstructive or restrictive pulmonary diseases or diseases affecting cardiovascular health were excluded. All participants underwent measurements for all steps of measurements. In order to increase the compliance the participants were donated all masks they had used.

Data collection forms. The data collection forms included sociodemographic information, indoor room-air quality measurements, room air quality, humidity and temperature measurements in the mouth-nose area (MNA) before the facemask was worn (no-mask), and same measurements in MNA after the facemask was worn (in-mask).

Measurement instruments. iBRID MX 6. Multi-gas monitoring device (Industrial Scientific Corporation, Pittsburgh, U.S.A.) was used for air quality and pollution measurements. This device can measure approximately 120 types of different substances like oxygen (O_2) saturation in air as a value in percentages (%), and carbon monoxide (CO), sulphur dioxide (SO_2), nitrogen oxides (NO_x), VOC (volatile organic compounds) concentrations in parts per million (ppm). The device has a warning alarm for high and hazardous concentrations. The warning time-point of the device was recorded during in-mask measurements.

VRN501 Veron. Fingertip pulse oximeter (Shanghai International Trading Company, Hamburg, Germany) was used to perform simultaneous peripheral blood O_2 saturation (SpO_2) measurements before and after wearing the mask.

Humidiometer and thermometer were used to perform simultaneous indoor ambient air quality measurements, no-mask and in-mask air quality measurements.

All the instruments were calibrated before starting the experiments.

Measurements. A total of 150 measurements were performed while wearing or not wearing facemasks in 30 healthy participants, all while the individual was resting in a closed room and 30 measurements in ambient air, with a resulting total of 180 measurements. The procedure was performed in three stages:

New, unused, standard, three-layer SM, FFP2 and vFFP2 type filtering facepiece respirators (FFR) were used during in-mask measurements. FFRs may be named shortly as "facemasks" throughout the text. These are nomenclatures classes for defining standards of facemasks. FFP2 is a European standard (Europe EN 149-2001) with a filtering performance of ≥ 94% and it is equivalent to N95 which is a US standard (United States NIOSH-42CFR84) with a filtering performance of ≥ 95% as indicated by the manufacturer [5].

The first stage included ambient air measurements of the room for a period of 10 minutes. The second stage measurements consisted of air quality parameters in MNA while the participant was not

wearing any facemask. The third stage included in-mask MNA measurements after the mask was worn. Both MNA measurements lasted 15 minutes each.

The measurements included six steps:

First step measurements: Room air quality and pollution measurements consisting of O_2, CO, SO_2, NO_x, VOC concentrations, and humidity and temperature.

Second step measurements: Before wearing any mask, MNA room air quality and pollution measurements consisting of O_2, CO, SO_2, NO_x, VOC concentrations, and humidity and temperature with simultaneous SpO_2 and heart rate measurements. Mean values at the fifteenth minute were recorded. Air quality measurements were performed by using disposable single-use soft medical cannulas for each participant. The probes were fit in the MNA tightly, not permitting any gas exchange with outside. Probes attached to the humidiometers and thermometers were changed for each participant in humidity and temperature measurements. The measurements were recorded after the 15th minute in order to free ambient air resident inside the cannula.

Third step measurements: Same measurements of the second stage were repeated, but this time after wearing SM (in-mask). Again, mean values at the fifteenth minute were recorded. In-mask air quality measurements were performed by using disposable, single-use, soft, medical cannulas inserted inside the mask. Probes attached to the humidiometers and thermometers were similarly changed after each participant in humidity and temperature measurements.

Fourth step measurements: Same procedure of the third step was repeated this time while wearing FFP2 facemasks with no exhalation valve. Again, mean values at the fifteenth minute were recorded.

Fifth step measurements: Same procedure of the third step was repeated this time while wearing vFFP2 facemasks. Again, mean values at the fifteenth minute were recorded.

Sixth step measurements: Same procedure of the third step was repeated this time while wearing FFP2 facemasks with exhalation valves covered by a surgical mask (SM+vFFP2). Again, mean values at the fifteenth minute were recorded.

