

To Comparatively Evaluate Oxygen Saturation Level Among Dental Health Professionals Using 3 Different Types of Masks -N95, KN95 And Surgical Three-Layered Mask

Research Article

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Abstract

Aim: To Comparatively Evaluate Oxygen Saturation Level Among Dental Health Professionals Using 3 Different Types of Masks -N95, KN95 And Surgical Three-Layered Mask.

Settings and Design: Double blinded Randomized Clinical Trial

Methods & Materials: Total 90 Dental health professionals were randomly assigned into three groups; Group A-N 95 mask (3M), Group B-KN 95 mask (3M) and Group C- Surgical three-layered mask (3 ply Surgical mask). The oxygen saturation level was measured for all the Groups before wearing the mask and after 1 hour wearing the mask using a pulse oximeter (MedTech).

Results: The statistical analysis showed that there was no significant difference in Pre-op (before wearing mask) & Post-op (1 hour after wearing mask) in the oxygen saturation level among all three experimental Groups. Although, as an individual group, Group B (KN95) showed statistically significant change in the oxygen saturation within the same group (Intra group) pre-op and post-op.

Conclusion: This study confirms the fact that wearing any of these mask (N95, K95 or Surgical) continuously for 1 hour doesn't affect the oxygen saturation level. So it can be concluded that for any dental procedure taking up to 1 hour, it is safe to wear any of the above mentioned mask.

Keywords: Dental Professionals; KN9 Mask; N95 Mask; Oxygen Saturation; Pulse Oximeter; Surgical Three-Layered Mask.

Introduction

Each system and structure in the body requires oxygen for living. Without oxygen, cells begin to malfunction, eventually die ultimately leading to organ failure [1]. Standard oxygen saturation values are between 95 and 100 percent. Oxygen saturation levels below 90 percent are considered abnormally low and can be a clinical emergency [2]. The device used to measure the Oxygen saturation level is called as 'Pulse Oximeter'. This device can be attached to a finger, a wrist, a foot, or any other area where the device can detect blood supply [3-5].

Health care personnel (HCP) who are routinely exposed to viral respiratory infections in the workplace may transmit infection

to others [6, 7]. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is primarily spread via respired airborne droplets [8, 9].

Dental healthcare professionals cannot always follow the interpersonal distance of more than a meter and are frequently exposed to saliva, blood, and other body fluids during surgical procedures. Moreover, many dental surgical procedures generate aerosol, and the risk of airborne infection is to be considered higher and hence spent long time wearing personal protecting equipment especially a mask [10-12].

The WHO and the United States Centers for Disease Control and Prevention (CDC) recommend wearing a mask as an essential

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Received: September 18, 2021

Accepted: November 13, 2021

Published: November 24, 2021

Citation: Dr. Ajay Singh Rao, Dr. Suwidhi Ranka, Dr. Unnati Shah, Dr. Meghna Kothari. To Comparatively Evaluate Oxygen Saturation Level Among Dental Health Professionals Using 3 Different Types of Masks -N95, KN95 And Surgical Three-Layered Mask. *Int J Dentistry Oral Sci.* 2021;8(11):5141-5145.
doi: <http://dx.doi.org/10.19070/2377-8075-210001033>

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measure to protect the health personnel from accidental exposure through nose and mouth. Hence a variety of masks are available in the market.

An N95 mask is designed to accomplish a tight facial fit and very effective filtration of airborne particles. Note that the edges of the mask are designed to form a seal around the nose and mouth [13].

KN 95 is almost similar to N 95 mask. Both masks are appraised to capture 95% of minute particles (0.3-micron particles, to be exact). Both ratings need masks to be tested for filtration effectiveness at capturing salt particles (NaCl).

Surgical three-layered masks are often referred to as face masks, although not all face masks are regulated as surgical masks. A surgical mask is meant to help block large-particle droplets, splatter, splashes or sprays, that may hold microorganisms (viruses and bacteria), keeping it away from nose and mouth. Surgical masks may also help to reduce exposure of saliva and respiratory secretions to others [14].

