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Impact of wearing a surgical mask on respiratory function in view of a widespread use during COVID-19 outbreak. A case-series study

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Abstract

Background: *Because of the COVID-19 outbreak, the widespread use of Respiratory Protective Devices (RPD) is recommended to prevent the spread of infection. This recommendation involves not only healthcare workers but other category of workers and the general population as well, in public places, especially where social distancing is difficult to maintain. The use of facemasks should not cause physical impairment to individuals, especially for people suffering from lung and heart diseases.* **Objectives:** *To evaluate the impact of RPDs on the respiratory function in healthy and asthmatic subjects, in order to identify the fitness for use mainly, but not only for, occupational purposes during COVID-19 outbreak.* **Methods:** *Ten individuals were included, three of which affected by asthma and three current smokers. A Respiratory Functional Test (RFT) was performed at three times: at the beginning of the work shift 1) without wearing and 2) wearing surgical masks, and 3) after 4 hours of usual working activities wearing the masks. Arterial Blood Gas (ABG) samples were also tested before the first test and the third test.* **Results:** *Observed RFTs and ABG parameters did not suffer significant variations, but for Maximal Voluntary Ventilation (P=0.002). Data on asthmatic subjects and smokers were comparable to healthy subjects.* **Discussion:** *Our results suggest that wearing a surgical mask does not produce significant respiratory impairment in healthy subjects nor in subjects with asthma. Four hours of continuing mask-wearing do not cause a reduction in breathing parameters. Fitness for use in subjects with more severe conditions has to be evaluated individually. Our adapted technique for RFTs could be adopted for the individual RPDs fitness evaluation.*

Riassunto

«Impatto dei dispositivi di protezione delle vie respiratorie sulla funzionalità respiratoria in vista di un uso diffuso durante l'epidemia di COVID-19. Una serie di casi». Introduzione: *A causa dell'epidemia di COVID-19 si raccomanda un uso diffuso di dispositivi di protezione delle vie respiratorie (RPD) per prevenire la diffusione dell'infezione. Questa raccomandazione coinvolge non solo gli operatori sanitari ma anche altre categorie di lavoratori e la popolazione generale nei luoghi pubblici, in particolare dove è difficile mantenere il distanziamento sociale. L'uso di maschere non dovrebbe causare danni fisici agli individui, specialmente per le persone che soffrono di malattie polmonari e cardiache.* **Obiettivo***: Valutare l'impatto degli RPD sulla funzione respiratoria in soggetti sani e asmatici, al fine di identificare l'idoneità all'uso, principalmente ma non solo, a fini professionali durante l'epidemia*

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di COVID-19. **Metodi***: Sono stati inclusi dieci soggetti, tre dei quali affetti da asma e tre attualmente fumatori. Test di funzionalità respiratoria (RFT) sono stati eseguiti tre volte: all'inizio del turno di lavoro con e senza indossare una maschera chirurgica, e con la maschera dopo 4 ore di normali attività lavorative. Un'emogasanalisi (EGA) è stata effettuata prima del primo e del terzo test.* **Risultati***: I parametri di RFT e EGA osservati non hanno subito variazioni significative, eccetto per la ventilazione volontaria massima (P = 0,002). I dati dei soggetti asmatici e fumatori sono paragonabili a quelli dei soggetti sani.* **Discussione***: I nostri risultati suggeriscono che indossare una maschera chirurgica non produce una compromissione respiratoria significativa in soggetti sani né in soggetti con asma o fumatori. Quattro ore di uso della maschera non causano una riduzione dei parametri respiratori. L'idoneità all'uso in soggetti con condizioni più gravi deve essere valutata individualmente, anche attraverso l'uso della nostra metodica per eseguire i RFT.*

Introduction

The outbreak of Novel Coronavirus disease (COVID-19) has become a pandemic, and the World Health Organization (WHO) has announced the highest infectious-disease level (Phase 6). Control of COVID-19 is a worldwide public health problem that governments and individuals are trying to overcome (31-33).

International guidance suggests transmission through direct and airborne droplets due to aerosol-generating processes such as talking, coughing, and sneezing. The 5 μm diameter threshold used to differentiate airborne from direct droplets is an oversimplification of multiple complex and poorly understood biological and physical variables (28).

Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Occupational Safety and Health Administration (OSHA), and Food and Drug Administration (FDA) sustain it is important to recognize that the optimal way to prevent COVID-19 transmission is to use a combination of interventions such as handwashing, social distancing, air change, and not just RPD alone.

