TABLE II. Recommendations for future oral immunotherapy investigations

Hold daily dose if febrile or ill with symptoms of viral illness (eg, upper respiratory tract infection, gastroenteritis).
Resume dosing at home if <3 missed daily doses.
Return to research unit for observed dose if 3-5 missed daily doses.
Consider repeat desensitization or significant dose reduction if >5 missed daily doses.
Closely monitor lower and upper respiratory symptoms.
Initiate asthma controller medication if needed.
Perform peak flow and spirometric monitoring.
Ensure optimal control of allergic rhinitis.
Take daily OIT dose with meal or snack
In subjects with exercise-induced symptoms, limit exertion for 2 hours after dosing.
Closely monitor during menstrual cycle, especially when coupled with infection or exercise.

atopic conditions. Regular peak flow measurements and pulmonary function testing have been implemented to optimize asthma control.

It has not been uncommon for a subject taking a daily OIT dose without eating a meal or snack in the 2 hours before dosing to have symptoms with a dose that had been previously tolerated; taking the same dose with a substantial meal or snack the next day and thereafter prevents further reactions. Additionally, several subjects have experienced allergic symptoms with exercise after OIT dosing, and we advise these subjects to avoid exertion for 2 hours after dosing. Finally, 1 subject had several systemic reactions when menses was coupled with exercise despite no symptoms with daily dosing in the interval between episodes and was eventually withdrawn from the study. She was not taking other medications (eg, nonsteroidal anti-inflammatory drugs). Of note, she did not have systemic reactions each time she exercised during menses. At this time, the role of menses is unclear, and further study is needed.

In the studies to date, peanut and food OIT have a good safety profile, and home dosing is infrequently associated with adverse reactions.[2,6] However, allergic symptoms should be expected, and subjects and their families should be counseled about circumstances associated with an increased possibility of reacting to previously tolerated OIT doses. As OIT for food allergy becomes increasingly studied in research settings, implementing these recommendations and modifications can improve the safety of these experimental protocols.

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Disclosure of potential conflict of interest: P. Varshney received the National Institutes of Health T32 Training Grant. B. P. Vickery has received research support from the Thrasher Research Foundation. J. A. Bird has received research support from the Food Allergy Initiative. A. M. Scurlock has received research support from the National Institutes of Health. T. T. Perry has received research support from the National Institutes of Health and the Robert Wood Johnson Foundation. S. M. Jones is a consultant for and board member of the Food Allergy & Anaphylaxis Network and has received research support from the National Institutes of Health and DYAX Corporation. A. W. Burks is a Consultant for ActoGeniX NV, Intelliject, McNeil Nutritionals, and Novartis; is a minority stockholder of Allertein and MastCell, Inc; is on the Advisory Board for Dannon Co. Probiotics; is on the Expert Panel for Nutricia; has received research support from the National Institutes of Health, the Food Allergy & Anaphylaxis Network, and the Wallace Research Foundation; has served as an expert witness on the topic of food allergies; is on the Medical Board of Directors for the Food Allergy & Anaphylaxis Network and the Dermatological Allergy Committee for the American College of Allergy, Asthma & Immunology; is a member for the National Institutes of Health Hypersensitivity, Autoimmune and Immune-mediated Disease Study Section; and is on the *Journal of Allergy and Clinical Immunology* reviewer board. The rest of the authors have declared they have no conflict of interest.

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Available online November 13, 2009.
doi:10.1016/j.jaci.2009.09.042

Pilot study of budesonide inhalant suspension irrigations for chronic eosinophilic sinusitis

To the Editor:

Chronic sinusitis (CS) is often associated with nasal polyposis (NP). CS represents several disease processes including chronic hyperplastic eosinophilic sinusitis (CHES).[1] Many immune and pathological features of CHES are shared with asthma, suggesting that these are similar disease processes involving the upper and lower airways. Historically, patients with CS were approached as having a chronic infectious disorder, and treatment consisted of antibiotics and surgery to promote drainage. Often these approaches proved unsatisfactory for patients with CHES.[2] Given the marked eosinophilia and pathological similarity of CHES to asthma,[3] corticosteroids could be used as a treatment for this disorder. Systemic corticosteroids shrink hyperplastic tissue and associated NP, reduce symptoms, and restore the senses of smell and taste.[4] However, their side-effect profile has precluded long-term use.

