Feasibility Study to Evaluate Fractional Expired Nitric Oxide (FENO) during Hospitalization for Acute Exacerbation and Two Weeks Post Discharge for Patients with Chronic Obstructive Pulmonary Disease

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Introduction

American Thoracic Society established guidelines in 2011 recommending the use of Fractional Expired Nitric Oxide (FENO) to determine the likelihood of steroid responsiveness in individuals with chronic respiratory symptoms possibly due to airway inflammation (strong recommendation, low quality of evidence). FENO has primarily been studied in the pathogenesis of asthma; patients with asthma were found to have high levels of FENO that increased in response to treatment with corticosteroids, which prompted this to be a potential noninvasive method to monitor the response to anti-inflammatory therapy. Additional research is needed to better define the use of FENO in different clinical settings.

One of the challenges in the treatment of COPD is to identify which patients benefit from inhaled corticosteroid treatment. A study performed in New Zealand noted that COPD has many different phenotypes and recognized that some subgroups of COPD patients may display a greater therapeutic response and have better clinical outcomes to corticosteroids than others. There is evidence that steroid responders are more likely to be characterized by the presence of eosinophilic airway inflammation and be of the COPD asthma pre-dominant phenotype. Measurement of FENO is simple and reliable. FENO correlates with eosinophilic airway inflammation, particularly with asthma, and to date its application among patients with COPD has not been systematically assessed.

Inhaled corticosteroid use in patients with stable COPD does not significantly improve mortality and there is evidence of increased incidence of pneumonia in these patients. Therefore it would be beneficial to identify a subgroup of patients with COPD that may benefit from corticosteroids and contribute to a better risk-benefit ratio to corticosteroid therapy.

FENO could become useful as a clinical tool in different applications such as predicting steroid responsiveness in COPD. Recent studies have utilized FENO in patients with stable COPD after ICS/oral corticosteroid therapy. This study is unique in which we are exploring a target population in acute COPD exacerbation. We hypothesize that measured FENO levels could be used to identify the patient population that would best benefit from additional oral corticosteroid therapy after COPD exacerbation. We are not formally testing a hypothesis at this time, but rather designing a feasibility study to potentially enable randomized controlled studies in the future.

Methods

Project Status: This project is currently under IRB review, instrument acquisition and data collection has not yet been initiated. Study design is outlined below.

Patient Selection: Twenty-five patients undergoing inpatient treatment of acute exacerbation of documented COPD will be sequentially selected for participation in this study. This study will take place at Arnot Ogden Medical Center in Elmira, NY. The inclusion criteria are symptoms consistent with COPD exacerbation including cough, change in sputum production volume/and or color, worsened dyspnea. The patient is to have previously documented COPD. Exclusion criteria include documented restrictive lung disease, pulmonary malignancy, suspected or documented concurrent heart failure decompensation, documented lung carcinoma, any disease process that may obscure obstructive pulmonary disease data.

Description of planned interventions: FENO will be measured at time of exacerbation while inpatient and at two weeks post-discharge. At admission, subjects will undergo treatment of COPD exacerbation as indicated. The investigators will be using the Niox Vero FeNO Machine, which is a non-invasive method of measuring expired FENO. Higher concentrations of FeNO in the patients’ breath is indicative of higher levels of airway inflammation. Subjects will also complete the St. George’s Respiratory Questionnaire for COPD patients (SGRQ-C) with repeat FeNO measurement at two weeks post-discharge. Additional corticosteroids will be tailored per FENO measurement and results of SGRQ-C. Distributions of the NO parameters and symptom scores will be calculated, correlations between changes in FeNO and symptoms during the treatment will be examined.

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References