In view of the differences in clinical manifestations (6) and the difficulties in early diagnosis, during the COVID-19 outbreak, the extended use of Respiratory Protective Devices (RPD) is however recommended to prevent the spread of the infection. The recommendation regards not only healthcare workers (9) but the general population at large, in public places, especially where social distancing is difficult to apply.

Generally, the purpose of an RPD is to prevent the inhalation of harmful airborne substances or to provide a source of respirable air when breathing in oxygen-deficient atmospheres. RPDs are used during the COVID-19 outbreak both to limit the possible inhalation of infectious agents and to reduce the transmission risk due to droplet emission.

In specific conditions, RPDs are prescribed in occupational environments by the occupational physician after a risk assessment and a careful examination of both individual physical conditions and information on RPDs technical characteristics.

Individuals must be able to wear a respirator without causing them physical impairment (27), and special attention must be paid to lung or heart diseases.

The RPD may harden the breathing effort leading to earlier dyspnea and fatigue for a given submaximal exercise task (7, 29, 30). This may worsen respiratory muscle fatigue when the subject wearing an RPD is affected by chronic airways obstruction, asthma, interstitial lung diseases, as well as by clinically significant heart disease.

Wearing a respirator mask increases the dead space volume, which can increase the depth and frequency of breathing (15, 23).

Some clinical studies (2, 5, 7, 19) have shown that increased resistance and increased dead space can lead to a very mild reduction in maximal work performance by approximately 10%.

Regarding groups of individuals with obstructive or restrictive pulmonary diseases, some Authors have found no difference in their exercise performance while using a respirator (1, 4, 14, 16, 17, 22). It is to be considered that this evidence refers only to certain types of respirators such as a half-face air-purifying respirator, full-face air-purifying respirator, powered air-purifying respirator, supplied-air respirators, and others.

A similar study was conducted by Lucero and coll. (18) on military personnel wearing standard military M40 protective mask. Military personnel with exercise-induced bronchospasm who exercised with the M40 protective mask did not overall have significantly increased airway hyperreactivity compared to control subjects.

Airways Infection prevention RPD and Respiratory Impairment During Their Use

In the health sector, but also in the general living environment, two types of RPD are used for preventing infections of the airways: N or FFP Respirators and Surgical Masks. According to the FDA (8), an N95 respirator is an RPD designed to achieve a very close facial fit and very efficient filtration of airborne particles. Note that the edges of the respirator are designed to form a seal around the nose and mouth. Surgical N95 Respirators are commonly used in healthcare settings and are a subset of N95 Filtering Facepiece Respirators (FFRs), often referred to as N95s.

A surgical mask is a loose-fitting, disposable device that creates a physical barrier between the mouth and nose of the wearer and potential contaminants in the immediate environment. These are often referred to as face masks, although not all face masks are regulated as surgical masks. Note that the edges of the mask are not designed to form a seal around the nose and mouth.

In literature, there are few studies regarding the assessment of the respiratory function in patients with respiratory diseases during the use of the surgical mask or the filtering facepiece class 2 or 3 (FFP2, FFP3) analogous to N95 and N99 Respirators, with or without valve.

Gruper and coll. (12) investigated the effect of a filtering facepiece class 3 (Pall PF 30) on lung function measurements in 92 children and adolescents with bronchial asthma and cystic fibrosis. In a randomized sequence, flow-volume curves and spirometry were registered in a whole-body plethysmograph. Values measured with filter correlated closely to those registered without; individual values remained close to the line of identity. With high flow rates, however, there was a minimal tendency towards lower measurements with filter; this damping effect was flow-dependent and remained of a clinically insignificant dimension.

Roberge and coll. (25) assessed the physiological impact of the N95 FFR on ten healthy healthcare workers. The authors monitored heart rate, respiratory rate, tidal volume, minute volume, blood oxygen saturation, and transcutaneous measured pCO_2. Each subject conducted multiple 1-hour treadmill walking sessions, at 1.7 miles/h, and 2.5 miles/h, while wearing FFR with exhalation valve, FFR without exhalation valve, and without FFR (control session). There were no significant differences between FFR groups and control in the physiological variables, exertion scores, or comfort scores.

The same Authors (26) conducted a similar study on healthy subjects wearing a surgical mask as an outer barrier added to the N95 FFR. During large-scale infectious outbreaks, filtering facepiece respirators, such as N95 Masks, may be in short supply. The paucity of PPE also happened, in our days, during the COVID-19 outbreak. For this reason, some authors suggested extending N95 masks' useful life by using a surgical mask as an outer barrier. For instance, Roberge and coll. (26) assessed the physiological impact of this added barrier. They found no significant differences in physiological variables between those who used surgical masks in addition to N95 and controls. Added surgical masks decreased dead space oxygen concentrations of the filtering facepiece respirators at the lesser work rate (P=0.03) and for filtering facepiece respirators with an exhalation valve at the higher work rate (P=0.003).

