Research Protocol

Title: Does Use of a Facemask Reduce the Risk of Aerosolization During Anesthesia Assisted Upper Endoscopic Procedures: A Randomized Controlled Pilot Trial

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Introduction

There is little evidence describing the aerosolization of potentially infectious particles during gastrointestinal endoscopy. Such a phenomenon could potentially place medical staff and patients alike at exposure risk despite the use of personal protective equipment as once aerosolized, microscopic water droplets could remain suspended in the air for hours and represent a potential risk of spread of infectious agents. We propose a randomized controlled pilot trial to assess aerosolization and the potential use of an endoscopic patient facemask to reduce the risk of viral transmission.

Background and Significance

Unfortunately there is a lack of data regarding infectious risk posed to healthcare providers by aerosolization during upper endoscopy. Furthermore, the current COVID-19 pandemic has heightened stress surrounding the danger of potential aerosolizing procedures. While personal protective equipment may reduce some risk, aerosolized particles can remain suspended in the procedural room environment and may lead to transmission despite the use of personal protective equipment. There is only one prospective observational study assessing aerosolization during endoscopy, which used a handheld particle detector in 93 patients undergoing upper endoscopy and found significant increases in particle suspension within the air in the endoscopy procedure room at a distance from the subject where the endoscopist and support staff would be located.

Given the current lack of evidence on particle aerosolization during endoscopy, we plan to conduct a randomized controlled trial utilizing a commercially available particle detector to assess particle suspension in the air during upper endoscopic procedures. We hypothesize that use of an endoscopic patient facemask reduces periprocedural aerosolization during upper endoscopic procedures. Our initial effort will be focused on conducting a pilot trial to assess population variability as no baseline data exists for aerosolization in the general population. We hope to subsequently conduct a larger scale trial to fully test our hypothesis. If an endoscopic facemask significantly reduces aerosolization it could be used to decrease infectious risk to providers while posing minimal risk to the patient and without significantly altering the endoscopic procedure.

Methods

Study Design: Prospective randomized controlled trial

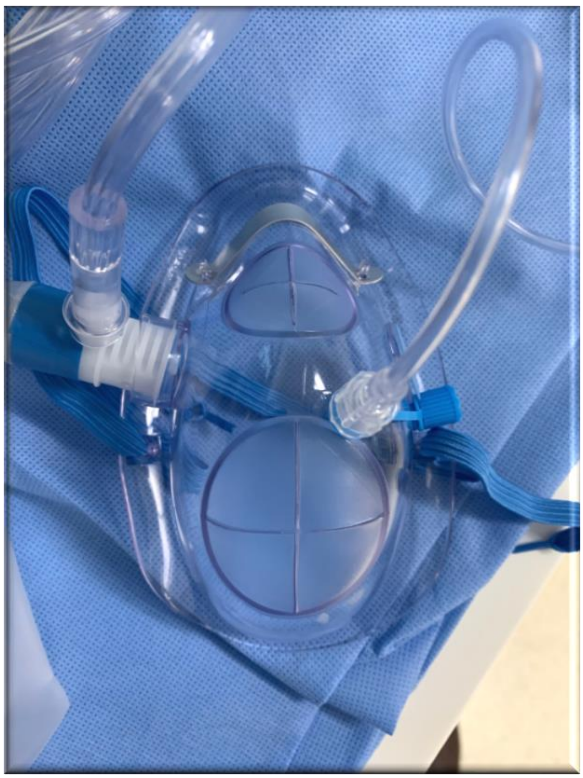
Sample Population

- All patients presenting for an elective upper endoscopic procedure with monitored anesthesia care
- For the pilot trial we plan to recruit 50 total patients, 25 patients in the control arm without a procedural facemask and receiving 2-4 L/min of oxygen via nasal cannula and 25 with a specially designed facemask. An additional 10 patients will be enrolled to account for subject dropout as necessary. Sample size calculation was conducted for the purpose of estimating population variability with a 0.05 level of significance and 0.8 power level. This was done with the assistance of the Department of Quantitative Health Sciences at the Cleveland Clinic
- Inclusion Criteria;
  - All patients undergoing elective upper endoscopic procedures (upper endoscopy, ERCP, endoscopic ultrasound) with monitored anesthesia care at main campus Cleveland Clinic Q3 inpatient endoscopy unit.
- Exclusion Criteria:
  - Any patient requiring endotracheal intubation
  - Pregnant patients
  - Emergency procedures
  - Patients who require use of a facemask before or during the procedure due to medical necessity
  - Patients under the age of 18
  - Non-English speaking individuals
  - Patients unable to provide consent.
  - Any procedure done outside the designated procedure room.
  - If in the opinion of the anesthesiologist, a subject who was randomized to the control arm requires placement of the procedural mask to augment oxygenation, the subject will be removed from the study

Research Procedure:

- All patients undergoing an upper endoscopic procedure in the designated procedure room with monitored anesthesia care will be eligible for recruitment into the study once exclusion criteria are applied

- Patients will be randomized to receive an endoscopic procedural facemask or to undergo endoscopy without one at the time of enrollment in the pre-procedure holding area. Control subjects will receive supplemental oxygen (2-4 L/min) via nasal cannula as per our standard protocol. Use of this mask will not affect the risk of the procedure nor change the nature of the patient's endoscopy in any way. An example of this commercially available facemask is pictured below. The mask is currently used in the inpatient endoscopy unit at the main campus of the Cleveland Clinic is selected patients for oxygen delivery.