It has been suggested that topical intranasal corticosteroids would prove effective for eosinophilic forms of CS, given their utility for asthma and allergic rhinitis, while maintaining a minimal risk profile. Although intranasal corticosteroids reduce NP,[5] they have never been shown to improve the sinusitis component of this disorder, likely reflecting their inability to access the sinus cavity. Saline irrigations have proven to be an effective method of addressing sinus disease,[6] likely through their ability to lavage the nasal and sinus cavities. It has been speculated that the addition of a corticosteroid such as budesonide inhalation suspension (Pulmicort respules; Astra Zeneca, Wilmington, De), a medication already approved for asthma, to the lavage fluid

would more effectively treat sinus inflammation. This study was performed to obtain pilot data documenting objective and subjective evidence for improvement in patients who used this approach for a period of ≥3 months. For information regarding the study design, see Methods in the Online Repository at www.jacionline.org.

Patients with CHES or aspirin-exacerbated respiratory disease having failed to respond to previous medical therapy and having been treated with budesonide nasal irrigation for ≥3 months were recruited. A total of 8 subjects were enrolled (see this article's Table E1 in the Online Repository at www.jacionline.org). All subjects had allergy as defined by a positive skin prick test (≥5-mm wheal) to at least 1 aeroallergen, 4 subjects were classified as having aspirin-exacerbated respiratory disease, and all but 1 had physician-diagnosed asthma. None of the subjects took oral steroids during treatment with budesonide, and 5 were on montelukast, with 2 also taking zileuton.

Our primary outcome measure for sinus improvement was the change in CT score. The median CT score before treatment was 15 (maximum, 30), which improved to 5 ($P < .05$) after treatment (Fig 1). By using our visual analog scale (see this article's Fig E1 in the Online Repository at www.jacionline.org), we calculated scores for each of 16 sinus symptoms on a scale of 0 to 6, with 6 being severe and 0 none (maximum, 96). After budesonide treatment, subjects' sinus scores decreased (mean ± SD) from 43.1 ± 5.4 to 20.1 ± 3.0 ($P < .02$; Fig 2). Sense of smell was separately examined (0, none, to 6, complete) because of its particular impact on quality of life. Subjects reported a significant improvement in their sense of smell (mean ± SD) (see this article's Fig E2 in the Online Repository at www.jacionline.org), from 1.1 ± 0.7 to 3.6 ± 0.8 ($P < .05$). Other sinus measures displayed similar improvement. Of the 6 subjects who had prerhinoscopy and postrhinoscopy, 5 showed improvement after treatment, and 3 of 4 subjects had complete resolution of NP (see this article's Fig E3 and Table E2 in the Online Repository at www.jacionline.org).

It has been suggested that improvements in upper respiratory disease can lead to improvements in lower respiratory symptoms. The asthma visual analog scale (see this article's Fig E4 in the Online Repository at www.jacionline.org) was converted to a scale ranging from 0 to 6 and scored (maximum, 36). Of the 7 patients in the study with asthma, there was a trend toward a decrease in the asthma score (mean ± SD) from 15.3 ± 2.9 pretreatment to 11.4 ± 2.2 posttreatment (Table E2). Using the National Institutes of Health definition of asthma control,[7] 3 of 4 subjects who had poorly controlled disease at the beginning of the study improved to well controlled (Table E2). The remaining 3 patients with asthma had well controlled disease throughout the study.

The current study suggests that the addition of budesonide suspension to nasal saline irrigations produces a significant improvement in sinus symptoms including sense of smell. It is possible, given the construct of the study's methodology, that the findings may overestimate the true benefit of this therapy, especially with regard to recall bias. However, previous works have indicated that patients are able to recall symptoms of smell accurately.[8] The lack of a control group makes it difficult to determine what role a placebo effect and the natural course of the disease may have played. That being noted, the cohort was one of patients who remained symptomatic on previous therapy and for whom the addition of budesonide irrigations to the sinus regimen represented the only change.