Subjective tolerance to respirator use outside of traditional industrial settings was also evaluated in subjects with mild respiratory impairment (13). The results of the study showed that half-face mask respirators typically had a more significant adverse impact than N95 mask and suggested that the latter use may be feasible on a widespread basis if necessary, in the face of epidemic concern.

As for the surgical masks, again, Roberge and coll. (24) found that surgical mask use for 1h at a low-moderate work rate, in healthy subjects, was not associated with clinically significant physiological impact or significant subjective perceptions of exertion or heat.

The effect of using a surgical mask, indicated to minimize the risk of cross-infection in patients with lung diseases, was studied by Person and coll. during the execution of a six minutes walking test (21). Results suggested that wearing a surgical mask modifies significantly clinical dyspnea without influencing walked distance.

One more study assessed the influence of surgical masks on transcutaneous oxygen saturation. The authors observed a slight saturation fall only in surgical proceeding with a duration of 60 minutes or more. The authors concluded that the small decrease of the saturation might be either due to the facial mask or the operational stress (3).

In literature, there are very few studies regarding respiratory impairment in healthy subjects as well as in subjects suffering from obstructive respiratory conditions during the use of surgical masks. Also, occupational physicians have to express their professional opinion regarding the fitness for the use of the RPDs in the working population, not only in industrial and healthcare settings, and with particular regard for workers with pulmonary or hearth conditions. A particular concern is that RPDs could lead to respiratory discomfort or an acute exacerbation of asthma. Thus, we conducted an experimental study on a group of ten subjects, three of which affected by asthma. We have aimed to evaluate the impact of RPDs on the respiratory function in healthy and asthmatic subjects, in order to identify the fitness for use mainly but not only for occupational purposes during COVID-19 outbreak.

Methods

Study design

We conducted an experimental case series evaluating the impact of a specific RPD (i.e., surgical masks) on lung function of 10 subjects. Subjects were tested at three times: i) at basal conditions subjects performed Respiratory Functional Tests (RFT) and had an arterial blood gas test (ABG) without wearing a surgical mask ("basal"); ii) modified basal conditions by wearing a surgical mask ("mask-basal"), at this time only RFTs were performed as no substantial changes were expected in the ABG test; iii) after 4 hours of continuous use of the surgical mask during mild-moderate usual working activities ("mask-active") subjects repeated RFTs and ABG.

Participants

Ten healthcare workers were included in the study. Subjects were equally distributed between males and females (five men, five women) with a median age of 38.5 ys (range 29-71, 95% CI 33.3-51.1). Most of the subjects had a healthy weight with a median Body Mass Index of 22.6 kg/m^2 (range 18.6-30.1, 95% CI 20.6-25.5). Four subjects were current smokers. Three individuals had asthma: one with partially controlled asthma and the other two with well-controlled asthma according to GINA evaluation criteria (10). All subjects have been screened for COVID-19 infection resulting negative. The characteristics of the sample are reported in Table 1.

Table 1. Demographic characteristics of the ten subjects

ID	Professional category	Sex	Age (years)	Weight (Kg)	Height (Cm)	BMI (kg/m^2)	Current smoker	Asthma
1	Medical doctor	M	71	87	170	30,1	Yes	No
2	Medical doctor	M	36	73	179	22,8	No	Yes
3	Medical doctor	F	39	68	174	22,5	No	No
4	Resident	F	29	64	172	21,6	Yes	No
5	Resident	M	30	66	186	19,1	Yes	No
6	Nurse	M	36	72	163	27,1	No	No
7	Medical doctor	F	38	73	181	22,3	No	No
8	Nurse	F	52	59	159	23,3	No	Yes
9	Medical doctor	M	43	69	171	23,6	No	Yes
10	Medical doctor	F	48	57	175	18,6	No	No

Surgical mask characteristics

We used a four layers surgical mask model AFLUID®. This model has an external liquid splash resistant polyethylene layer, and three non-woven layers with a protective, filtering, and non-macerating function. It is recommended in case of possible transmission of infective viruses via potentially contaminated liquids due to a hexagonal structure of the polyethylene film (resistant at a pressure of 16kPa). Masks have one size fitting with a metal nose clip. The bacterial filtration efficiency was > 98%, with a breathing resistance of 79 Pa/cm^2, and a bioburden ≤ 30 CFU/g according to the norm UNI EN 14683:2019. Having four layers, hypothetically, the mask is characterized by higher resistance to respiratory flows compared to less layered surgical masks.

