

Comparative Analysis of CO2 Monitoring Methods in Patients with CF Undergoing
General Anesthesia

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PROTOCOL

Title: Comparative Analysis of CO₂ Monitoring Methods in Patients with CF Undergoing General Anesthesia

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Introduction:

CO₂ measurements obtained using different methodologies are used as a marker for ventilatory status in various clinical settings. Accuracy of CO₂ measurements is especially important in cystic fibrosis patients. During procedures requiring general anesthesia, CO₂ is monitored through the endotracheal tube (EtCO₂) and/or arterial blood gas (ABG) and anesthesia adjusted to maintain healthy CO₂ levels. Outside of the operating room, fingerstick capillary (CapCO₂) or transcutaneous (TCO₂) are used to manage other treatments in cystic fibrosis patients. Unfortunately, there are very little data in the literature to compare and contrast accuracy of the differing methodologies. Comparative studies are needed to identify the most accurate method for measuring CO₂ in various settings. This study will obtain CO₂ measurements simultaneously using four different methodologies (EtCO₂, ABG, CapCO₂, and TCO₂) in cystic fibrosis patients undergoing general anesthesia.

Primary Objectives:

1. Validate the use of EtCO₂ monitoring of cystic fibrosis patients during general anesthesia.
2. Compare the results of EtCO₂ with CapCO₂, TCO₂ and ABG in CF patients undergoing general anesthesia.

Secondary Objective:

1. Stratify CF patients based on FEV₁ and genotype to determine if discrepancies between EtCO₂, CapCO₂, TCO₂, and ABG change based on level and type of disease. This comparative study will use data FEV₁ and genotype data collected through separate chart review.

Study Population:

All patients that have a confirmed diagnosis of cystic fibrosis (positive sweat chloride value ≥ 60 mEq/L) and/or genotype with two identifiable mutations consistent with CF, accompanied by one or more clinical features consistent with the CF phenotype) and are hemodynamically stable undergoing general anesthesia for a scheduled procedure will be approached and asked to participate in the study. Patients undergoing emergency procedures will not be included in the study. Patients meeting the criteria for participation will be identified during their CF clinic visit or during an inpatient stay.

Procedures:

1. When a patient is scheduled for a procedure requiring general anesthesia, a secure message will be sent to Julie Rice, Sam Barry, Heather Dellinger, and Linda Humston with patient identification, date and time of procedure.

2. Just prior to the procedure, an anesthesia research nurse will obtain informed consent/assent for the study.
3. After anesthesia induction, simultaneous EtCO₂, ABG, TCO₂, and CapCO₂ will be measured and results entered on a data form attached to the signed consent.
4. The research nurse will place the signed consent form and the data form in a locked file cabinet in anesthesia.
5. Linda Humston from Pulmonary Medicine will pick up the documents from anesthesia and enter the information into the password-protected study database. No patient identifiers will be entered into the database.