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Original Article

Physiology Section

The Effect of N95 Mask on Peripheral Oxygen Saturation and Heart Rate among Indian Medical Professionals: A Quasi-experimental Study

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ABSTRACT

Introduction: Among all face masks, N95 masks have been recommended for medical professionals involved mainly in patients with severe respiratory illnesses. Studies showing a decrease in peripheral oxygen saturation (SpO_2) and an increase in heart rate after N95 mask usage have already created panic/concern among medical professionals. On the contrary, a few studies have shown no such negative impact of N95 mask usage, thereby urging scientific communities to investigate/explore these contrasting results.

Aim: To study the effect of wearing an N95 mask continuously for three hours on SpO_2 and heart rate specifically in Indian medical professionals.

Materials and Methods: This was a quasi-experimental study conducted for a period of 2 months from June 15, 2022, to August 15, 2022, at Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, Uttar Pradesh, India, with a total of 105 healthy Indian medical professionals aged 18-40 years (55 males, 50 females) (12 study participants dropped from the study midway). In each participant, SpO_2 and heart rate were recorded first without a mask (M0) and then with a mask (M3) after three hours of routine work in the hospital. Using Mystat statistical software (version 12.0), results were expressed as mean±Standard Deviation (SD), and Student's paired t-test was used to compare the pairs of means.

Results: Among the 105 eligible participants, 93 successfully completed the study, whereas 12 participants were excluded (dropout rate=11.42%). The study included 55 males (52.38%) and 50 females (47.61%) with an age range of 18-40 years and a mean age of 30.2±6.4 years. The SpO_2 levels statistically showed a highly significant decrease after three hours of wearing an N95 mask (96.5±0.83% in M0 vs. 93.98±0.6% in M3). Similarly, the heart rate statistically showed a highly significant increase after three hours of using an N95 mask (73.45±3.6 in M0 vs. 89.6±6.1 beats/min in M3).

Conclusion: The authors highlighted lower SpO_2 levels and an increase in heart rate after three hours of N95 mask usage specifically in Indian medical professionals and thereby appeal to develop/upgrade the N95 mask by lowering its humidity, thermal stress, and breathing resistance.

Keywords: Cardiorespiratory, Microclimate, Oximeter, Respiratory stress, Thermal stress

INTRODUCTION

In the medical field, masks were introduced by von Mikulicz Radecki J in 1897 and have been used by medical practitioners since then [1]. Face masks act as crucial defense against the transmission of numerous respiratory illnesses, from the common cold to the deadly Coronavirus Disease-19 (COVID-19) infection [2]. Mask usage specifically helps prevent droplet-transmissible infections that spread when an infected person talks, sneezes, or coughs into the air. Masks are widely available and recommended for use among medical professionals, especially during surgical procedures and when dealing with various patients in the Outpatient Department (OPD) [3,4].

Undoubtedly, the most popular filtering disposable facepiece respirator is the N95 mask, which has a 95% filtration rate for particles smaller than 0.3 microns, providing protection against highly transmissible diseases such as Severe Acute Respiratory Syndrome (SARS), Tuberculosis, and COVID-19 [5]. Surgical masks, on the other hand, are not as effective as N95 masks in filtering particles smaller than 0.3 microns [6]. During the COVID-19 global pandemic, health authorities worldwide, including the Centres for Disease Control and Prevention (CDC) and World Health Organisation (WHO), have recommended the use of N95 masks specifically for medical professionals to prevent/contain the spread of COVID-19, especially in workplace settings [7-10]. Throughout the COVID-19 pandemic, N95 masks have emerged as a crucial tool in preventing the spread of infection among medical professionals [11]. However, it should be noted that various studies on the potential impact of N95 mask usage on vital sign parameters such as peripheral SpO_2 and heart rate have yielded contrasting results [12-17]. Notably, a few studies have pointed out significantly reduced SpO_2 levels and an augmented heart rate in oral surgeons using N95 masks, thereby warning of the cardiorespiratory impact of N95 masks [18,19].

