

THE IMPACT OF INTRANASAL STEROID AS AN ADJUNCT TO THERAPY FOR SINUSITIS

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ABSTRACT

Inflammation of nasal mucosa plays an essential role in the development of sinusitis. Topical nasal steroids are helpful to reduce the mucosal swelling. In this study, the efficacy of topical nasal steroid spray combined with antibiotic for the treatment of sinusitis was studied in a double blind trial. Two randomly assigned groups were treated with amoxicillin / clavulanate potassium combined with topical nasal steroid spray of either budesonide or placebo to each nostril twice a day for 3 to 4 weeks. Clinical symptoms and signs decreased significantly in both treatment groups, but the difference between study groups was not statistically significant.

Key Words: Sinusitis, Inflammation, Topical steroids

INTRODUCTION

Sinusitis is an infection of one or more of the paranasal sinuses. Infectious or non-infectious rhinitis and inflammation play an important role in the etiology of sinusitis. Inflammatory edema induced sinus ostial obstruction results in stasis in the sinuses and encourages development of infection (1). Recently, noninfectious inflammation predisposing to sinusitis has stimulated renewed interest in developing and documenting efficacious therapies that could supplement or abrogate antibiotic use (2). Topical nasal steroids are being increasingly stressed in suppressing and modulating cellular inflammation thus reducing mucosal swelling and inflammatory response in sinusitis (3).

In this study, the effectiveness of nasal topical steroid was investigated in a randomised double-blind

manner as an adjunct to antibiotic therapy in the treatment of sinusitis.

PATIENTS AND METHODS

One hundred and sixty - three patients (90 male, 73 female; aged 3-55 years, mean age 15.2 years) presenting to the Marmara School of Medicine Hospital otolaryngology clinics with sinusitis took part in the study. Patients with general health problems, who were pregnant, uncooperative, under 3 years of age or older than 55 years, allergic to penicilline derivatives excluded from the study. They were interviewed and examined before and during the course of treatment. Previous sinusitis attacks and passive or active exposure to cigarette smoke were also cited. Signs and symptoms of sinusitis were noted including headache, rhinorrhea, postnasal drip, cough, and facial pain. The ENT examination included a complete nasal and nasopharyngeal examination. The diagnosis of sinusitis was made on the basis of a medical history, nasal and nasopharyngeal examination, and positive sinus radiograph (Waters and / or Caldwell views). Sinus x-rays were considered positive if opacity, air-fluid level, and/or mucosal thickening (greater than or equal to 5 mm) were present.

The patients were randomly allocated to one of the two treatment regimens. These treatment regimens included with amoxicillin / clavulanate potassium 40 mg/kg/d in three divided doses combined with either budesonide 50 mg spray to each nostril twice a day or placebo for 3 to 4 weeks. 4 patients who had gastrointestinal complaints of amoxicillin / clavulanate and 15 patients who did not attend the study regularly, dropped out from the study (19/163, 11%).

During treatment the patients completed a daily symptom diary card including symptoms such as rhinorrhea, cough, headache, postnasal drip, and other specific symptoms that they experienced.,

The patients were rated as cured if their symptoms had completely abated and there was no clinical evidence of infection. If there was no demonstrable response to therapy, the treatment was rated as failure. In cases in which radiographs were repeated, the x-rays were categorized as cleared, improved or unchanged after comparison with pretreatment radiographs. The clinical response rating was independent of the radiographic findings, but supportive in the final assessment of the patient.

Forty - nine of 144 patients were tested for IgE level and/or skin prick test. In the skin prick test 12 common allergens were used. Total serum IgE concentration was measured by (age adjusted) radioimmunoassay.

RESULTS

The results obtained from 144 patients were evaluated in this study. Ninety - seven patients were under 16 years old.

Seventy-two patients were treated with amoxicillin / clavulanate combined with budesonide and 72 patients were in the amoxicillin / clavulanate plus placebo group. These two groups were similar with respect to age, sex distribution and mean duration of treatment but atopic characteristics were unevenly distributed. Of 72 patients treated with budesonide, 64 have been cured clinically (88 %). Of 72 patients

in the placebo group, 58 patients have been cured (80 %).

The presenting symptoms and signs of the 144 patients are shown in table I. The most common complaints were postnasal drip, rhinorrhea, headache, and cough.

The mean duration of rhinorrhea symptom was 8.41 days in budesonide. Mean durations of cough, headache, and postnasal drip were 6.63, 6.68, and 11.97 days, respectively.