Outcomes

The following RFT parameters were considered: Vital Capacity (VC), Forced Vital Capacity (FVC), Forced Expiratory Volume at timed interval of 1.0 second (FEV_1), FEV_1/FVC, Tidal Volume (TD) and Maximal Voluntary Ventilation (MVV). Acceptability, usability, and repeatability criteria of the American Thoracic Society and European Respiratory Society were followed (11).

For arterial blood gas (ABG), we determined the arterial partial pressure of oxygen (PaO_2), the arterial partial pressure of carbon dioxide ($PaCO_2$), and the arterial oxygen saturation (SaO_2).

Instrumentation

Basal RFTs were performed through the mouth according to the standard method recommended by the American Thoracic Society (ATS) (9). To perform the RFTs wearing the surgical mask, we adopted a modified RFT technique. In this technique, the mouthpiece of the spirometer was modified by applying a sealed pocket mask (Figure 1). The nose was completely sealed by the pressure applied through the pocket mask to prevent air dispersion. To test whether the modified RFT technique involves the introduction of a bias, two subjects performed two sequential RFTs using the standard and the modified techniques. The various RFT results were overlapping with a random mean percentage deviation ranging from 0.06% to 2.24%. We used an open circuit spirometer from GANSHORN Medizin Electronic GmbH. ABG tests were analyzed immediately after sample collection with a New GEM Premier 5000 blood gas testing system.

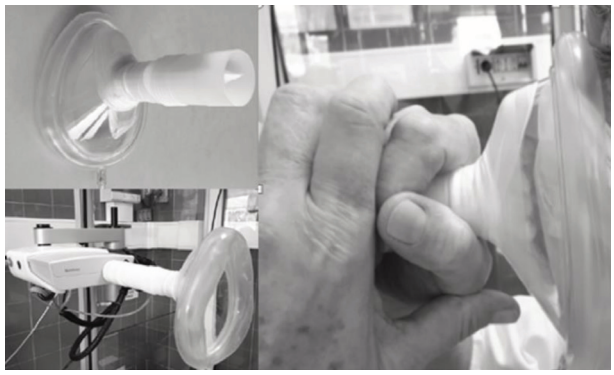

Figure 1 - The modified Respiratory Function Test technique. The mouthpiece of the spirometer was modified by applying a sealed pocket mask

Statistics

Descriptive analysis was carried out. Categorical variables were presented as numbers, and continuous data were expressed as medians with interquartile ranges (IQR, with 95% CI) as a measure of variability. Due to the small sample size, the Krustal-Wallis test for non-parametric data was used to assess the difference between RFT and ABG values at different times. The Kolmogorov-Smirnov test was used for comparison between paired times. Before data analysis we tested randomness (P>0.05) and checked that all observations were independent. All analyses were performed with SPSS (IBM Corp. Released 2019. IBM SPSS Statistics for MacOs, Version 26.0. Armonk, NY: IBM Corp.)

Results

Observed RFTs and arterial blood parameters are reported in Tables 2 and 3, and Figures 3A-F. As shown in Table 2 and Figures 3A-E, the functional parameters usually measured (VC, FVC, FEV_1, and