Statistical analyses. Data were analysed by using SPSS 22 ® software. Normal distribution was tested with the Kolmogorov Smirnov test. Mean values were compared using repeated-measures analysis of variance (ANOVA) test. Bonferroni test was applied in post-hoc analyses. Statistical significance was accepted as $p<0.05$.

RESULTS

The average age of 30 healthy participants included in the study was calculated as 36.8±11.6 (min:23-max:60). The male to female ratio was 8:7. In-mask inhaled air quality parameters, SpO_2 and heart rates measured in the 15th minute after wearing three types of masks were presented in Table 1. The multi-gas monitor device did not give any warning alarm in none of the measurements; i.e. inhaled O_2 concentrations never fell below 19.5%, which is a hazardous atmospheric environmental oxygen level (Table 1).

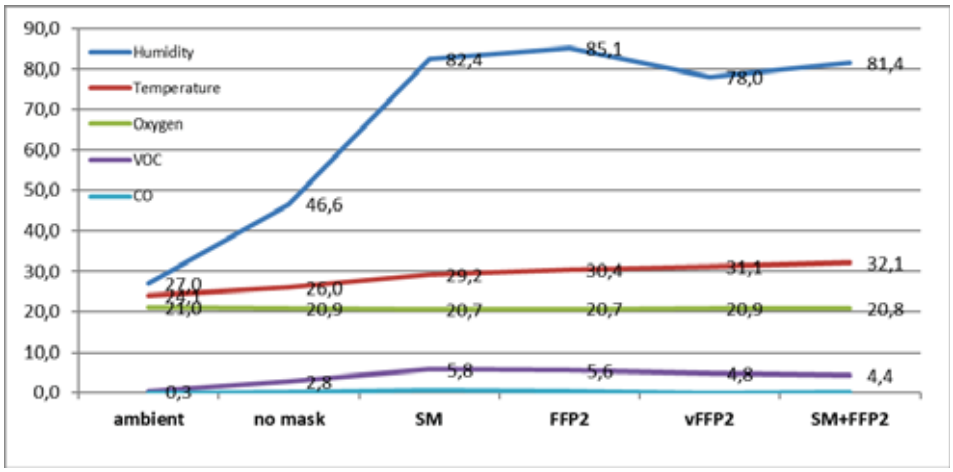


FIGURE 1
Mean ambient and in-mask mouth-nose-area measurement values
(SM: surgical facemask, vFFP2: FFP2 facemask with exhalation valve, VOC: volatile organic compounds, CO: carbon monoxide)

TABLE 1
In-mask air quality parameters and oxygen saturation comparisons according to facemask types

	Ambient (1)	No mask[1] (2)	SM[2] (3)	FFP2[2] (4)	vFFP2[2] (5)	SM+vFFP2[2] (6)	p	Partial eta[2]
O_2 (%)	21.04±0.11	20.96±0.14	20.68±0.25	20.71±0.26	20.86±0.15	20.81±0.16	**<0.001**	0.592
$CO_{(ppm)}$	0.00±0.00	0.26±1.03	0.73±1.53	0.46±1.24	0.00±0.00	0.26±1.03	0.146	0.104
$SO_{X\ (ppm)}$	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	-	-
$NO_{X\ (ppm)}$	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	0.00±0.00	-	-
VOC $_{(ppm)}$	0.32±1.23	2.88±4.25	5.84±6.22	5.58±6.38	4.79±5.96	4.39±4.96	**0.006**	0.286
Humidity (%)	27.00±2.47	46.60±16.82	82.46±11.23	85.13±12.11	78.00±9.95	81.40±11.47	**<0.001**	0.861
Temperature (^{0}C)	24.15±0.85	26.05±1.80	29.24±1.36	30.36±1.41	31.10±1.22	32.12±1.00	**<0.001**	0.912
Heart rate/minute		80.46±9.10	83.20±11.25	81.26±9.55	80.40±10.59	82.73±11.27	0.146	0.123
SpO_2		97.53±0.91	97.60±0.91	97.60±0.98	97.53±0.91	97.53±0.83	0.991	0.005