Dental health professionals like Surgeons and Endodontists, etc are often using mask on regular basis and they work for longer period. Prolong wearing of any kind of mask may cause breathless or suffocation and may affect the oxygen saturation level.

No literature was available that evaluated and compared effect of these above-mentioned masks on oxygen saturation levels of dental healthcare professionals.

Hence, this study aims to Comparatively Evaluate Oxygen Saturation Level among Dental Health Professionals Using 3 Different Types of Masks -N95, KN95 And Surgical Three-Layered Mask. Null hypothesis stated there was no difference in evaluation of oxygen saturation level among Dental health professionals using 3 different types of masks-N95, KN 95 and Surgical Three-Layered mask (P value <0.05).

Materials and Methods

CTRI Registration was done as per central trial registry for this randomized clinical trial (CTRI/2021/03/032201). After obtaining ethical clearance (SVIEC/ON/DentSRP/20133).

The total sample size required for the study was 90 (30 per group) achieves 80% power using this formula:

$$(Z_{\alpha} + Z_{\beta})^2 \cdot \frac{\sigma^2}{n \cdot \Delta^2} = 2kS^2$$

A total of 90 permanently/provisionally registered dental health professionals aged 20 to 50 years, having experience of wearing mask on regular basis were included in the study after obtaining signed informed consent from all dental health professionals. Dental health professionals with habit of smoking, pre -oxygen saturation level less than 91, previous medical history and ongoing medications, covid -19 recovered and pregnant females were excluded.

Selected professionals were allocated randomly in 3 groups: Group A: N 95 mask, Group B: KN 95 and Group C: Surgical

three-layered mask.

Hence study design was randomized double blinded clinical study. The seat numbers were written on the desk and participants were asked to sit randomly by maintaining 6ft distance. At a time only 30 Dental health professionals were participating in the study; all of them were randomly selected for any of the 3 groups (10 per group).

The pulse oximeter (MedTech) with a reusable clip type finger probe on index finger was used to measure the blood Oxygen saturation during the study (Fig 1A).

The primary investigator measured the Oxygen saturation level of all the participants according to the seat numbers. 2 readings of Oxygen saturation level were recorded and average value was taken for each participant (Fig 1G).

The co-investigator randomly distributed the masks to each group respectively. 10- N95 mask (Fig1B); 10- KN95 Mask (Fig1C); 10- Surgical mask (Fig1D). Allotment of the masks as well as measurements of oxygen saturation levels of all the participants were done by the Co-investigator.

The primary investigator was totally unaware (blinded) of mask distribution procedure to avoid bias. After distributing the mask, an educational video was played (Fig 1F) for 1 hour (every day from 10 am -11am for each batch of 30 people).

After 1 hour when the video ended, the co-investigator gave an additional green cloth mask (Fig 1E) which were customized and were large enough to cover the entire surface of the pre-worn experimental mask on the face (irrespective of the type of mask they were already wearing) just to keep the primary investigator blinded (Fig1H) when he comes back to measure the oxygen saturation after 1 hour.

Now once again, the primary investigator measured the oxygen saturation level of all the participants according to their seat numbers. Again, 2 readings of Oxygen saturation level were recorded and average value was taken for each participant.

Those participants who experienced breathlessness or suffocation were immediately ask to remove the mask and were excluded from the study.

Statistical Analysis

The data were entered into spreadsheets, and Statistical analysis was analysed using one-way ANOVA test for quantitative data with multiple Tukey tests and categorical data using non parametric tests. The data was analysed with IBM SPSS 20 for windows statistical software (P=0.05)