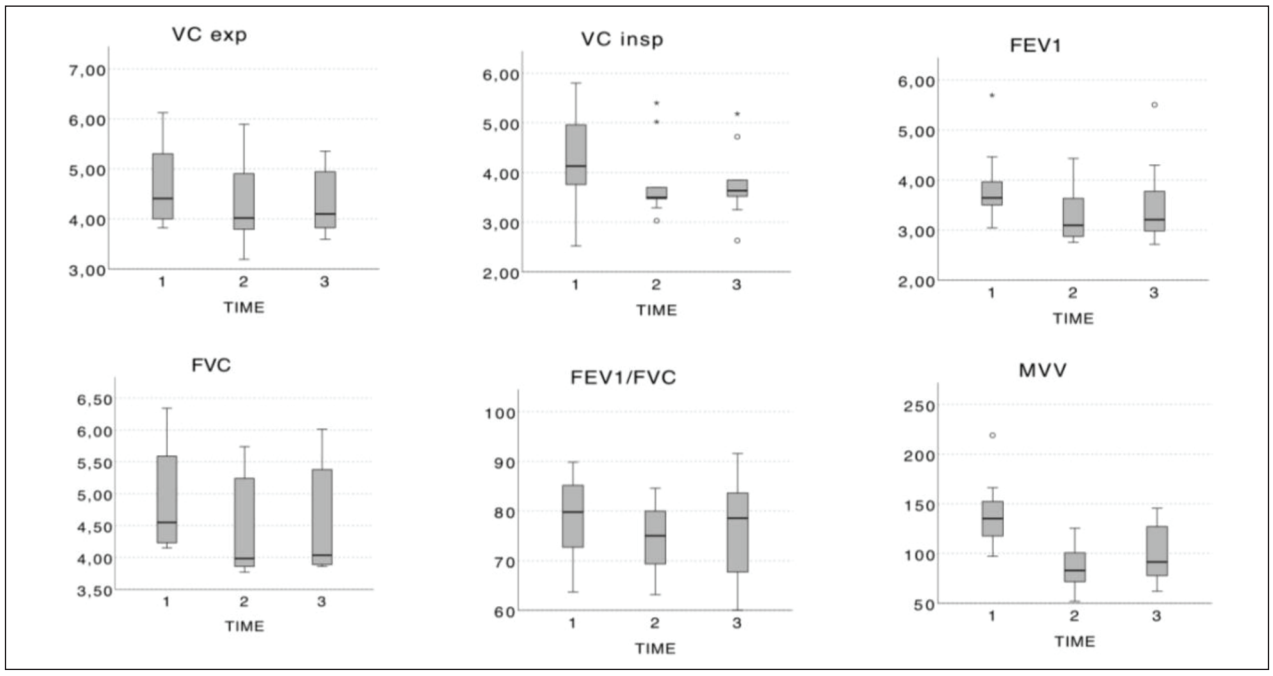

Figure 2 - Respiratory Function Test values at basal (1), mask-basal (2), and mask-active (3) times. Circles and asterisks represent outlier values

FEV_1/FVC) did not suffer significant variations. A reduction or an increase of FEV_1 is considered significant when the variation exceeds 20%. FEV_1 is the most commonly used bronchoprovocation test result, as it is easy to test and shows excellent reproducibility. Methacholine concentration at the point that FEV_1 is decreased to 20% of baseline in the dose-response curve is called PC20 (provocation concentration causing FEV_1 20% fall) and is regarded as an index of the bronchial hyperresponsiveness (20). On these bases, we considered as significant a variation of 20% or more for all the volumes mentioned above.

Therefore, there was no statistically significant difference between VC exp (P=0.431), VC insp (P=0.087), FVC (P=0.125), FEV_1 (P=0.157), FEV_1/FVC (P=0.673), TV (P=0.072) at the different times. Even with the presence of an obstacle due to the physical structure of the mask, the forced respiratory parameters (FVC, FEV_1, FEV_1/FVC) showed no significant reduction (less than 20%). The tests performed after 4 hours of use of the mask were substantially similar to those recorded during "mask-basal", which proves the absence of a cumulative or progressive phenomenon.

However, MVV showed a statistically significant difference between times (P=0.002) (Figure 3F). In particular, tests wearing the surgical mask registered a reduction from basal condition (basal vs. mask-basal, P=0.002; basal vs. mask-active, P=0.041), but did not differ at the two times wearing the mask, before and after the working activity. (mask-basal vs. mask-active, P=0.310). The reduction could be attributed to the mechanical barrier of the mask, which becomes noticeable at high rate ventilatory volumes. This is confirmed by the lack of significant difference between the "mask-basal" and the "mask-active" tests, which rules out a respiratory physiological impairment.

Differences for observed ABG values are reported in Table 2, and no statistically significant difference was found between ABG values at the basal condition and after 4 hours of the surgical mask active wearing (PaO_2, P=0.759; $PaCO_2$, P=0.988; SaO_2, P=0.759) (Figure 4A-C). The absence of a respiratory functional load is demonstrated by the constant levels of PaO_2 and SaO_2 during the three tests, while