Several studies have documented that there is nearly zero effect of N95 mask use on peripheral SpO_2 and heart rate [12-15]. However, on the contrary, a few authors have elucidated that N95 masks lead to a decrement in blood SpO_2 levels, an increment in heart rate, and further cardiopulmonary stress [16,17]. Moreover, an elevated heart rate (regardless of the underlying cause) is an independent cardiac risk factor that may gradually progress toward the development of cardiovascular diseases [20]. These diametrically opposed study outcomes have sparked the urge or rationale for further inquiry or exploration of the problem among research scientists. To the best of the authors' knowledge, the use of N95 masks and their impact on vital signs in medical professionals is a subject that is understudied in India and has mostly been studied with smaller sample sizes. Hence, there is a need to conduct a research study that specifically includes Indian medical professionals with a larger sample size to clarify the doubts and concerns related to the effect/influence of N95 mask use on vital sign parameters such as peripheral SpO_2 and heart rate.

Therefore, the present study aimed to study the effect of wearing an N95 mask continuously for three hours on SpO_2 and heart rate specifically in Indian medical professionals.

MATERIALS AND METHODS

The present study was a quasi-experimental study was conducted for a period of two months from June 15, 2022, to August 15, 2022, at Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly, Uttar Pradesh, India. The study was reviewed and approved by the Institutional Ethical Committee (IEC reference no. - SRMS IMS/ ECC/2021-22/068 dated 18-06-2022).

Inclusion criteria: A total of 105 healthy Indian medical professionals belonging to the age group of 18-40 years (55 males, 50 females), including doctors, paramedical staff, and nursing staff working in the study institute were selected for the present study. Informed written consent was obtained from all study participants.

Exclusion criteria: Individuals suffering from diabetes, chronic respiratory illnesses such as asthma, Tuberculosis (TB), active COVID-19 infection, and those with pre-existing cardiovascular co-morbidity (hypotension, shock, arrhythmias, heart failure, etc.) were excluded. Individuals who were smokers, pregnant females, have a history of panic attacks, claustrophobia, movement disorders such as Parkinson's disease, or seizure disorder were also excluded.

Sample size calculation: The minimum sample size of the present study was calculated using MedCalc statistical software version 22.0. According to Machin D et al., and the Medcalc manual for sample size calculation in paired t-test, the expected values of the mean of paired differences and SD of paired differences should be estimated based on previous similar studies [21,22]. Therefore, using the data obtained from a previous study conducted by Jaiswal S et al., [23], the expected values of the mean of paired differences and SD of paired differences were roughly estimated to be 3.0 and 10.0, respectively. In the present study, the Type-1 error value (alpha) was set at 5% (or 0.05 when expressed as 1), corresponding to a 95% Confidence Interval (CI), while the Type-2 error value (beta) was set at 20% (or 0.2 when expressed as 1), corresponding to 80% statistical power (Statistical power=1-beta). Using these statistical values, the final calculated sample size of the present study was determined to be 90. Therefore, approximately 105 healthy Indian medical professionals aged 18-40 years, willing to give informed consent, were enrolled in the present study. However, 12 study participants were dropped from the study midway due to the development of co-morbidity or removal of the mask before the stipulated three-hour time period, leaving a total of 93 participants overall.

Study Procedure

In the present study, blood SpO_2 levels and heart rate were recorded in all study participants using a peripheral pulse oximeter device (Oxiline-Pulse 7 Pro fingertip peripheral pulse oximeter), which was Food and Drug Administration (FDA)-approved and categorised as prescription use or medical use. The N95 masks (without exhalation valve) used were manufactured by Piramal Nextgen Trading Private Limited, Mumbai, India, and were approved by the Bureau of Indian Standards (BIS).

It is important to note that all standard protocols recommended by various health agencies, including the WHO, were followed while using the pulse oximeter. According to WHO recommendations [24-28], the person should be in a sitting position and remain still. Shivering or cold extremities can interfere with accurate readings, so the person's hand should be warm, relaxed, and kept steady in a resting position below the level of the heart. The index finger is preferably used for measurement and should not have nail polish, artificial fingernails, pigments, or deformities. The measurement probe should be properly positioned, and readings should not be taken under a direct bright light source. Readings should be allowed to stabilise for a minimum of 30 seconds before recording. The pulse oximeter should be cleaned properly and gently with an alcohol swab to avoid blockage of the light source by dirt or dust. To ensure the device is working correctly, it is recommended to use it on another symptom-free person. If there is any uncertainty or suspicion, using a new pulse oximeter is recommended.

