



# Common surgical masks and unattended blood pressure changes in treated hypertensive patients

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## Abstract

Although the effect of face masks on preventing airborne transmission of SARS-CoV-2 is well studied, no study has evaluated their effect on blood pressure (BP). Therefore, we investigated the effect of surgical masks on BP in 265 treated hypertensive patients. Following the routine mask-on office BP measurement, patients were left alone and randomized to automated office BP measurement, with measurements taken after first wearing a mask for 10 min, then without wearing the mask for 10 min, and vice versa. Among the participants, 115 were women (43.4%), the mean age was  $62 \pm 12$  years, and the mean office BP was  $134 \pm 15/81 \pm 12$  mmHg. There was no significant difference between mask-on unattended systolic BP ( $133 \pm 15$  mmHg) and mask-off unattended systolic BP ( $132 \pm 15$  mmHg) ( $P = 0.13$ ) or between mask-on unattended diastolic BP ( $77 \pm 13$  mmHg) and mask-off unattended diastolic BP ( $76 \pm 13$  mmHg) ( $P = 0.32$ ). Surgical masks had no effect on BP in treated hypertensive patients.

**Keywords** Face masks · Automated blood pressure · Attended blood pressure · Blood pressure measurement

## Introduction

The COVID-19 pandemic might be considered an emerging barrier to hypertension control due to (1) physician–patient distancing, (2) the reduction of regular medical visits, (3) the instauration of an unhealthy lifestyle, and (4) the reinforcement of inadequate prescription refill and adherence to medications [1–3]. Public health authorities strongly advise using face masks, at least in indoor public places, including outpatient hypertension clinics, to limit the transmission of SARS-CoV-2 [4, 5]. While there are several studies that have focused on the role of face masks in preventing airborne transmission of SARS-CoV-2 [6], few data are available on their effects on physiological measures [7, 8], and no study has examined their effects on blood pressure

(BP) levels. We hypothesized that wearing a face mask during office unattended BP measurements may have a differential effect on BP levels because it may trigger alerting reactions and sympathetic activation. We limited our investigation to drug-treated hypertensive patients to avoid the confounding effect of relatively increased BP levels related to newly diagnosed or untreated hypertension.

## Methods

The study included already treated hypertensive patients aged >18 years who had a routine follow-up visit to a university hospital outpatient hypertension clinic. Participants were recruited between March 2021 and July 2021. Demographic characteristics, antihypertensive drug treatment, and comorbidities were recorded during the visit. The exclusion criteria were atrial fibrillation or any other arrhythmia affecting the BP measurement, an arm circumference >42 cm, mental disorders, Parkinson's disease, pregnancy, intolerance to the BP measurement method, or unwillingness to participate.

A new surgical mask was provided to all participants to replace the face mask that was already in use. After the routine attended office BP measurement, all patients were

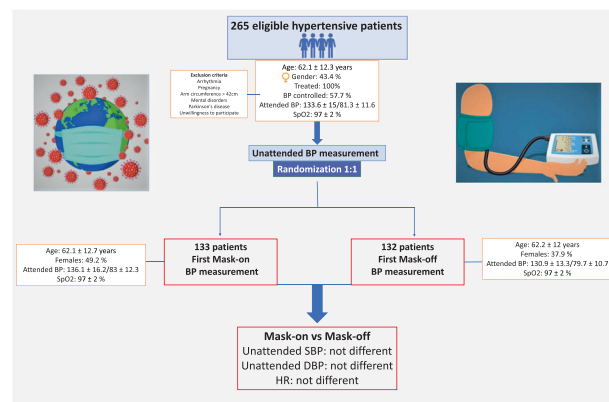
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## Graphical Abstract

### Design of the study.



left alone in a ventilated examination room and randomized to automated office BP measurement, with measurements taken after first wearing a face mask for 10 min, then without wearing the mask for 10 min, and vice versa. All patients provided written informed consent. Attended office BP evaluation was performed according to the current guidelines using a validated upper-arm cuff electronic device (Omron HEM-907 XL). The same type of device was used for the unattended BP measurements and following the 5-minute rest period (plus the 10 min mask on or off steady-state), 3 measurements were performed. The mean value of the 3 attended and unattended (mask-on, mask-off) measurements was recorded. In addition, arterial oxygen saturation was measured after the two steady-state periods and before the BP measurements. The study's primary outcome was the difference between unattended mask-on and mask-off BP measurements.

### Statistical analysis

Power calculations indicated that a total sample size of 265 subjects would provide the study with a power of 90%, an alpha of 0.05, and a Cohen's *d* of 0.2 to detect a clinically important absolute BP difference of 2 mmHg between groups. Continuous variables are presented as the mean  $\pm$  standard deviation, while categorical variables are reported as percentages. The Kolmogorov–Smirnov statistic was used to test continuous variables for normality. According to data distribution, the paired and unpaired Student's *t* test or the Wilcoxon signed-rank test and the Mann–Whitney *U* test were used to compare continuous variables. To evaluate whether the attended systolic/diastolic BP difference between the unattended mask-on first and mask-off first groups influenced the unattended BP measurements, we compared the attended minus unattended systolic/diastolic BP difference in the total population using a paired samples *t* test. A chi-squared

test was used for the comparison of the categorical variables. Statistical significance was set at  $P < 0.05$ , and all tests were 2-tailed. Data management and statistical analysis were performed using IBM SPSS Statistics (Version 25.0. Armonk, NY: IBM Corp).