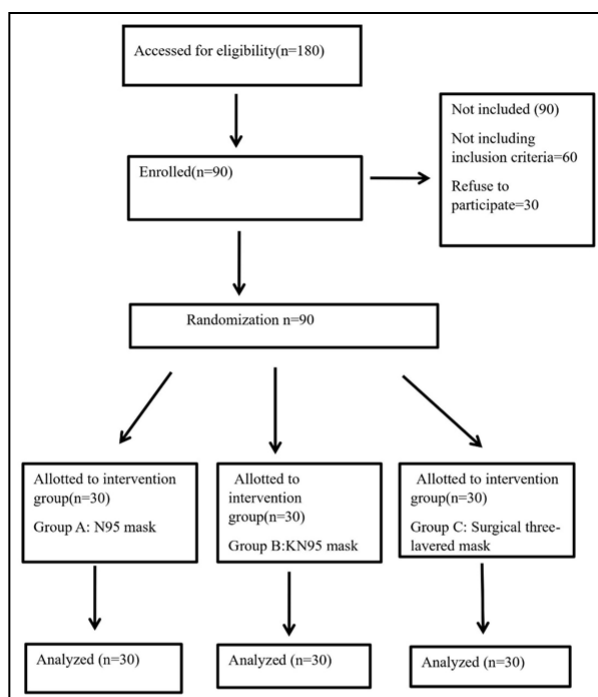
Results

The result states that there is no statistically significant difference in oxygen saturation level among Dental health professionals using 3 different types of masks-N95, KN 95 and Surgical Three-Layered mask (P value <0.05).(Table-5)

Figure 1. a). Pulse Oximeter device, b). N95 Mask, c). KN95 Mask, d). Surgical three-layered Mask, e). Customized Green Cloth Mask, f). Random distribution of Masks among the participants, g). Measuring the Oxygen Saturation Values, h). Masking/ Covering all the mask with Green Cloth mask.



Figure 2. A Consort Flowchart of The Participants Throughout the Trial.



But if we look at the individual groups it shows statistically significant difference in Group B (KN95) mask at pre and post 1 hour interval ($P < 0.005$) (Table-1-4).

Discussion

Oxygen is essential to life. If the supply of oxygen is interrupted, this energy generating process is curtailed or ceases, with resulting cell injury and, ultimately, cell death and organ failure. Blood oxygenation is most frequently measured non-invasively by pulse oximetry. This allows convenient and safe continuous monitoring of oxygen saturation in peripheral (capillary) blood (SpO₂) [15].

Oxygen saturation can drop for many reasons, including suffocation, choking, infections: such as pneumonia, Covid 19, drowning diseases, such as emphysema, lung cancer, and lung infection gasping poisonous chemicals, heart or a history of heart attack allergic reactions, general anaesthesia, sleep apnea [14].

Healthcare professionals are always exposed to a high risk of infection. The WHO and the United States Centers for Disease Control and Prevention (CDC) recommend a series of essential

protective procedures, such as protective equipment for health workers during the care of patients with suspected or confirmed COVID-19, one of the most effective being masks [15, 16].

Dental healthcare professionals cannot always respect the interpersonal distance of more than a meter and are exposed to saliva, blood, and other body fluids during surgical procedures. Moreover, many dental surgeries can generate aerosol, and the risk of airborne infection is to be considered higher and hence spent long time wearing personal protecting equipment especially mask [16-18]. As mentioned earlier, scarcity of literature was seen that examines the physiological effects of various mask in dental healthcare professionals.

Depending on their structure and filtering capacity 2 types of masks: surgical masks and respiratory masks. Surgical three-layered masks are considered a medical device with a certified nomenclature of the EN 14683 standard. They are utmost effective for offering a microbial barrier and resistance to splashes, contributing a filtration percentage of around 80% [19-21]. It provides protection in only 1 direction to avoid the transmission of infectious agents carried by the user. They prevent the passage of microorganisms present from the inside out; therefore, the use

Table 1. Mean Oxygen Saturation Level among All the Experimental Groups with Standard Deviation.

Name of Variables (n=30)	Mean \pm SD	Range (Min, Max)
Group A S-1	97.20 \pm 1.97	7 (92, 99)
Group A S-2	97.20 \pm 1.64	5 (94, 99)
Group B S-1	98.03 \pm 0.96	3 (96, 99)
Group B S-2	97.20 \pm 1.45	4 (95, 99)
Group C S-1	98.13 \pm 0.86	3 (96, 99)
Group C S-2	97.57 \pm 1.85	8 (91, 99)

Table 2. Comparison of Oxygen Saturation Level in Group A (N-95 Mask).