In the present study, pulse oximetry measurements/readings of both variables, SpO_2 and heart rate, were recorded first without wearing a mask and then after three hours of continuous mask usage. Initially, the study participants were made to sit (or rest) for at least five minutes on the patient's bed. The pulse oximeter was then attached to the right index finger of each study participant without wearing a mask. The readings were recorded after one minute, followed by repeat readings using another pulse oximeter device. The average of the two readings in each participant was considered as the final reading (referred to as "M0" value). Subsequently, all participants were instructed to wear the N95 mask and were asked to carry out their daily routine work in the hospital without removing the mask. After three hours of continuous mask usage, the pulse oximetry readings were recorded again in the same manner. The average value of the two readings measured by two different oximeter devices was considered as the final reading (referred to as the 'M3' value).

STATISTICAL ANALYSIS

The data obtained in the study were evaluated using Mystat statistical software (version 12.0) at a 95% CI. Results were expressed as mean±SD for all continuous variables. First, the mean and SD were calculated using all M0 values, and then using M3 values for both variables, SpO_2 and heart rate. The difference values were calculated by subtracting the M0 and M3 values of each paired measurement, followed by measuring the mean and SD of all those differences (i.e., mean of paired differences and SD of paired differences). For further statistical analysis, the aforementioned statistical values were used to conduct a paired t-test to compare the pairs of means. Values of $p<0.05$ were considered statistically significant, and $p<0.01$ as statistically highly significant, while $p>0.05$ was considered statistically non significant.

RESULTS

Among the 105 eligible and consenting participants, 93 participants successfully completed the study, resulting in a dropout rate of 11.42% (12 participants were excluded). The study included 55 males (52.38%) and 50 females (47.61%) with an age range of 18-40 years and a mean age of 30.2±6.4 years. The mean±SD values calculated using M0 and M3 values for SpO_2 (in %) were 96.5±0.83 and 93.98±0.6, respectively. The p-value was found to be 0.00001, indicating that the results are statistically highly significant [Table/Fig-1]. Similarly, for heart rate, the mean±SD values calculated using M0 and M3 values were 73.45±3.6 and 89.6±6.1 beats/min, respectively. The p-value was found to be 0.00001, indicating that the results are statistically highly significant [Table/Fig-2].

Variable- SpO_2 (in %)			
Statistical measures / Paired measurements	Mean±SD	Paired t-test statistic value (t)	p-value
Without mask (M0)	96.5±0.83	85.083142	0.00001*
After 3 hours of wearing mask (M3)	93.98±0.6		

[Table/Fig-1]: Student's paired t-test comparison between M0 and M3 groups for SpO_2.
p<0.05 is statistically significant; *p<0.01 is statistically highly significant; p>0.05 is statistically non-significant; Student's paired t-test

Variable- Heart rate (beats/min)			
Statistical measures / Paired measurements	Mean±SD	Paired t-test statistic value (t)	p-value
Without mask (M0)	73.45±3.6	-21.956388	0.00001*
After 3 hours of wearing mask (M3)	89.6±6.1		

[Table/Fig-2]: Student's paired t-test comparison between M0 and M3 groups for heart rate.
p<0.05 is statistically significant; *p<0.01 is statistically highly significant; p>0.05 is statistically non-significant; Student's paired t-test

DISCUSSION

In the present study, the authors investigated the possible effect of N95 mask use on blood SpO_2 levels and heart rate in Indian medical professionals. The SpO_2 levels showed a highly significant decrease after three hours of wearing an N95 mask (96.5±0.83% in M0 vs. 93.98±0.6% in M3). This indicates a lowering of SpO_2 in medical professionals after continuous N95 mask use for three hours while performing their routine healthcare work. Supporting the present study, Bao R et al., documented that wearing an N95 mask for even one hour led to a significant decline in SpO_2 levels [16]. Additionally, the findings by Marek EM et al., highlighted that the negative effects in the form of decreased SpO_2 levels were more pronounced with N95 masks compared to other mask types [29]. Studies conducted on dental surgeons wearing N95 masks revealed lowered SpO_2 levels, thus supporting the results of the current study [18,19]. Similarly, Saccomanno S et al., found a significantly negative effect on SpO_2 levels in dental surgeons wearing N95 masks for four hours, along with several symptoms of fatigue, pain behind the ear, headache, etc. [30]. Moreover, a systematic review with meta-analysis conducted by Engeroff T et al., further strengthens and supports the findings of the current research study [31].