[1]In mouth-nose area outside the mask
[2]In mouth-nose area inside the mask
O_2: Oxygen, CO: Carbon monoxide, SO_2: sulphur dioxide, NO_x: nitrogen oxides,
VOC: volatile organic compounds, SpO_2: peripheral blood O_2 saturation)

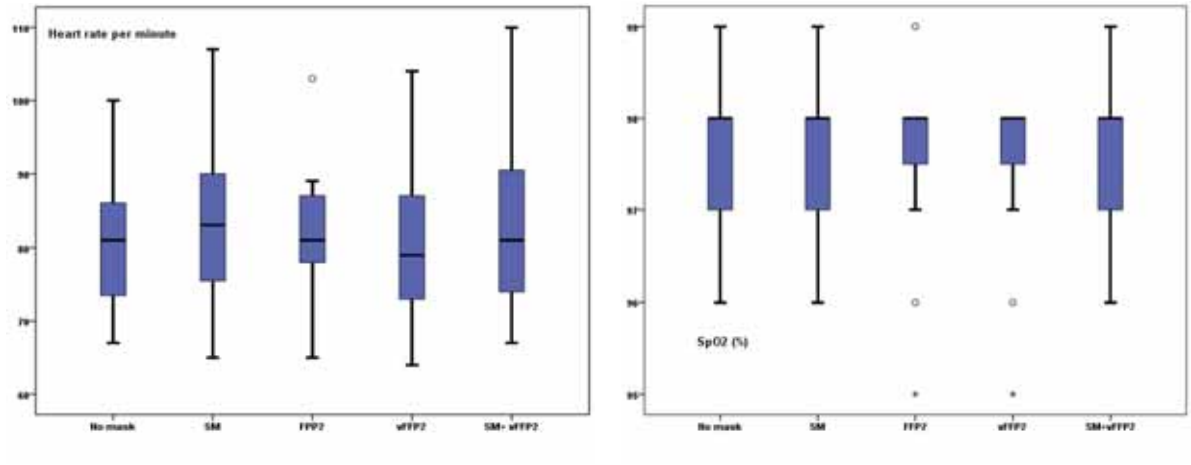


FIGURE 2
SpO_2 and heart rate changes according to facemask types (box-plot graphic)
SM: Surgical facemask, vFFP2: FFP2 facemask with exhalation valve, SpO_2: peripheral blood O_2 saturation

Significant alterations were observed in in-mask O_2, VOC, humidity and temperature parameters. In-mask O_2 saturation alterations were found to be related to facemask type in 59.2% of measurements, VOC values alterations in 28.6%, humidity alterations in 86.1% and temperature alterations in 91.2% of measurements. The most prominent differences between atmospheric and in-mask values were observed in humidity and temperature (Figure 1).
Significant differences were observed between the measurements of oxygen, VOC, humidity and temperature parameters after the mask was wore. The type of mask with the least change in humidity compared to the external environment was vFFP2. The measurements of oxygen level revealed decrease in all types of masks compared to the external environment, with the least decrease in vFFP2 and the most decrease in SM. A significant increase in VOC measurements was observed in SM and FFP2, while temperature significantly increased in all types of masks (Table 2).

TABLE 2
Post-hoc comparisons of O_2, VOC, humidity and temperature measurements

Measurement		O_2 (%)		VOC (ppm)		Humidity (%)		Temperature (°C)	
I	**J**	**(I-J)[1]**	**p**	**(I-J)[1]**	**p**	**(I-J)[1]**	**p**	**(I-J)[1]**	**p**
Ambient	**No mask**	0.080	0.128	2.560	0.404	-19.600	**0.005**	-1.900	**0.028**
	SM	0.367	**0.001**	-5.520[1]	**0.021**	-55.467	**<0.001**	-5.087	**<0.001**
	FFP2	0.333	**0.002**	-5.267[1]	**0.039**	-58.133	**<0.001**	-6.207	**<0.001**
	vFFP2	0.180	**0.003**	-4.473	0.113	-51.000	**<0.001**	-6.947	**<0.001**
	SM+vFFP2	0.233	**<0.001**	-4.073	0.059	-54.400	**<0.001**	-7.967	**<0.001**

