Project Title
End Tidal CO2 and Masks: Is There a Correlation?

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Objectives

The primary objective of this study is to evaluate if there are changes present with end tidal carbon dioxide while wearing a mask. A secondary objective is to assess possible changes in end tidal carbon dioxide while walking moderate distances while wearing a mask.

Research Question/Hypothesis

This aim of this study is to test the null hypothesis that end tidal carbon dioxide (ETCO2) will not change with mask wearing while at rest and while walking a moderate distance of 100 meters in a small sample of healthy adult volunteers.

Background to Research Questions

In light of the ongoing COVID-19 pandemic, wearing a mask has become a universal standard as an attempt to reduce the spread of COVID-19. As of 2020, more than half of all U.S. states have implemented a state wide mandated mask policy[1]. There are many schools of thought regarding the benefits and risks of donning a mask to prevent the spread of COVID-19. There is an unproven theory among some that wearing a mask interferes with our natural respiratory function, causing hypoxia, altered mental status and other various health issues[4]. This dangerous perception has led some to believe wearing a mask is harmful, and encourages against wearing a mask in public. This theory, recently refuted by a study investigating oxygen levels while participants wore masks, performed in 2020 by Chan et al. encouraged increased compliance with wearing masks[2]. Another study, preformed by Samannan et al, evaluated whether gas exchange abnormalities occurred with the use of surgical masks in subjects with and without lung function impairment[6]. The conclusions of the Samannan studied showed that regardless of lung function impairment, the presence of surgical masks did not impact gas exchange[6].

Additionally, a more recent study conducted by Barbeito-Caamano et al concluded that the presence of a facemask did not have a significant change in physiologic parameters while during exercise[5]. Although there is evidentiary support that facemasks do not negatively affect oxygen status[2] and physiologic capacity, there is not strong evidence examining the relationship between ETCO2 and facemasks. The relationship between ETCO2 and facemasks is one of importance because mild decreases in oxygen have much less dangerous effects compared to the effects of rapid accumulations of carbon dioxide. Increases in end tidal carbon dioxide lead to confusion, acidosis and in severe cases, respiratory distress and failure. A study performed by Somers et al., in 1989 showed that hypercapnia has greater increases in blood pressure, minute ventilation and sympathetic nerve activity than hypoxia[3].

In this newly proposed study, healthy volunteers will all wear the same type of three layer surgical mask. Their end tidal carbon dioxide will be measured while at rest without a mask, while resting with a mask and then after walking 100 meters in the mask. While previous studies have focused on changes in oxygen, there is a lack of research dedicated to analyzing end tidal carbon dioxide. This study will hope to show evidence supporting that there is no increase in end tidal carbon dioxide while wearing a mask.

METHODOLOGY

Study design

This study is a prospective, controlled study involving healthy adult volunteers all of whom are resident and faculty physicians, or other medical staff. There will be no financial compensation.

Intervention

After obtaining appropriate consent, subjects will have their end tidal carbon dioxide levels measured in three separate scenarios. Subjects will have their baseline end tidal carbon dioxide measured while at rest and without a mask. The second measurement will also occur at rest, but while subjects are wearing a mask. Lastly, end tidal carbon dioxide will be measured after each participant walks 100 meters, both with and without a surgical mask. These values will be compared during the data collection. In each of these scenarios, volunteers will also have their oxygen saturation measured.

Setting

A maximum of 200 healthy adults will be enrolled at a Level 2 trauma center. Activities will be conducted inside of the hospital, where there is a large enough space to accommodate subjects walking the length of 100 meters. They will walk 100 meters twice, for a total of 200 meters.

Expected Start Date

Upon IRB approval.

Duration of Study

The study should take approximately six months to gather the data. An additional six months will be required to analyze the data and to prepare the study findings.

Study Subjects

The sample population will include Residents and staff members at Christus Spohn Shoreline. The maximum number of participants for this study will be 200**.**

Inclusion Criteria:
Healthy individuals between the ages of 18 and 75
Consent to participate in this study
Resident and ancillary staff

Exclusion Criteria:
Patients
Inability or refusal consent
Inability to walk the predetermined distance
History of lung disease

History of significant cardiac disease
People under the age of 18 and over the age of 75

Equipment/Supplies/Services

Supplies and services used for the study will consist of standard issued surgical masks, portable vital sign monitors of an undetermined brand, end tidal carbon dioxide measuring device better known as mask capnography, oxygen saturation measurement device, respiratory therapists.