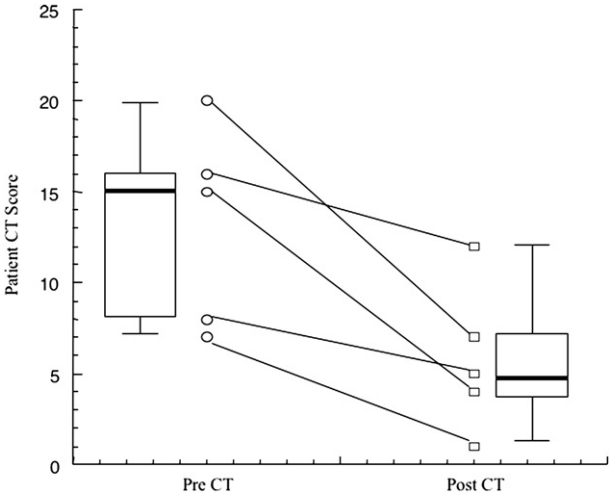

FIG 1. Change in CT score after budesonide nasal irrigation. Each *dot* represents an individual with a *line* connecting the prebudesonide and postbudesonide CT scores. The *bold lines* to the side of the data points indicate the median, with the interquartile range and inner fence indicated with a *box* and *whisker plot*, respectively ($P < .05$ for prebudesonide compared with postbudesonide sinus score).

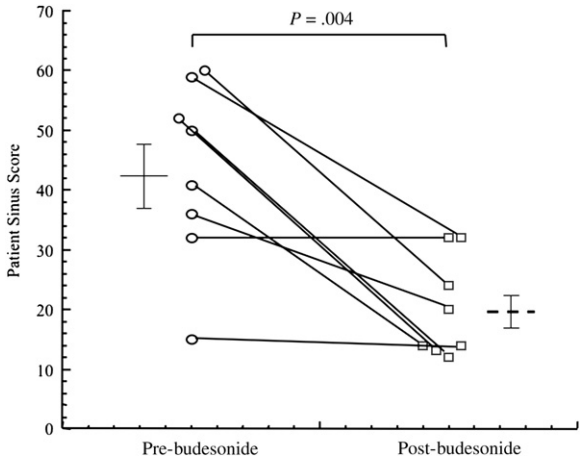

FIG 2. Self-assessed change in sinus symptom score after budesonide nasal irrigation. Each *dot* represents an individual, with a line connecting the prebudesonide and postbudesonide sinus scores. *Lines* to the side of the data points indicate the mean ± SEM ($P < .01$ for prebudesonide compared with postbudesonide sinus score).

Subjective improvements were corroborated by objective findings on CT scans and nasal endoscopy. CT scanning is validated for accurately quantifying the extent of mucosal inflammation/hypertrophy within the sinuses. Previous studies have shown that, at least in the short term, radiographic findings of CS are stable. The significant improvement in CT scores is therefore compelling. The complete regression of polyps observed in 3 of 4 patients with NPs before initiation of therapy is consistent with reports of the ability of intranasal corticosteroids to reduce polyposis[5] and is indicative of the role that corticosteroid irrigations may play in the management of this disease.

Modest trends toward improvement in asthma symptom scores were also observed. A lack of significance in the pilot data was likely driven by the inclusion of patients with well controlled

asthma; however, 3 of 4 subjects who did not have controlled disease at baseline did show improvement. Given the low probability that topical corticosteroids in the upper airway would access the bronchial airway, improvement in asthma more likely reflects 1 or more of the indirect pathways by which reduced sinusitis has been proposed to affect asthma positively.[9] Although it remains possible that improvement in asthma symptoms could reflect systemic absorption of the steroid, especially considering the high dose of budesonide used in this study (500 μg twice a day), the nature of sinus irrigations is that most of the sinus irrigant does not remain. As such, likely <50 μg of budesonide remains in the sinuses, a dose equivalent to rhinitis therapy. Absorption from the sinuses is not likely to be dissimilar to that from the airways. These studies provide support for the unified airway concept.