[1] The difference between the mean
O_2: Oxygen, VOC: volatile organic compounds

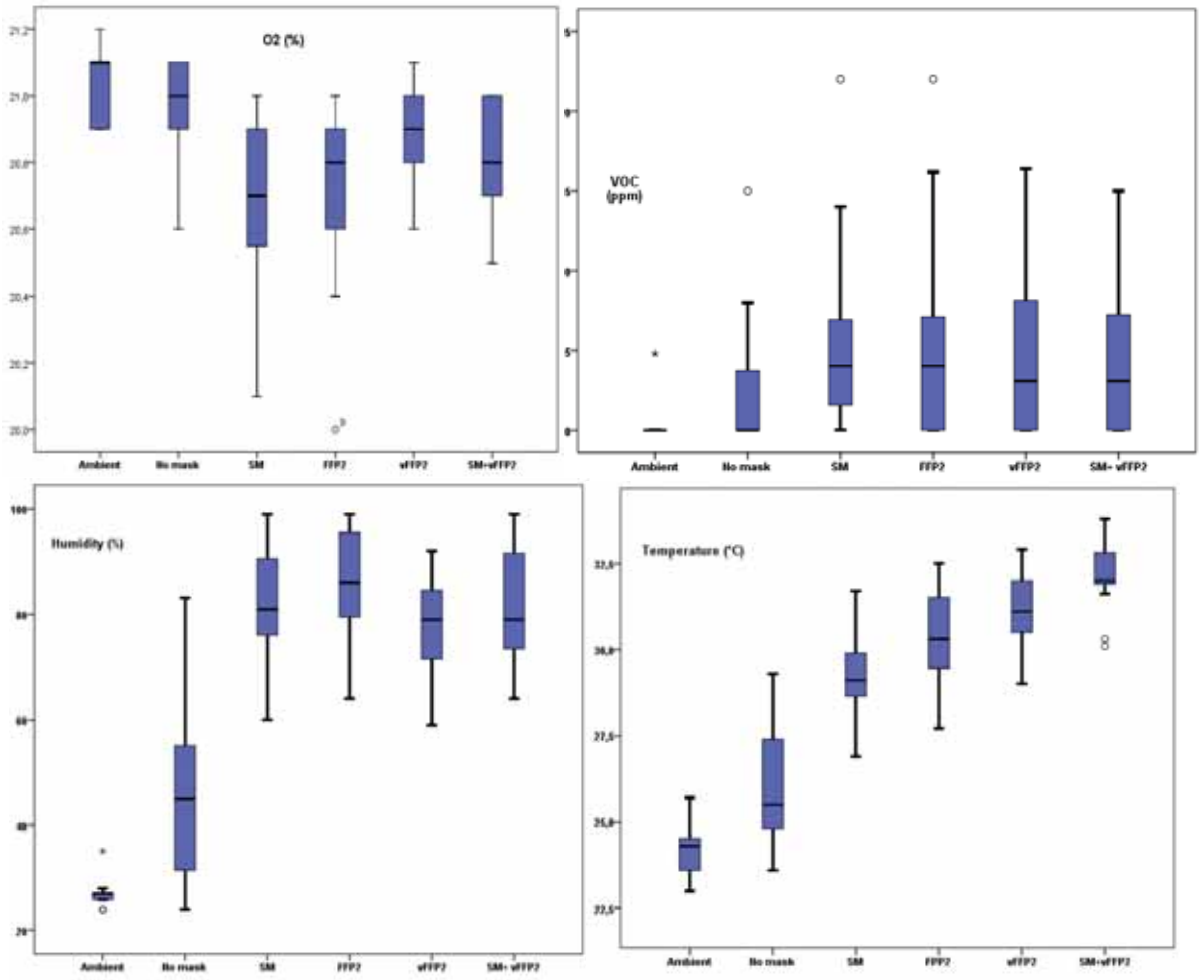


FIGURE 3
In-mask O_2, VOC, humidity and temperature changes according to facemask types (box-plot graphic)
SM: Surgical facemask, vFFP2: FFP2 facemask with exhalation valve, VOC: volatile organic compounds, O_2: oxygen

