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CLINICAL TRIAL REPORT

Oral and Nasal Steroids for Nasal Polyps

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Trial: Vaidyanathan S, Barnes M, Williamson P, et al.: Treatment of chronic rhinosinusitis with nasal polyposis with oral steroids followed by topical steroids: a randomized trial. Ann Intern Med 2011; 154:293–302.

Rating: •Of importance.

Introduction: Chronic rhinosinusitis (CRS) with nasal polyps is a common form of the disorder with distinct immunopathology and significant impact on the health-related quality of life of patients. Several treatment options—depending on the clinical course and severity of the disease—have been recommended, from medical therapy with oral or topical corticosteroids to various methods of surgical management. Short courses of oral steroids have been recommended and used in clinical practice, usually by specialists in patients with severe CRS with nasal polyps and for management of severe exacerbations of the symptoms with which these patients present. Several studies demonstrated that such treatment results in rapid symptomatic improvement and in shrinking of nasal polyps (pharmacologic polypectomy) in most patients. However, the long-term effects of a short course of oral steroid therapy for CRS with nasal polyps have not been studied in randomized controlled trials.

Aims: The aim of this study was to assess whether initial therapy with oral steroids would lead to greater and sustained reduction in polyp size and greater improvement in symptoms, nasal airflow, and quality of life during the follow-up treatment with topical steroids.

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Methods: Adult patients with CRS associated with nasal polyps were recruited from a single-center specialty clinic based on the presence of bilateral moderate- to large-sized nasal polyps (grade >1 according to Lildholdt scale) and typical symptoms of CRS, including anterior or postnasal discharge, nasal obstruction, and decreased sense of smell for more than 12 weeks. Patients who had been treated with oral steroids in the past 3 months, had sinus surgery in the past year, or had significant mechanical nasal airway obstruction due to septal deviation were excluded. After a 2-week run-in period without use of CRS/nasal polyposis medications, patients were randomly assigned to receive oral prednisolone, 25 mg/d, or placebo in identical tablets for 2 weeks. Then, patients in both groups received fluticasone propionate nasal drops, 400 μg twice daily, for 8 weeks, and then fluticasone nasal spray, 200 μg twice daily, for an additional 18 weeks. No other medications for rhinitis were permitted during the study.

The primary outcome measure was nasal endoscopic polyp grading performed by two independent, study-blinded investigators, who assessed standard video sequences stored on the computer. Secondary efficacy outcome measures included subjective (visual analogue scale) and objective (smell test) assessment of olfaction, symptom scores, peak inspiratory flow, and rhinitis-related quality of life. Safety measures included urinary and serum cortisol level measurements, low-dose adrenocorticotropic stimulation test, and markers of bone turnover.

All primary and secondary outcomes and safety measures were assessed at randomization and after each treatment period: 2, 20, and 28 weeks from randomization.

Results: Of the 118 patients screened, 60 were randomly assigned, and 51 completed the study. Baseline characteristics with respect to demographics, disease duration, airway inflammation, airway obstruction, and indices of severity were similar in both groups, and only a few randomly assigned patients (four in the placebo arm, three

in the prednisolone group) had previously received oral corticosteroids (6–24 months before the study).

Patients taking oral prednisolone, but not those receiving placebo, demonstrated a significant mean decrease in the polyp grade from baseline to 2 weeks .The difference in polyp size between those in the oral corticosteroid group and those receiving placebo was still visible at 10 weeks but was not significant at week 28 of treatment (although at this time point, both groups had significantly decreased polyp size compared with baseline). Similarly, hyposmia assessed by visual analogue scale improved significantly in the oral steroid group at 2 weeks and was still significantly better as compared with the placebo group after 10 weeks, but not after 18 weeks. The smell test score improvement observed after 2 weeks in the oral corticosteroid group was maintained up to week 28 of the study, although the difference between this group and the placebo group was significant only after 2 weeks.

Interestingly, in the placebo group, sense of smell as assessed by both visual analogue scale and smell test was improved after administration of intranasal drop (at 10 weeks) but almost returned to baseline value after treatment with nasal spray (at 28 weeks).

The mean Total Nasal Symptom Score and closely related Rhinitis Quality of Life score, although they were significantly better in the oral corticosteroid group after 2 weeks, were decreased to a similar extent in both the placebo and oral corticosteroid group after 10 and 28 weeks. In total, 25 patients (83%) in the oral corticosteroid group improved by more than the minimal important difference in polyp grade or hyposmia at the end of 28 weeks, as compared with only 17 patients (57%) in the placebo group.

Basal and dynamic adrenal function were suppressed by oral prednisolone at 2 weeks but returned to normal values after 10 and 28 weeks. Similarly, markers of osteoblast activity, which deceased after 2 weeks, returned to normal values at 10 weeks.

Discussion: In this study, the authors demonstrated that a 2-week course of oral steroid therapy, in addition to exerting rapid effects on symptoms of CRS with nasal polyps, had a long-term effect extending beyond the time of treatment. In most patients with CRS with nasal polyps, a burst of 25 mg of oral prednisolone followed by intranasal steroids was generally more effective than topical therapy alone in decreasing polyp size and improving sense of smell over 20 weeks of observation. A short course of oral steroids turned out to be safe, as after transient suppression of adrenal function and an increase in bone turnover, these safety parameters returned to baseline at 10 weeks. In practical terms, the study demonstrated that a short course of oral corticosteroids could be recommended for most patients with moderate to severe CRS with nasal polyps as an initial therapy if subsequent chronic treatment with topical steroids is planned.

However, Total Nasal Symptom Scores, Rhinitis Quality of Life scores, as well as an objective measurement of nasal obstruction (peak nasal inspiratory flow) at 10 and 28 weeks of the study were improved to a similar extent in patients receiving placebo or an initial course of oral corticosteroids, suggesting limited efficacy of the proposed treatment regimen. One cannot dispute that pretreatment with a higher dose of oral corticosteroids or extension of the treatment beyond 2 weeks, as recommended by some guidelines, could result in better long-term effects, including the effect on nasal symptoms and objective measures of nasal obstruction.

Comments

One limitation of the study is the relatively small number of patients and possible selection bias, as out of 118 patients screened, only 60 were randomly assigned, 51 of whom completed the study (ie, 43% of screened population). Furthermore, lack of objective assessment of the sinus mucosal hypertrophy (with CT scans or nuclear magnetic resonance) both at baseline and at follow-up, does not allow for comparison of changes in the mucosal hypertrophy in both groups.

In conclusion, this randomized controlled study of the long-term effects of initial therapy with a short course of oral steroids is of practical value, showing efficacy and safety of such a treatment regimen. The study results may encourage use of such a treatment regimen in clinical practice, especially in patients with unsatisfactory response to intranasal corticosteroids.

Disclosure

No potential conflict of interest relevant to this article was reported.