

The Safety of Salt Pipes in Asthmatic Patients.

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Abstract:

The usage of salt pipes in respiratory conditions is increasing despite a paucity of clinical evidence and safety data. We conducted a safety study of salt therapy in a small but defined asthma cohort (n=12).

Each patient inhaled from the Cisca Easy Saltpipe® for 5 minutes. Serial FEV₁ was conducted at intervals after inhaler use. The maximum fall in FEV₁ was 16.9%, however overall the mean change in FEV₁ from baseline was an increase of 0.5%.

We conclude that although safe in the majority this form of therapy does have the potential to elicit a significant bronchospastic response.

Keywords: Asthma, salt, therapy, inhaler, safety, bronchospasm

To the Editor,

Salt pipes are commercially available products which are advertised for use in a wide range of respiratory conditions, including asthma. They use micronized salt crystals which are inspired into the lungs. Advocats of the device propose that they enhance sputum clearance from the lungs with resultant improvement in breathing [1,2]. However, there is a lack of robust clinical efficacy and safety data available to support this claim. Airway hyperresponsiveness is a characteristic feature of asthma and results in an exaggerated bronchoconstrictive reaction of the airways to nonspecific stimuli. Only a small volume of hypertonic saline is needed to provoke airway narrowing in patients with asthma [3]. Hence, concern remains that salt pipes may provoke a bronchoconstrictive response particularly in potentially susceptible asthmatic subjects.

Our group conducted a short study to evaluate and determine the safety profile of salt pipe inhalers in asthmatic patients. Ethical approval was granted by The Clinical Research Ethics Committee of the Cork Teaching Hospitals. 12 patients who suffered from asthma (a bronchodilator response of 12% and 200ml change in FEV₁ or a positive methacholine test) were recruited. Mean age was 41.3 ($\pm$ 18.9) years, with an average FEV₁ of 87.3% predicted and an ACQ-7 score of 1.9 indicative of poor control [4]. Patients did not take their short or long term bronchodilators, in accordance with standard inhaled challenge guidelines [5]. FEV₁ was determined by spirometry to obtain a baseline lung function. Each patient then inhaled from the Cisca Easy Saltpipe® (Cisca Limited, Durham, United Kingdom) for 5 minutes, performing normal breathing, as per product instructions. Serial FEV₁ was conducted at 5, 10, 15 and 30 minutes after using the salt pipe inhaler. Patients were then asked if they felt there had been any clinical improvement or deterioration. They were asked this again 24 hours later.

The maximum change in FEV₁ over the test's duration was determined. Baseline and post-inhalation FEV₁ values were analysed, using a paired t-test, with no significant change observed ($p=0.58$). The maximum fall in FEV₁ was 16.9% from baseline and the mean decrease, among those with a decrease in FEV₁, was 3.8%. A maximum increase of 7.2% was recorded and, of those who responded positively to

the treatment, the mean increase was 3.0 %. Overall, the mean change in FEV₁ from baseline was an increase of 0.5%. **Of note the patient that had the maximum fall in FEV₁ during the study also demonstrated the largest bronchodilator response (20.9%) on formal testing for reversibility prior to study entry.** There was no correlation observed between age, sex, BMI, atopic status and response to salt pipe using standard ANOVA. Clinical efficacy was not formally assessed but six patients reported improvement in breathing in the 24 hours after using the salt pipe (5/6 of whom had experienced an increase in FEV₁ during the test). Three patients reported feeling worse after using the salt pipe, mentioning an unpleasant salty aftertaste, headache and experiencing tightness in the chest.

This study was limited by a small sample size but based on the results obtained we would exercise caution when using salt pipe inhalers. While, the device was safe in the majority of our asthmatic subjects, it did cause a decrease in FEV₁ of almost 17% in one of the patients.

Abbreviations:

FEV₁ – forced expiratory volume in 1 second

ACQ-7 – Asthma Control Questionnaire, a simple questionnaire to measure the adequacy of asthma control and change in asthma control which occurs either spontaneously or as a result of treatment.

ANOVA - Analysis of variance is a collection of statistical models used to analyze the differences among group means and their associated procedures.

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Authors' Contributions;

MW, EH and BB carried out the spirometry as well as administration of the salt pipe inhaler. SB and MW participated in the design of the study and performed the statistical analysis. DM and SB conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

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Legend;

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Figure 1: Represents the change in FEV₁ as a % of predicted value. Each patient is represented by a different coloured line. Baseline FEV₁ is represented as time zero in this graph, with time in minutes.