It was observed there not to be any statistically significant change in SpO_2 and heart rate values measured using different facemask types before and after wearing the mask, and the measured minimum and maximum values were within physiological limits (Figure 2).

In-mask oxygen saturation never fell below to the dangerous threshold and the amount of VOC did not rise to a dangerous level, while temperature and humidity levels were observed to have increased (Figure 3).

DISCUSSION

Spanish Flu, which occurred in the last century (1918-1920), infected about half a billion people and 17-50 million people died due to this epidemic. Trilla et al. [6] reported that the second period of the epidemic witnessed 75% of deaths from the disease. Subsequent influenza pandemics were relatively mild, and it is thought that the presence of vaccines and antiviral drugs changed the extent of the epidemic in the outbreak of the H1N1 virus in 2009 as indicated by Sullivan et al. [7]. The COVID-19 pandemic is the first infectious disease outbreak of this coverage and magnitude that the world has faced after the Spanish Flu. As of February of 2021, the number of cases in the world reached 111 million and deaths approached 2.5 million as published on the website of Worldometer [8]. The fact that the SARS COV-2 virus is novel and the lack of a virus-specific drug emphasize preventive strategies in the fight against the epidemic. Developments occurring every new day help us to develop new strategies in combating the epidemic. As of the beginning of 2021, the introduction of vaccines has allowed us to enter a new phase in the combat. However, inequalities in the provision of vaccines pointed out that non-pharmacological prevention strategies such as wearing facemasks will continue until effective social immunity is achieved. Wearing a mask is considered an inexpensive and effective method in the control of the epidemic. Liang et al. [9] observed that the combination of wearing a mask and physical distance measures provided a suppression in the epidemic curve. It is emphasized that the combined application of non-drug interventions like social distance, mask,

and quarantine, etc.) in some European countries leaded to a prominent decrease in R_0 as reported by the Eurosurveillance editorial [10]. Considering all these factors, it is obvious that the use of facemasks will continue for a while in the community. Compulsory widespread use of facemasks provokes worries about the quality of inhaled air. Brooks et al. [11] indicated that the community needed consistent and explicit messages for normalizing the use of facemasks.