Name of Comparative Variables (n=30)	Mean Rank	Median (IQR)	P-Value
Group A S-1	10.86	98 (96, 99)	0.845
Group A S-2	12.14	97 (96, 99)	

Table 3. Comparison of Oxygen Saturation Level in Group B (KN95).

Name of Comparative Variables (n=30)	Mean Rank	Median (IQR)	P-Value
Group B S-1	8.8	98 (97, 99)	0.005
Group B S-2	12.29	97 (96, 99)	

Table 4. Comparison of Oxygen Saturation Level in Group C (Surgical Three-Layered Mask).

Name of Comparative Variables (n=30)	Mean Rank	Median (IQR)	P-Value
Group C S-1	7.29	98 (97, 99)	0.125
Group C S-2	17.14	98 (97, 99)	

Table 5. Comparison of All the 3 Groups; N-95/KN-95/Surgical Three-Layered Mask.

Name of variables	Name of Grouping Variable			p-value
	N-95 mask (n=30)	KN-95 Mask (n=30)	Three Layered Surgical mask (n=30)	
	Mean Rank	Mean Rank	Mean Rank	
Without mask (Pre-op) oxygen saturation level)	38.8	47.92	49.78	0.189
After 1 hour with mask (Post-op oxygen saturation level)	43.13	42.35	51.02	0.338

of these masks is recommended for COVID-19 patients [20-23].

However, these surgical three-layered masks do not certify a good airtight seal, and thereby permit particles to enter around the ends. The present study resulted that oxygen saturation level in dental health professional wearing three layered surgical masks before was mean range of 7.29 and after one hour was 17.14 that did not elicit a statistically significant difference (P value-0.125) (Table-4). The usage of N95 masks has been measured a US standard administered by the NIOSH. These masks are designed to protect users from air particles, including aerosols [24], with a particle filtration size of 0.3 microns of 95% and have a lesser amount of leakage in the face seal due to the close-fitting to the user's face [20, 23, 25, 26].

The present study shows that oxygen saturation level in dental health professional wearing N-95 mask before was mean range of 10.86 and after one hour was 12.14 that did not elicit a statistically significant difference (P value-0.84).(Table-2)

KN95 masks are accessible in the market and comply with GB 2626-2006 guidelines. These masks have a filtration capacity of 94-95% of particles with 4 overlying coatings, which are attached together to evade the exit of particles from the carrier and the aspiration of aerosols that may incorporate the virus.

A study found out that the filter layer of N95 is 8-fold thicker than that of KN95, which explains its 10% higher filtration ef-

iciency (97.03 %) versus KN95 (87.76 %) [27-30]. Till now, no studies have been done on physiological effects of KN95 respirators. The results of present study showed that oxygen saturation level in dental health professional wearing KN-95 mask before was mean range of 8.80 and after one hour was 12.29 that did elicit a statistically significant difference (P value-0.005) (Table-3). Considering the limitation of the study, comparison of different type the mask showed that there was not statistically significant difference in Pre/Post oxygen saturation levels thus the null hypothesis was accepted in the study.

Acknowledgements

This study has been registered at ClinicalTrials.gov with ID: CTRI/2021/03/032201.

Conclusion

This study confirms that wearing the mask (N95, K95 or Surgical) continuously for 1 hour doesn't affect the oxygen saturation level. So it can be concluded that for any dental procedure taking up to 1 hour, it is safe to wear any of the above mentioned mask. Although in Group B, there was a significant difference found in pre & post 1 hour oxygen saturation, but that was within the safe range (average 95%).

Limitation

1. Since we evaluated Oxygen saturation level at 1 hour interval, more studies are required to evaluate at different time intervals.
2. The sample size taken in the present study is relatively small (90). Hence, studies with larger sample size should be done.
3. Only 3 types of masks were evaluated in the study, other types of masks such as respirator's, FFP2 and double masking needs to be evaluated.

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