This study supports the concept that addition of budesonide inhalation suspension to standard nasal saline irrigation produces subjective and objective benefit in eosinophilic sinus disease. It is hoped that these data will support enthusiasm for performing a double-blind, placebo-controlled study of budesonide inhalation suspension in nasal saline washes in CS.

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Supported by National Institutes of Health grant nos. RO1 AI01793 and PO1 AI50989. Disclosure of potential conflict of interest: J. W. Steinke has received research support from the National Institutes of Health. S. C. Payne has received honoraria from Acclarent, Inc, has received research support from the American Academy of Otolaryngologic Allergy, and has provided legal consultation or expert witness testimony on the topic of tonsillectomies. L. C. Borish is on the speakers' bureau for Merck, is on an advisory board for Genentech and Novartis, and has received research support from Genentech and Merck. The rest of the authors have declared that they have no conflict of interest.

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Available online November 12, 2009.
doi:10.1016/j.jaci.2009.09.018

Quoting a landmark paper on the beneficial effects of probiotics

To the Editor:

Probiotics are defined as "live microorganisms that when administered in adequate amounts should confer a health benefit on the host."[1] Intriguingly, the rapid expansion of commercially available products that contain probiotics is in sharp contrast with the lack of scientific evidence for their efficacy and working mechanism. Few well conducted trials have appeared in high-impact journals. Amongst these is an article by Kalliomaki et al,[2] "Probiotics in primary prevention of atopic disease: a randomized control trial." To date, this is the most quoted clinical trial on probiotics and atopic disease in peer-reviewed journals. Kalliomaki et al[2] reported a double-blind, placebo-controlled trial on supplementation of *Lactobacillus rhamnosus* GG to pregnant women with a family history of atopic disease starting 2 to 4 weeks before delivery. After delivery, breast-feeding mothers ingested the probiotics, and bottle-fed children received the supplementation mixed with water by spoon for 6 months. The intervention resulted in a reduced incidence of atopic eczema at the age of 2 years but had no effect on allergic sensitization or respiratory allergic disease. We speculate that the high quotation numbers may reflect an apparent urge to establish probiotics as a useful prevention measure. We therefore determined the quality of scientific quotations of this landmark publication.

By November 1, 2008, this article had been quoted in 663 separate publications. We were able to retrieve and examine 458 articles in English (supplemental text of this article's Online Repository at www.jacionline.org). All quotations were randomly collected in a database, blinding the assessors to authors, year of publication, and specific journal. Each quotation was assigned to a specific section of the article by Kalliomaki et al[2] and assessed for accuracy by 2 researchers separately. Incorrect quotations were further subcategorized based on 4 model types of errors (misquotation of result or overinterpretation of data, secondary citing, no evidence for cited result, and specific misquotations of the materials and methods section). To establish a possible relation between the quality of a quotation and potential interfering

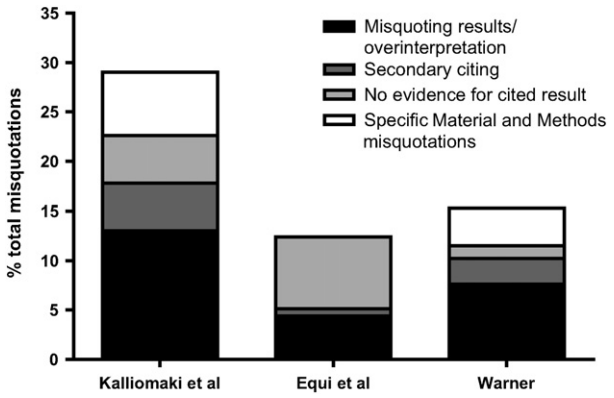

FIG 1. Total percentage of incorrect quotations of the landmark paper by Kalliomaki et al,[2] Equi et al[4] (antibiotic treament in cystic fibrosis), and Warner[3] (asthma prevention) further subcategorized into the different model types of error.