## Results

Following the implementation of the predetermined exclusion criteria and the removal of patients with incomplete unattended BP measurements ( $n = 28$ ), the final number of patients eligible to participate in the study was 265, with 115 women (43.4%). The mean age was  $62 \pm 12$  years, and the mean attended office BP was  $134 \pm 15/81 \pm 12$  mmHg. Notably, oxygen saturation was not different between the groups during the attended and unattended office BP measurements (Table 1). No significant difference was noted between mask-on unattended systolic/diastolic BP ( $133 \pm 15/77 \pm 13$  mmHg) and mask-off unattended BP ( $132 \pm 15/76 \pm 13$  mmHg) (Fig. 1). Moreover, there was no difference in the heart rate (mask-on first,  $69 \pm 11$  bpm; mask-off first,  $69 \pm 11$  bpm,  $P = 0.7$ ). Subgroup analyses according to sex and the sequence of wearing the mask (mask-on first or mask-off first) did not reveal any significant differences (data not shown). The systolic/diastolic BP difference between the attended minus the first unattended (mask on or mask-off) BP measurement in the total population was not significant:  $-0.6$  mmHg ( $p$  value, 0.12) for systolic BP and  $-0.2$  mmHg ( $p$  value, 0.33) for diastolic BP.

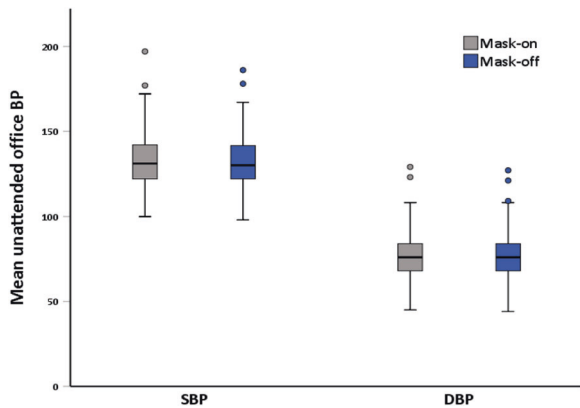
## Discussion

The present study investigated the direct effect of a regular surgical mask on office unattended BP measurements. There was no differential effect of wearing a mask during

**Table 1** Demographic and clinical characteristics of patients

Characteristic	All patients ( <i>n</i> = 265)	Mask-on BP as first measurement ( <i>n</i> = 133)	Mask-off BP as first measurement ( <i>n</i> = 132)	<i>P</i> value
Age (years)	62 ± 12	62 ± 13	62 ± 12	0.98
Females (%)	43	49	38	0.06
Diabetes (%)	17	15	18	0.49
Current smoker (%)	24	21	28	0.35
Respiratory disease (%)	9	8	11	0.38
N of antihypertensive drugs	2 ± 1.2	1.9 ± 1.3	2.1 ± 1.1	0.11
At least 1 combination of antihypertensive drugs (%)	62	58	66	0.16
b-blockers, %	5	4	6	0.65
Attended Office SBP (mmHg)	134 ± 15	136 ± 16	131 ± 13	<0.01
Attended Office DBP (mmHg)	81 ± 12	83 ± 12	80 ± 11	0.02
SpO <sub>2</sub> (%)	97 ± 2	97 ± 2	97 ± 2	0.99

BP blood pressure, DBP diastolic blood pressure, SBP systolic blood pressure, SpO<sub>2</sub> oxygen saturation percentage, *n* number



**Fig. 1** Differences in systolic and diastolic blood pressure between the mask-on and mask-off BP measurements. BP blood pressure, DBP diastolic blood pressure, SBP systolic blood pressure

unattended BP measurements between systolic and diastolic BP, independent of the mask sequence and the attended BP difference between the groups.

The finding that treated hypertensive patients had a similar unattended BP whether wearing a mask or not, under the same levels of arterial oxygen saturation, suggests that masks alone cannot increase BP levels. However, the confounding of habituation in wearing the mask for a long period before the conduction of the study cannot be excluded. Although patients randomized to the unattended mask-on BP measurement showed higher BP levels during the attended BP measurement, this pre-randomization BP difference appeared not to influence the randomized comparison between the mask-on vs. mask-off conditions of the unattended BP measurements.

Whether routine office BP measurements are similar while wearing a mask or not should be determined in a

future study, when a waiver of wearing masks indoors has been issued. In the future, it should be determined whether wearing a mask is associated with (1) significant BP changes over a 24-h period or during home BP measurements, (2) BP changes in specific patients, such as those with underlying vascular disease or chronic obstructive pulmonary disease, (3) an increase in sympathetic nervous system activity during office BP measurements, and (4) unbiased hypertension diagnoses in untreated patients with elevated BP levels.

Regarding the limitations of the present study, the most important limitation was that the effect of face masks on BP was only assessed after a relatively short time of usage; therefore, any potential effect on BP after a longer time of usage cannot be excluded. Another limitation concerns the use of surgical masks only; thus, our results cannot be extended to different masks. Additionally, we acknowledge that the alternate allocation to wearing a mask was not the ideal randomization technique. However, we refrained from using more sophisticated, although time-consuming, randomization methods because we prioritized minimizing the interaction between the patients and personnel. Furthermore, our findings cannot be extended to (1) individuals without hypertension, (2) newly diagnosed untreated hypertensive patients, especially those visiting an outpatient hypertension clinic for the first time, and (3) longer or shorter steady-state periods with or without wearing a mask.

## Conclusion

Common surgical masks do not affect systolic/diastolic BP levels during unattended BP measurements.

## Compliance with ethical standards

**Conflict of interest** The authors declare no competing interests.

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