Table 2 - Respiratory Functional Tests values at different times

ID#	TIME	VC exp (Δ)	VC insp (Δ)	FVC (Δ)	FEV_1 (Δ)	FEV_1/FVC (Δ)	TV (Δ)	MVV (Δ)
1§	*Basal*	3.9	3.8	4.2	3.1	72.7	1.4	142.9
	Mask-basal	4.0 (0.1)	3.6 (-0.1)	4.0 (-0.3)	2.8 (-0.3)	69.3 (-3.4)	1.1 (-0.3)	104.7 (-38.2)
	Mask-active	4.2 (0.1)	3.8 (0.2)	4.0 (0.03)	2.7 (-0.1)	67.7 (-1.6)	1.0 (-0.1)	96.6 (-8.1)
2†	*Basal*	5.3	5.0	5.4	4.5	81.8	4.1	152.5
	Mask-basal	4.9 (-0.4)	5.0 (0.1)	5.2 (-0.2)	4.4 (-0.0)	84.6 (2.8)	3.7 (-0.4)	125.5 (-27.0)
	Mask-active	4.8 (-0.1)	3.2 (-1.8)	5.1 (-0.1)	4.3 (-0.1)	83.9 (-0.7)	3.6 (-0.1)	145.6 (20.1)
3	*Basal*	4.7	4.3	4.7	3.7	77.8	2.5	166.1
	Mask-basal	3.2 (-1.5)	3.5 (-0.8)	3.8 (-0.9)	2.9 (-0.8)	75.5 (-2.3)	1.2 (-1.3)	76.9 (-89.2)
	Mask-active	4.0 (0.8)	3.8 (0.3)	3.9 (0.1)	3.0 (0.1)	76.4 (1.0)	2.2 (1.0)	127.1 (50.3)
4§	*Basal*	4.1	3.7	4.4	3.8	86.3	2.3	113.8
	Mask-basal	4.0 (-0.1)	3.3 (-0.4)	3.8 (-0.6)	3.0 (-0.8)	78.9 (-7.4)	0.9 (-1.4)	51.9 (-61.9)
	Mask-active	3.7 (0.3)	3.5 (0.2)	3.9 (0.2)	3.2 (0.2)	80.6 (1.7)	1.2 (0.3)	65.3 (13.4)
5§	*Basal*	5.6	5.4	6.3	5.7	89.8	2.7	219.0
	Mask-basal	5.9 (0.3)	5.4 (0.03)	5.7 (-0.64)	4.2 (-1.4)	74.5 (-15.3)	1.4 (-1.3)	83.6 (-135.4)
	Mask-active	4.9 (-0.9)	5.2 (-0.2)	6.0 (0.3)	5.5 (1.2)	91.5 (17.0)	2.2 (0.8)	142.4 (58.8)
6	*Basal*	4.0	4.0	4.2	3.6	85.2	2.3	133.5
	Mask-basal	3.9 (-0.1)	3.5 (-0.5)	3.9 (-0.3)	3.1 (-0.4)	80.0 (-5.2)	2.1 (-0.2)	100.6 (-32.9)
	Mask-active	3.8 (-0.04)	2.6 (-0.9)	3.9 (-0.04)	3.2 (0.1)	82.5 (2.6)	2.3 (0.1)	110.5 (9.9)
7	*Basal*	6.1	5.8	6.2	4.0	63.7	1.8	136.3
	Mask-basal	5.3 (-0.8)	3.0 (-2.8)	5.7 (-0.5)	3.6 (-0.3)	63.2 (-0.5)	1.2 (-0.6)	71. 6 (-64.7)
	Mask-active	5.0 (-0.4)	4.7 (1.7)	5.9 (0.2)	3.8 (0.1)	63.5 (0.3)	1.2 (0.01)	62.1 (-9.5)
8†	*Basal*	4.1	4.0	4.1	3.0	73.3	2.9	117.5
	Mask-basal	3.8 (-0.3)	3.5 (-0.5)	3.9 (-0.3)	2.7 (-0.3)	71.3 (-2.0)	1.3 (-1.6)	96.7 (-20.8)
	Mask-active	4.0 (0.2)	3.6 (0.1)	3.9 (0.01)	2.8 (0.03)	71.7 (0.4)	1.1 (-0.2)	86.4 (1.2)
9†	*Basal*	5.3	4.8	5.6	3.6	64.4	3.6	134.0
	Mask-basal	4.6 (-0.7)	3.7 (-1.1)	4.7 (-0.9)	3.1 (-0.5)	65.7 (1.3)	3.1 (-0.5)	82.3 (-51.7)
	Mask-active	5.3 (0.7)	3.7 (-0.04)	5.4 (0.7)	3.2 (0.2)	60.0 (-5.7)	2.5 (-0.6)	83.5 (-10.3)
10	*Basal*	3.8	2.5	4.3	3.5	82.0	3.0	97.1
	Mask-basal	3.3 (-0.5)	3.5 (0.9)	4.0 (-0.3)	3.4 (-0.1)	84.1 (2.1)	2.0 (-1.0)	52.2 (-44.9)
	Mask-active	3.6 (0.3)	3.5 (0.05)	4.1 (0.1)	3.4 (0.04)	83.6 (-0.5)	3.2 (1.2)	77.8 (25.6)