Data Collection

Trained respiratory therapists will use the portable monitors to measure End tidal carbon dioxide values as well as oxygen saturation values. All values will be recorded into Excel.

Data Analysis

Statistical support will be provided by a member of the research team specializing in statistical analysis. De-identified ordinal data will be entered into an Excel spreadsheet and imported into a statistical analysis software program. Data will be analyzed by chi-square testing.

Data Management

There will be minimal collection of protected health information including a name and signature. All data will be de-identified. Numerical data will be stored on a private, secure computer, owned by the principal investigator under fingerprint and password encryption. The signed consent forms will be kept in a locked file, stored in the locked office of Lynn Carrasco, Research Coordinator. Her office is located on the 9th floor administrative office of CHRISTUS Spohn Hospital Corpus Christi-Shoreline. Only the Principal Investigator, Co-Investigators, and Statistician will have access to the data. All identifying information will be destroyed upon completion of the study.

Identified Risks/Ethical Considerations

Foreseeable risks include participant discomfort, shortness of breath and incidental exposure to COVID-19 as there will be measurements taken while a mask is not worn. There will be a session of counseling to discuss risks and complications of the participating in the study. There is a possible risk of breach of confidentiality. However, all effort will be made to protect the subjects' personal information. Identifying features of the patients will not be used, recorded, or presented in any abstract, manuscript, or oral presentation.

Benefits of Proposed Research to the Subjects and Others

Results of this study should disprove the theory that wearing a face mask interferes with natural respiratory function, causing hypoxia, altered mental status and other various health issues and instead provide evidence of the safety in compliance of wearing face masks in public to reduce exposure to the COVID-19 virus. This will benefit the general public by encouraging ongoing compliance with mask wearing policies.

Study Registration

This study will be registered with Clinicaltrials.gov after approval by the IRB and prior to participant enrollment.

References

1. https://masks4all.co/what-states-require-masks/
2. Chan NC, Li K, Hirsh J. Peripheral Oxygen Saturation in Older Persons Wearing Nonmedical Face Masks in Community Settings. *JAMA*. Published online October 30, 2020. doi:10.1001/jama.2020.21905

3. Somers, V. K., et al. “Contrasting Effects of Hypoxia and Hypercapnia on Ventilation and Sympathetic Activity in Humans.” *Journal of Applied Physiology*, vol. 67, no. 5, 1989, pp. 2101–2106., doi:10.1152/jappl.1989.67.5.2101.

4. Rosner E (2020) Adverse Effects of Prolonged Mask Use among Healthcare Professionals during COVID-19. J Infect Dis Epidemiol 6:130. doi.org/10.23937/2474-3658/1510130

5. Barbeito-Caamaño, C, Bouzas-Mosquera, A, Peteiro, J, et al. Exercise testing in COVID-19 era: Clinical profile, results and feasibility wearing a facemask. *Eur J Clin Invest*. 2021; 51:e13509. https://doi.org/10.1111/eci.13509

6. Samannan, Rajesh, et al. “Effect of Face Masks on Gas Exchange in Healthy Persons and Patients with Chronic Obstructive Pulmonary Disease.” *Annals of the American Thoracic Society*, vol. 18, no. 3, 2021, pp. 541–544., doi:10.1513/annalsats.202007-812rl.

CONSENT

We are conducting a study to assess the impacts of mask wearing on end tidal carbon dioxide in at most two hundred healthy volunteers.

This experiment will involve wearing a standard issued hospital surgical mask. You will wear this mask while at rest and while walking one hundred yards. You will be attached to a portable vital sign monitoring machine and your end tidal carbon dioxide will be measured while at rest and while walking the predetermined distance. Should you have systemic health issues or barriers to this experiment, you will not be able to participate in this study. Additionally, if you are not able to comfortably walk one hundred yards, you will not be able to participate in this study. The entire study should take between five and ten minutes.

Wearing a mask and exerting one's self has very mild, but present risks. Risks include discomfort, shortness of breath and possibly light-headedness or syncope. In order to prevent these risks, if you become too uncomfortable throughout walking one hundred years you will be asked to discontinue the study.

Your participation in this experiment is completely voluntary and will have no effect on your relationship with CHRISTUS Spohn Health Hospital Corpus Christi. There will be no financial benefit should you choose to help, which will be provided at time of participation. Please know that I will work to ensure that your privacy is protected. I will not identify you and all information that is recorded will be stored in a secure location.

Do you agree to voluntarily be subject to this research study?

Please circle one:

Yes No

PRINT name:

_____

SIGNATURE:

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