- In order to collect particle aerosolization data, use of a Met One GT-526S Handheld Particle Counter will be used. This device can detect particles of six different sizes (0.3µm, 0.5µm, 1µm, 2µm, 5µm and 10µm). This data can be directly downloaded from the device using the associated Comet software. Device pictured below:

- Endoscopy will be performed in accordance with standard procedures at the Main Campus Cleveland Clinic by either a staff gastroenterologist or a gastroenterology fellow trainee under direct supervision by a staff gastroenterologist.

- The device will be placed in a standardized position 12 inches from the head of the subject on a tripod. The device location will not hinder access to the subject by anesthesia, nursing or gastroenterology staff.

Data Collection:

- Data collected before the patient enters the procedure room:
    - Patient Demographics (age, gender)
    - BMI
    - Upper Endoscopic Procedure Type (ex: esophagogastroduodenoscopy, endoscopic ultrasound, endoscopic retrograde cholangiopancreatography)
    - Patient Mallampati Score
- Data collected in the procedure room prior to start of endoscopy:
    - Patient vitals including BMI and oxygen saturation
    - Patient positioning (left lateral decubitus, supine, prone).
    - Oxygen flow rate being administered by anesthesia staff
    - Number of individuals in the room
    - Peak and mean aerosolized particle counts for 5 minutes prior to endoscopy start
- Data collected during the procedure
    - Any change in supplemental oxygen requirement
    - Any intra-procedural manipulation of the patient's head and neck (ie. head tilt, jaw thrust)
    - Any removal and reinsertion of the endoscope
    - Any opening of the designated procedure room door
    - Any use of the endoscope working channel
    - Peak and mean aerosolized particle counts. This will be obtained during three intervals for six different sizes (0.3μm, 0.5μm, 1μm, 2μm, 5μm and 10μm). The three intervals are: A. A 5-minute baseline period before initiation of sedation. B. Intra-procedurally and C. Post procedurally for 5 minutes, which is defined as beginning after the endoscope is removed.
- Data collected post-procedurally
    - Total procedure duration
    - Total dosage of medications utilized for sedation
    - Use of any reversal agents
    - Peak and mean aerosolized particle counts for 5 minutes after endoscopy completed
- After the patient exits the procedure room no further patient data will be collected
- Post-procedurally patients will follow standard post endoscopy monitoring prior to discharge.

Sample Size Calculation and Data Analysis

Sample size calculation was conducted for the purpose of estimating population variability with a 0.05 level of significance and 0.8 power level. This was done with the assistance of the Department of Quantitative Health Sciences at the Cleveland Clinic.

Data will be described using means (standard deviations) for normally distributed continuous variables, medians [quartiles] for non-normally distributed continuous variables, and frequency (percentage) for categorical variables. Shapiro-Wilks test will be conducted for continuous variables to assess normality. Analysis of variance (ANOVA) or the non-parametric Kruskal-Wallis tests will be used to assess differences in continuous variables. The chi-square test and Fisher's exact test will be used to compare categorical variables as appropriate. A linear mixed model will be used to assess the association between the clinical factors and concentration level of each particle. The mixed model will be used to account for

within subject correlation. All tests will be two-tailed and performed at a significance level of 0.05. Analyses will be performed using R software

Particle concentrations for the six sizes measured by the device (0.3μm, 0.5μm, 1μm, 2μm, 5μm and 10μm) will be assessed during three intervals: (1) 5 minute baseline prior to the procedure (2) during the procedure and (3) 5 minutes after endoscope removal. The primary endpoint for the study will be the mean / median concentration of each particle for the three measurement intervals. Our hypothesis is that use of the facemask will significantly decrease aerosolization of all particle sizes during the procedure when compared to controls.

Demographic, procedural and particle concentration data will be placed into a RedCap database, by Drs. Vargo and Din. Additional access to the database will be granted to Ruishen Lyu, MS from the department of Quantitative Health Sciences who will be conducting the statistical analysis.

Adverse Events and Data Monitoring Committee (DMC)

This is a minimal risk study. The PI has been involved in procedures which utilized this device without any adverse events. Literature review as well as review of the MAUDE database failed to reveal any instances of complications stemming from the use of this facemask.

Consent

Consent will be obtained by one of the investigators in the pre-procedure area of the endoscopy suite. Patients will be given the option clearly to not participate in the research study while still participating in their planned endoscopic procedure. Subjects deemed not able to consent for the procedure themselves will not be included within the research study. Attached is the proposed consent document.