Table 3 - Arterial Blood Gas values at different times

ID#	TIME	pO_2	pCO_2	SaO_2
1§	*Basal*	96	32	98.9
	Mask-active	97 (1)	36 (4)	98.9 (0.0)
2†	*Basal*	101	40	99.3
	Mask-active	101 (0)	41 (1)	99.1 (-0.2)
3	*Basal*	95	40	99.0
	Mask-active	94 (-1)	41 (1)	98.8 (-0.2)
4§	*Basal*	100	38	99.0
	Mask-active	98 (-2)	37 (-1)	99.6 (0.6)
5§	*Basal*	96	42	98.8
	Mask-active	93 (-3)	41(-1)	98.8 (0.0)
6	*Basal*	90	36	98.1
	Mask-active	93 (3)	38 (2)	99.3 (1.2)
7	*Basal*	127	39	99.2
	Mask-active	112 (-15)	37 (-2)	100 (0.8)
8†	*Basal*	108	37	99.3
	Mask-active	106 (-2)	37 (0)	99.3 (0.0)
9†	*Basal*	109	42	99.1
	Mask-active	94 (-15)	41 (-1)	98.9 (-0.2)
10	*Basal*	92	38	99.3
	Mask-active	88 (-4)	39 (1)	99.6 (0.3)

$PaCO_2$ shows a slight increase, hypothetically due to the albeit minimal increase in the respiratory dead space produced by the presence of the mask and to the small expected rise of CO_2 concentration inside the same.

Data on asthmatic subjects and smokers were comparable to healthy subjects (Figure 4A-B).

Discussion

Our results suggest that wearing a surgical mask does not produce significant respiratory impairment in healthy subjects. Mainly, the functional parameters measured did not suffer significant variations. Only the observed reduction of MVV appears to be significant, and it may be explained by the mechanical barrier provided by the mask, which became noticeable only at high rate ventilatory volumes. We also observed the difficulty in performing this test, especially the first time, with the adapted technique, even in compliant subjects. This parameter, however, is of interest for the assessment of the ventilation only during intense physical activity. Therefore, we consider useful to extend, in further studies, our technique to a group of subjects tested during physical effort.

Our results suggest that using the surgical mask does not cause a physiological respiratory impair-

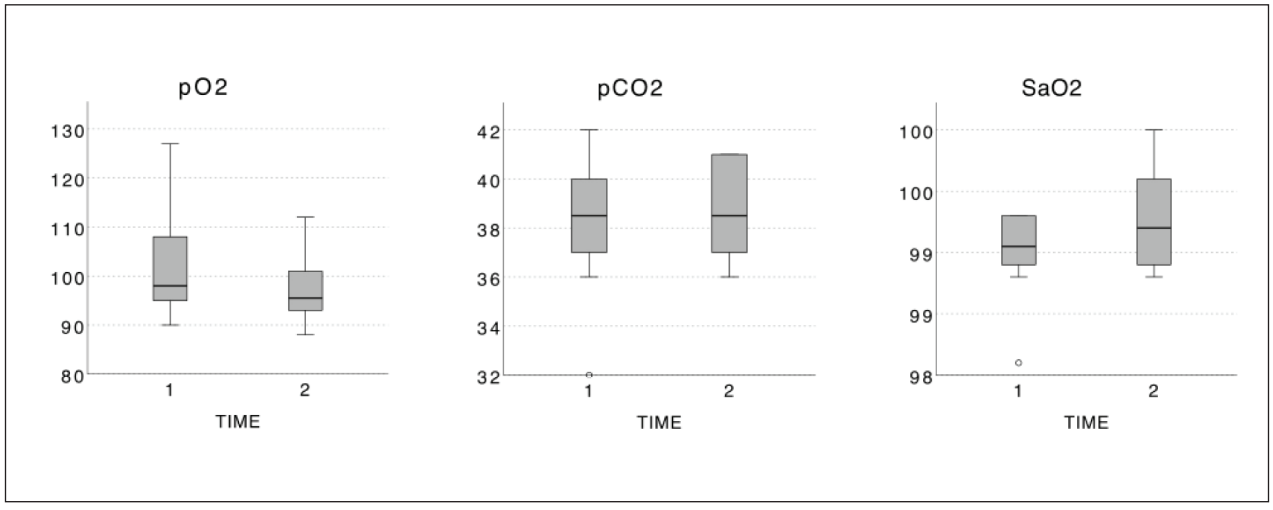

Figure 3 - Arterial Blood Gas test values at basal (1) and mask-active (2) times. Circles represent outlier values.