In this study facemasks that are used in daily life and by healthcare professionals to reduce Covid-19 transmission, were examined for their effects on the breathing air quality and human physiology. Significant changes were observed in the in-mask oxygen, VOC, humidity and temperature parameters after wearing the mask. When unmasked breathing air was compared with the masked one, the most prominent change was observed in the temperature and humidity parameters. FFP2 facemasks with exhalation valve (vFFP2) presented the smallest difference in the humidity compared to the external environment. Compared to the external environment, a decrease in oxygen measurements were observed in all types of masks, with the least decrease in vFF2 type facemasks. The temperature, instead, increased significantly in all mask types. It was observed there not to be any statistically significant change in SpO_2 and heart rate values measured using different facemask types before and after wearing the mask, and the measured minimum and maximum values were within physiological limits. In-mask O_2 concentrations never fell below a 19.5%, which is hazardous atmospheric environmental oxygen threshold. Haraf et al. [12] reported that physiological effects of the mask use were at a negligible level during rest or exercise, the perceived effect appeared to be much greater than the measured effect and the increasing frequency of mask use led to an increase in both physiological and psychological adaptation. It was stated that the N95 mask reduced tidal volume, increased heart rate, potentially increased pCO_2 (partial pressure of carbon dioxide), therefore it was suggested that N95 masks should be preferred by health workers in close contact with confirmed patients. On the other hand, surgical masks that did not show any negative effects were stated to be appropriate for use by the general public. In a study by Sinkule et al. [13], investigating the effects of N95 and surgical masks on respiratory resistance and inhaled carbon dioxide at 6 different oxygen (energy) consumption levels; filtering facepiece respirators (FFR) and masks with exhalation valves (EVs) were found to have a significant effect on mean inhaled CO_2, mean inhaled O_2, and respiratory pressure. In a simulator system established, it was found that as the oxygen consumption increased, the amount of inhaled oxygen increased. At an oxygen consumption level of 3 L/min it was found that, when a surgical mask was externally worn on an N95 mask, the amount of inhaled oxygen decreased compared to a state when a surgical mask was worn alone. Samannan et al. [14] showed that surgical masks did not have any physiological effect on gas exchange (as measured by end-tidal carbon dioxide and oxygen saturation) during a 6-minute walking test in both healthy individuals and chronic obstructive pulmonary disease patients. In another study that involved ten health workers care professionals, the physiological effects that might occur by wearing an N95 facemask with or without an exhalation valve and a surgical mask externally worn on an N95 mask were examined by Roberge et al. [15]. No significant differences in heart rate, breathing rate, tidal volume, minute volume, and transcutaneous carbon dioxide and oxygen saturations were observed with the application of a surgical mask. It was found that exercise and comfort scores were not significantly affected by the surgical mask either, and the use of a surgical mask as an external barrier on the N95 FFR did not significantly affect the user's physiological load or perception of comfort or effort, compared to those experienced without using a surgical mask.

In our study, it was similarly found that wearing different mask types did not have abnormal physiological effects while at rest. The temperature and humidity levels inside the mask were observed to increase significantly compared to the atmospheric values. Increased temperature and humidity might cause difficulty in breathing because of an increased resistance in the respiratory tract. The discomfort felt when using a surgical mask was attributed to neurological reactions or psychological conditions such as anxiety, claustrophobia, and perceived sensory difficulty in breathing. The neurological reactions are thought to be caused by increased afferent stimuli originating from the sensitive area of the face (highly sensitive to heat) when covered with the mask or by the increased temperature of the inhaled air according to an another report by Roberge et al. [16]. Nielsen et al. [17] investigated the effect of humidity and temperature on the acceptance or tolerance of the mask in exercising people: it was found that the acceptance of wearing a mask was highest when the temperature inside the mask was 27°C and below, while the increase in the amount of humidity inside the mask increased the resistance to wearing a mask.

In one of our previous studies performed during summer and indoor, where the average humidity was reported as 54% and the temperature as 28°C, the physiological effects of surgical facemask use were found not to be significant, but the humidity, temperature and VOC values inside the mask were observed to have increased. Additionally, the amount of oxygen inside the mask was found to be lower when compared to our study performed in the winter period (average O_2 was measured as 17.47% with a range between 16% and 19%). Outdoor atmospheric values, especially humidity and temperature values were found to affect the air quality inside the mask.

The limitations of the study are as follows: the sampling was made among health health-workers, the tests were performed while the participants were resting.

CONCLUSION

In this study, it was found that the use of different types of facemasks did not cause abnormal physiological responses (heart rate or blood oxygen saturations) in healthy and resting people. It was observed that the quality of the inhaled air decreased in terms of humidity and temperature, and the comfort decreased. Improvements may be recommended aiming at an increase in the comfort of facemasks and in the compliance regarding the use of masks.

RECOMMENDATIONS

Occupational health workers can establish their education and training for the use of facemasks or facepiece respirators referring to the evidence-based data from the study. The primary benefit is expected as increased compliance of personal protective equipment and the secondary one will be prevention from communicable diseases.

ACKNOWLEDGEMENTS

Ethical Considerations. The study was ethically approved by the Çukurova University Faculty of Medicine Ethics Committee for Non-interventional Clinical Studies (Date: October 2nd, 2020 Number: 104 – 13). Informed written consent was obtained from all participants before the study.

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