In the placebo group, the mean duration of rhinorrhea, cough, headache, and postnasal drip were 9.50, 6.48, 7.52, and 12 days, respectively (Table II).

When the duration of each symptom was compared, there was no statistically, significant difference between the study groups. (rhinorrhea: $p > 0.511$, cough: $p > 0.9373$, headache: $p > 0.2839$, and postnasal drip: $p > 1$).

Fourteen (28%) of the 49 patients were found to be allergic according to skin prick test and total serum IgE concentration. Four of the allergic patients were in the placebo group and 2 of them were cured. Ten of the allergic patients were in the budesonide group and 8 of them were cured.

Both groups had similar ratios of cure and failure. The rate of cure was found to be 88 % in the budesonide group and 80 % in the placebo group.

There was no reported adverse reaction with budesonide spray.

Results were compared with Student's t test ($p < 0.1$).

Table I: Presenting symptoms of patients:

Symptoms / Findings	No	%
Postnasal drip	138	95
Rhinorrhea	124	86
Headache	118	81
Cough	94	65
History of sinusitis attacks	52	36
Passive / active exposure to cigarette smoke	48	33
Facial pain	32	22

Table II: Comparison of the duration of symptoms (days) and p values between budesonide and placebo groups:

Group	Rhinorrhea	Cough	Headache	Postnasal Drip
Budesonide	8.41	6.63	6.68	11.97
Placebo	9.50	6.48	7.52	12
p >	0.51†	0.9373	0.2839	1

DISCUSSION

Sinusitis usually results from a prior respiratory inflammation or infection and may worsen due to nasal anatomical variations, incomplete treatment, immunologic incompetence, and other acquired or genetic mucociliary dysfunction. In mucopurulent sinusitis the inflammatory response may contribute to persistence of symptoms by obstructing drainage and reducing mucociliary clearance of the nose and sinuses (4-7). Mucociliary clearance is particularly important in the maxillary sinus since the ostium is high above the floor of the antrum, therefore clearance depends solely upon mucociliary transport. This may be compromised during infection leading to further accumulation of bacteria and inflammatory secretions (8).

Nasal secretions include many proteins that serve important functions in local mucosal host defence. Most of these host - defence molecules are synthesized and secreted by serous cells in the submucous glands, and it appears that the serous cell is the resident antimicrobial cell in mucous membranes. Current data suggest that serous cell secretion is abnormal in patients with recurrent sinusitis and that effective treatment leads to correction of the secretory abnormality along with improvement in sinusitis (9).

Younger children appear to be even more at risk of sinusitis, perhaps because of comparatively small anatomic structures, more frequent viral infections, and more exposure to indoor allergens and irritants. The prevalence of chronic sinusitis among children who presented to allergy clinics with chronic respiratory symptoms was found to be 63 % (10). Studies document the presence of allergic rhinitis and sinusitis in the same patient 25 % to 70 % of the time (11). Combining the symptoms of rhinorrhea and cough with minimum sneezing had a specificity of 95 % and a sensitivity of 38 % in predicting the presence of chronic sinusitis.

Anti - inflammatory therapy can be even more helpful in prophylaxis of sinusitis, especially in allergic patients. This therapy prolongs attack intervals and prevents the chronicity without side effects. Preventing upper airway infections and sinusitis will decrease the occurrence rate and severity of allergic asthma, particularly in atopic children.

Sykes et al (4) treated sinusitis with nasal sprays of dexamethasone, tramazoline, and neomycin; dexamethasone and tramazoline with no antibiotic, or matched placebo for two weeks. The response rates (for all symptoms and signs responding to treatment) were 62 % for dexamethasone, tramazoline, and neomycin; 60 % for dexamethasone and tramazoline, and 12 % for placebo. The lack of difference between the two active preparations in achieving symptomatic and objective improvement suggests that the most important part of treating chronic mucopurulent sinusitis is reduction of mucosal inflammation, allowing host clearance mechanisms to recover. If this recovery is achieved there seems to be no requirement for antibiotic treatment.

Meltzer et al (3) investigated the effect of intranasal flunisolide spray combined with oral antibiotic therapy for sinusitis. Intranasal flunisolide spray was found to be effective in global evaluations, tended to improve symptoms, to decrease inflammatory cells in nasal cytograms, and to aid regression of radiographic abnormalities compared with placebo spray.

Amoxicillin / clavulonate was reported to be effective and comprehensive in the treatment of sinusitis (12).

The results we obtained (88 % in the budesonide group and 80 % in the placebo group) were not statistically significant.

Future studies are essential for defining new applications of these agents, in the treatment and prophylaxis of these clinical entities.

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