

A Comparison of the Severity of Exacerbation in Asthmatics with and without Exposure to Alkaloidal Cocaine

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A. Study Purpose and Rationale

Use of alkaloidal cocaine (free base or crack cocaine) continues to be a rampant social problem, particularly affecting inner city populations. In recent years, the literature describing a broad spectrum of pulmonary complications of this smoked form of cocaine has also grown, as reviewed by Meisels et al.¹ These complications include clinical manifestations of airway injury, as demonstrated in one study of habitual crack cocaine users in which 32% of subjects reported wheezing during periods of use.² Case reports have documented development of clinical asthma symptomatology in chronic crack users without previous histories of asthma,³ and life threatening exacerbations warranting mechanical ventilation in asthmatics temporally related to the use of crack cocaine.⁴

A sizeable body of work has attempted to elucidate the etiology of the relationship between smoked alkaloidal cocaine and exacerbations of clinical asthma in patients with and without reactive airways disease. Histopathological evidence exists of tracheo-bronchial injury, including intraepithelial and subepithelial inflammation in habitual smokers of cocaine.⁵ The inhaled smoke is also known to contain respiratory irritants that are capable of eliciting cough⁶ and inducing abnormalities in airway dynamics, namely a temporally related increase in airway resistance and decreases in specific airway conductance and DL_{CO}.⁷

It is hypothesized that asthmatics who smoke cocaine are more likely to require aggressive treatment for their acute exacerbations, as demonstrated by increased use of corticosteroids in the emergency department, an increased hospitalization rate, and lengthier hospital stays. It is the purpose of this study to attempt to identify increased severity of exacerbation in asthmatics after having smoked alkaloidal cocaine in comparison to asthmatics without this exposure. This knowledge may change standard asthma exacerbation treatment protocols, in order to minimize poor outcomes in these individuals.

B. Study Design and Statistical Analysis

A preliminary pilot study is to be conducted, with the goal of gathering the following data: (i) the proportion of asthmatics that present to the emergency department in acute exacerbation that have had recent exposure to smoked freebase cocaine, as determined by a urine toxicological screen for benzoylecgonine, a cocaine metabolite; (ii) the proportion of asthmatic cocaine exposed patients in acute exacerbation that receive corticosteroids as part of their management in the emergency department; (iii) the proportion of asthmatic non-cocaine exposed patients in acute exacerbation that receive corticosteroids as part of their management in the emergency department; (iv) the proportion of asthmatic cocaine exposed patients in acute exacerbation that are admitted to the hospital for further management; (v) the proportion of asthmatic non-cocaine exposed patients in acute exacerbation that are admitted to the hospital for further management. The pilot study will be continued until the above proportions are obtained in order to estimate the sample size needed to ensure adequate power in the study.

A case-control study will be performed, with asthmatics who are given steroids, or are admitted to the hospital constituting the cases. They shall be compared with their respective controls (asthmatics who are not given steroids, or are not admitted) with regards to recent exposure to smoked alkaloidal cocaine, as determined by urine toxicological analyses performed on all patients that enter the asthma treatment center of the emergency department. Of note, controls will be individually matched to the cases

with respect to age, sex, race, socioeconomic status and tobacco use. Mean length of hospitalization will then be compared between those patients exposed to cocaine and those that were not. Chi square analysis and paired t-test are to be used to show statistical significance in the above outcomes between exposed and non-exposed asthmatics.

C. Study Procedures

All patients enrolled in this study will agree to have urine specimens submitted for toxicological analysis. They shall then be treated according to standard asthma center emergency department protocol, receiving nebulized bronchodilator therapy and monitored closely for signs of clinical improvement. If this improvement is not appreciated in a timely manner by the clinicians present, either oral or intravenous corticosteroids are administered. Finally, the decision of whether or not to admit the patient to the hospital for further management is made. At no time shall the emergency department staff have access to the results of the urine toxicological tests.

Most patients are not admitted to the hospital with acute asthma exacerbations, and admissions rarely last longer than one week. Thus, the anticipated duration of participation in the study for most subjects will not be long.

D. Study Drugs

No study drugs will be used.

E. Medical Devices

No medical devices will be used.

F. Study Questionnaires

A very basic questionnaire determining age, sex, race, occupation, and quantification of tobacco use will be used.

G. Study Subjects

Study subjects will be drawn from patients presenting to the Presbyterian Hospital adult emergency department for treatment of acute asthma exacerbation. Inclusionary criteria will include age over 18 years and clinical evidence of acute asthma exacerbation. Exclusionary criteria will include use of other illicit substances (including phencyclidine, heroin, opium, methamphetamine, and cannabis).

H. Recruitment of Subjects

Subjects will be recruited in the triage center, before transfer to the asthma treatment center.

I. Confidentiality of Study Data

Subjects will be assigned unique numerical identifiers. Only the investigators shall have access to subject data.

J. Potential Conflict of Interest

There are no potential conflicts of interest.

K. Location of the Study

The study shall be conducted in the Presbyterian Hospital adult emergency department.

L. Potential Risks

The study subjects will not incur any additional risks through involvement in the study.

M. Potential Benefits

If the study successfully demonstrates an association between crack cocaine use in asthmatics and the need for more aggressive treatment, it may become standard practice to test for this exposure upon presentation to expedite therapeutic maneuvers, and thus minimize potentially poor outcomes.

N. Alternative Therapies

The study follows standard treatment protocol.

O. Compensation to Subjects

There will be no compensation to patients.

P. Costs to subjects

The subjects will not incur any additional costs.

Q. Minors as Research Subjects

The study will be conducted solely on adult subjects.

R. Radiation or Radioactive Substances

The study will not involve radiation or any radioactive substances.

S. References

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