In the current study, the heart rate showed a highly significant increase after three hours of N95 mask use (73.45±3.6 in M0 vs. 89.6±6.1 beats/min in M3). This indicates an increased heart rate in medical professionals after continuous N95 mask use for three hours in healthcare settings. In agreement with the present study, Kim JH et al., Vishwanath V et al., and Jones JG reported that using N95 masks is associated with an elevated heart rate [32-34]. Additionally, Scarano A et al., and Bayoumi A et al., showed an increment in heart rate in dental surgeons wearing N95 masks [18,19]. A randomised crossover trial by Bao R et al., highlighted the negative influence of N95 mask use on heart rate, which may eventually cause cardiopulmonary overload, a matter of concern for regular N95 mask users [16]. Furthermore, Li Y et al., elucidated that N95 mask users have an increased heart rate compared to surgical mask users, resulting in greater thermal stress [35].

The physiological reasons behind the negative influences of N95 masks on SpO_2 and heart rate are attributed to the changes in the internal environment (or microclimate) inside the mask. There is an increase in skin temperature, microclimate temperature, and humidity (moisture) within the microclimate of N95 masks after prolonged usage, leading to thermal and respiratory stress [35]. This causes an increased inspiratory and expiratory flow resistance, resulting in difficulty breathing and a decrease in nasal airflow [36,37]. It is noteworthy that breathing difficulty is not solely due to the physical barrier created by the mask material and its tightness but also due to moisture retained in the mask material [38]. Consequently, there is continuous insufficient oxygen uptake/consumption, leading to a decrease in blood SpO_2 levels. Furthermore, oxygen shortage stimulates the sympathetic nervous system, which, in turn, increases the heart rate [39]. Additionally, the microclimate of N95 masks has increased levels of Carbon Dioxide (CO_2) due to the resistance created during expiration, ultimately causing excessive carbon dioxide inhalation and a decrease in SpO_2 [40].

Thus, it can be emphasised that the decrease in SpO_2 levels and increase in heart rate in N95 mask users are due to the altered/deleterious microclimate developed inside the N95 mask.

In contrast to the observations of the current study, studies conducted by Epstein D et al., Roberge RJ et al., Kim JH et al., and Fikenzer S et al., showed that N95 mask use has no effect on SpO_2 and heart rate [12-15]. However, it is noteworthy to mention that the biggest limiting factor in these studies was the excessively small sample size (<20), unlike the present study.

In the present study, in agreement with the findings of several previous studies, the authors have demonstrated a statistically significant decrease in peripheral SpO_2 and an increase in heart rate after three hours of continuous N95 mask use, specifically in Indian medical professionals, with a larger sample size.

Limitation(s)

In the present study, the authors evaluated the negative influence of N95 masks on vital sign parameters after wearing them for a three-hour timespan and therefore could not shed light on the detrimental influence of longer periods (i.e., more than three hours) of N95 mask usage. Additionally, the negative impact on peripheral SpO_2 levels and heart rate could be due to work-related stressful activity, such as performing complex surgeries or excess workload, which could not be negated in the present study.

CONCLUSION(S)

The authors of the present study have concluded that there is a decrease in SpO_2 levels and an increase in heart rate after using N95 masks continuously for three hours in Indian medical professionals. However, more research is warranted in the form of long-term prospective studies to ascertain whether heart rate alterations in N95 mask users are responsible for the genesis of cardiovascular complications in the future, especially in cases of prolonged usage for more than three hours. Additionally, future studies are needed to investigate the negative influence of N95 masks in cardiorespiratory compromised individuals. Considering the utility of N95 masks in preventing the spread of airborne infections and the shortcomings highlighted in the current study, there is potential scope for future research studies pertaining to the development of a better and upgraded/modified form of N95 masks that would specifically provide less humidity, less thermal stress, and less resistance to breathing, thereby providing an ideal microclimate in the interior environment of the N95 mask.

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