The Effect of Nasally Administered Budesonide Respules on Adrenal Cortex Function in Patients With Chronic Rhinosinusitis

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Objectives: To evaluate whether nasal administration of budesonide in adults with chronic rhinosinusitis for 30 days suppresses adrenal function and to assess its clinical efficacy.

Design: An open-label prospective study.

Setting: Academic medical center.

Patients: We assessed adrenal function in 9 patients using the cosyntropin test before and after budesonide therapy.

Intervention: Budesonide respule therapy.

Main Outcome Measure: Scores from the Sino-Nasal Outcome Test–20 (SNOT-20), a tool for assessing rhinosinusitis health and quality of life, were used to assess efficacy of budesonide treatment.

Results: All of our patients showed adequate adrenal response to cosyntropin stimulation before and after the budesonide trial. The mean difference in SNOT-20 scores was −1 (95% confidence interval, −1.77 to −0.23; $P=.02$), indicating clinically significant improvement after therapy.

Conclusion: Our findings suggest that using budesonide nasal wash may be clinically effective in decreasing the symptoms of chronic rhinosinusitis and does so without suppression of the hypothalamic-pituitary-adrenal axis in patients with chronic rhinosinusitis.

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CHRONIC RHINOSINUSITIS IS one of the most prevalent conditions among adults in the United States, affecting up to 14% of the population.[1] This condition has a considerable economic impact on patients' lives, which is mainly attributable to additional visits to primary care physicians and increased pharmacy fill use.[2]

Budesonide, as an aqueous nasal spray with anti-inflammatory properties, has been shown to have a positive impact for those with chronic rhinosinusitis[3] and perennial allergic rhinitis.[4,5] Multiple studies[6-8] demonstrate its safety as a topical nasal steroid spray. Budesonide is also available as a respule, a small, plastic, liquid-containing device that can be easily opened and used to deliver unit-dose medications in a sterile fashion (Pulmicort Respules, 0.25 mg and 0.5 mg; AstraZeneca LP, AstraZeneca LP, Wilmington, Delaware), for the maintenance treatment of asthma and as prophylactic therapy in children aged 12 months to 8 years. Yu et al[9] studied the use of budesonide respules as rehabilitation after functional endoscopic sinus surgery. They found that using budesonide respules locally was beneficial for relieving mucosal inflammation, shortening the stage of epithelization, and accelerating the recovery of mucosa after functional endoscopic sinus surgery. Anecdotally, we are aware of many physicians who also prescribe budesonide respules for patients with chronic sinusitis, many of whom have not had sinus surgery.

The safety of inhaled budesonide respules has been assessed in 3 separate 12-week randomized clinical trials,[10-12] and all have demonstrated no significant systemic effects in pediatric patients with asthma. Safety was assessed in these studies through measurement of the hypothalamic-pituitary-adrenal (HPA) axis function using a corticotropin-stimulation test and observation of rates of adverse events. To our knowledge, a similar demonstration of the safety of a nasally administered budesonide wash has not been performed.

Our primary aim in this study was to evaluate whether nasal administration of budesonide in adult patients with chronic

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