Calcium Glycerophosphate Nasal Spray Reduces Rhinitis Symptoms.
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ABSTRACT

Rationale: Many patients with rhinitis remain symptomatic and/or intolerant of treatment. Recently, Balas et al (2013) reported that AM is elevated in neutrophilic asthma, leading us to hypothesize that a topical spray of calcium glycerophosphate (CGP), an AM inhibitor, might be useful in treating rhinitis.

Methods: This study was approved by the Drexel University Human Research Protection Committee. Twenty subjects (16 F, 4 M, 18–67 years, with target composite scores for the three-week period of the study for linear trend to increase FVC (r=0.13, p=0.0112), but not FEV1 or PEF. The mean WBC tended to decline over the course of the study from 8.86x10^3 to 7.86x10^3, as did eosinophils (p=0.0095), but not lymphocytes (p=0.2347), neutrophils (p=0.1561), or monocytes (p=0.2740). Similarly, eosinophils tended to decline from 3.22x10^3 to less than 2.8x10^3 (p=0.064).

Conclusion: These data demonstrate that intranasal CGP effectively reduces the symptoms of rhinitis. More studies are needed in this very small study treatment group. Interleukin 1beta and 8 were not significantly different for each time point for both A.M. (p<0.0001) and P.M. (p=0.0061). There was a small but statistically significant linear trend to increase FVC over the time course of the study. Slope -0.032, p=0.0012.

INTRODUCTION

Many patients with rhinitis remain symptomatic and/or intolerant of treatment. Recently, Balas et al (2013) reported that alkaline phosphatase is elevated in neutrophilic asthma, leading us to hypothesize that a topical spray of calcium glycerophosphate (CGP), an alkaline phosphatase inhibitor, might be useful in treating rhinitis.

METHODS

The Drexel University Human Research Protection Committee approved this study. Sixteen subjects (19 F, 7 M, 18–67 years, with target composite scores for the three-week period of the study) were enrolled in the study. Of these, 12 completed the study. Subjects were tested for allergen sensitivities; of the twelve subjects completing the study, 11 subjects reacted to from 1 to 26 different allergens, while the remaining four subjects showed no identifiable allergens. Of these 11 subjects, two had a history of asthma, and one subject (M) had previously diagnosed COPD. All values given in this report are mean ± SEM.

RESULTS

The running and evening composite subject scores for rhinitis, itching, congestion and sneezing are presented in Figure 1. The mean pre-treatment composite score was 7.34 ± 0.03. Both the pre- and post-treatment scores were significantly lower than the run-in scores at each time point. Both the AM and PM post-treatment scores were significantly lower than the pre-treatment scores at each time point.

Symptomatic relief was unlikely the consequence of a change in seasons, or differing allergen sensitivities. Patients were enrolled in the study over a 14-month period, and exhibited a wide range of sensitivities, yet the decline in diary scores remained remarkably consistent between subjects. Furthermore, a sister study conducted in New Mexico (data not presented here) produced much the same results, despite being performed at a different time, by different investigators, and in a part of the country having a very different ambient allergen profile as compared to Philadelphia.

The subjective and objective data demonstrate that intranasal CGP effectively reduces the symptoms of rhinitis. Subjectively, both the pre-treatment and post treatment symptom scores decreased markedly over the course of the study. Objectively, an increase in FEV1 and decrease in WBC and EOS are consistent with the declining symptom scores.

The small increase in FVC is intriguing and bears further investigation. While the average increase in FVC was small, it suggests that treatment may improve pulmonary compliance. It is important to note that this was a 21-day study, and neither the diary-score nor the FEV data have reached plateau. It seems reasonable to speculate that both parameters may continue to improve. Similarly, the decreases in WBC and EOS were remarkable for a short study of only 12 patients.

Calcium glycerophosphate is an attractive candidate for rhinitis treatment. It is classified as “generally recognized as safe” by the FDA. As glycerophosphate is a normal metabolic intermediate, CGP is unlikely to have significant abuse liability, even when used over a long period of time. Twice daily use as a nasal spray not only provided symptomatic relief, but also may have a mild effect on pulmonary function.

REFERENCES


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