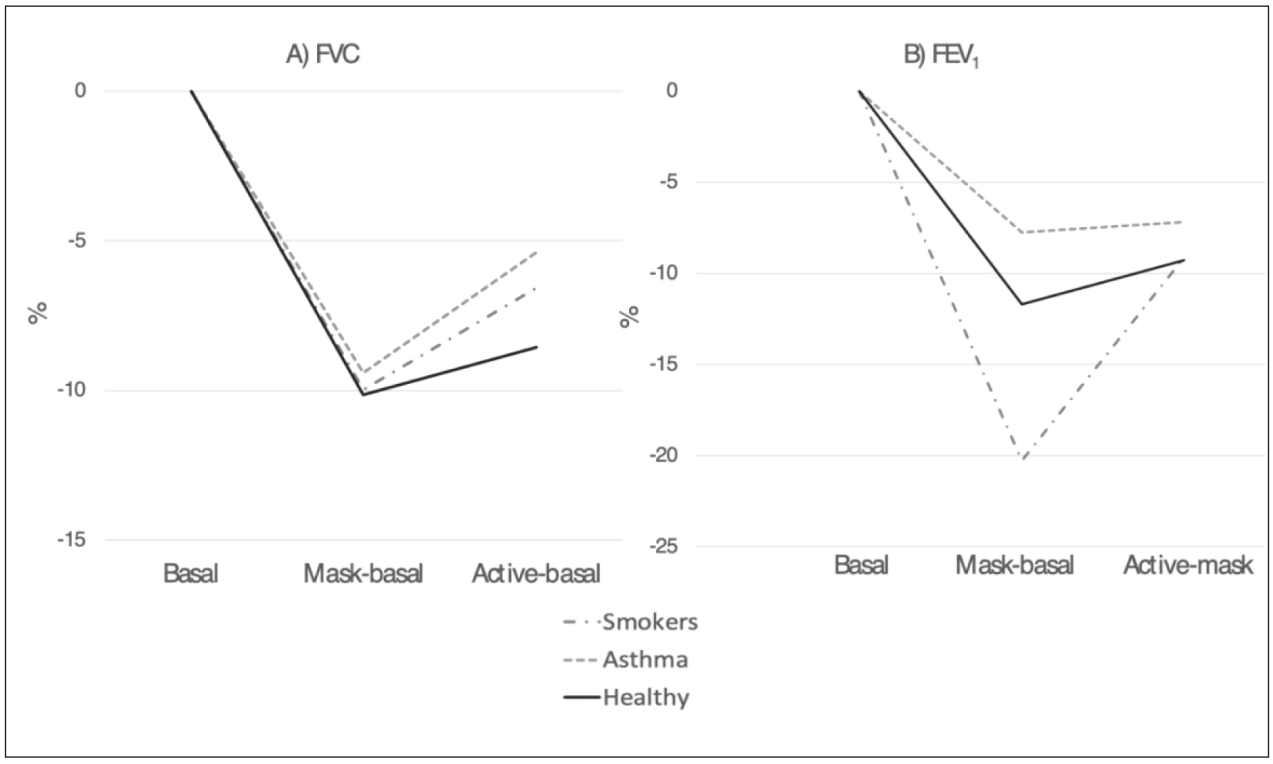

Figure 4 - FVC and FEV_1 median percentage variation between healthy, smokers, and asthmatic subjects at basal, mask-basal, and mask-active times

ment in healthy subjects nor well-controlled asthmatic subjects and smokers during mild-moderate working activity. However, further evidence is needed to extend this evaluation to subjects or active workers affected by uncontrolled asthma, other severe chronic pulmonary impairment, and critical heart diseases. Moreover, our findings are not entirely applicable to high-intensity physical activity.

In summary, healthy workers, as well as workers with controlled or mild asthma, can safely wear surgical masks during their usual activities at least for four hours continuously. For those with more severe conditions, the evaluation has to be individually expressed by the occupational physician, possibly after a clinical and functional examination. Our adapted technique could be adopted for individual RPDs fitness evaluation.

The main limit of our study is the small number of subjects included. Unfortunately, during the COVID-19 pandemic, it is not advised to use potential aerosol-generating procedures such as RFTs. Therefore, we underline that our volunteers were all selected among healthcare workers as they have all been tested for SARS-CoV-2. Thus, the test was conducted safely using an open-circuit spirometer with adequate filters without the risk of spreading the infection. Anyway, thanks to the high heterogeneity of our sample, our results seems to be reasonably applicable to the general population.

Besides, all our participants were healthcare professionals, already practical with traditional RFTs. Consequently, the tests were conducted with adequate compliance with the correct technique. Of notice, the subjects declared that they experienced minor difficulties in performing the RFTs with the modified technique. RFTs slightly improved during the last test, probably as subjects became more familiar with the modified technique.

Another limit is that there are many types of RPDs in commerce, and our results refer to only one type of surgical mask. However, we have chosen a four-layer face mask, which is characterized

by higher resistance to respiratory flows, therefore considering the worst-case scenario. Further studies are needed on a larger number of subjects.

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