METHODS

Study design and participants

Patients age 18 to 60 years with CHES who had failed to respond to medical and/or surgical therapy were recruited from the outpatient allergy/immunology and otolaryngology clinics at the University of Virginia. Medical therapy included antibiotics, large-volume saline irrigations, and topical intranasal steroid administration. Patients were subsequently treated with budesonide inhalation suspension 500 μg twice daily administered by diluting the budesonide suspension in a large volume of saline (>100 mL), which was then administered intranasally as part of standard sinus irrigation care. Patients who had been treated with budesonide nasal washes for at least 3 months were invited to participate. Participants were asked to provide a medical history with detailed information regarding symptoms of sinusitis, asthma, allergic rhinitis, aspirin allergy, and medication use. All subjects had a baseline sinus CT scan and rhinoscopy before initiation of treatment. Exclusion criteria included the diagnosis of cystic fibrosis, sinonasal tumor, or immunodeficiency. Informed consent was obtained from all subjects before enrollment under a protocol approved by the University of Virginia Institutional Review Board.

Visual analogue scale

A standardized visual analog scoring system of sinusitis[E1] (Fig E1) and asthma (Fig E3) symptoms was used to compare related symptoms before and after treatment with budesonide inhalation suspension. In addition, asthma control was determined using National Institutes of Health guidelines.[E2] Each visual analogue scale (VAS) question was converted to a numerical value (0-6) to allow statistical analysis of symptoms before and after treatment (maximum sinus score for 16 symptoms, 96; maximum asthma score for 6 symptoms, 36). Subjects were asked whether they had hypersensitivity to aspirin or other nonsteroidal anti-inflammatory drugs, defined as a severe asthma exacerbation occurring within 2 to 3 hours of ingestion, that would be suggestive of aspirin-exacerbated respiratory disease.

Sinus CT score

Sinus disease was evaluated by using coronal reconstructions of a helical CT scan obtained in the supine position with axial images taken at 1-mm-thickness intervals. All CT scans were assigned a quantitative score (0-30) by a blind investigator (S.C.P.) according to our previously published and validated methods.[E3-E6]

Rhinoscopy

Nasal rhinoscopy was performed using a 30° rigid endoscope before starting budesonide suspension and was compared with a rhinoscopy performed after $\geq$3 months of treatment. Bilateral examination of each nasal cavity was performed with reporting of crusting, erythema/swelling, purulent drainage, and thick mucus (1 point assigned for each with each naris scored separately; maximum score, 8). In addition, the presence of nasal polyps was noted with a score of 1 assigned for each naris if present (Fig E4).

Statistical analysis

Data are expressed as means ± SEMs or medians with interquartile ranges. Statistical significance was determined by using the Wilcoxon signed-rank test for the endoscopy scores and VAS questionnaire and a 1-tailed Wilcoxon signed-rank test for CT scores. A P value $\leq$.05 was considered statistically significant.

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None – None to occasional symptoms
Mild – Steady symptoms but easily tolerated
Moderate – Symptoms hard to tolerate, may interfere with activities of daily living/ sleep
Severe – Symptoms are so bad, person can not function virtually all the time

	None	Mild	Moderate	Severe
Example:			X	
Nasal Obstruction				
Discolored nasal drainage (Front)				
Discolored nasal drainage (Back)				
Facial pressure/ fullness				
Fatigue				
Ear pain/ pressure/ fullness				
Cough				
Halitosis (Bad breath)				
Dental/ Tooth pain				
Fever				
Headache				
Itching of nose/ roof of mouth				
Sneezing				
Overall assessment of severity of symptoms				
Sense of Smell	(no decrease)	(moderate decrease)		(complete loss)
Sense of taste	(no decrease)	(moderate decrease)		(complete loss)

FIG E1. VAS for sinus symptoms. Each subject was asked to rate each of 16 symptoms. The range of symptoms was none to severe.

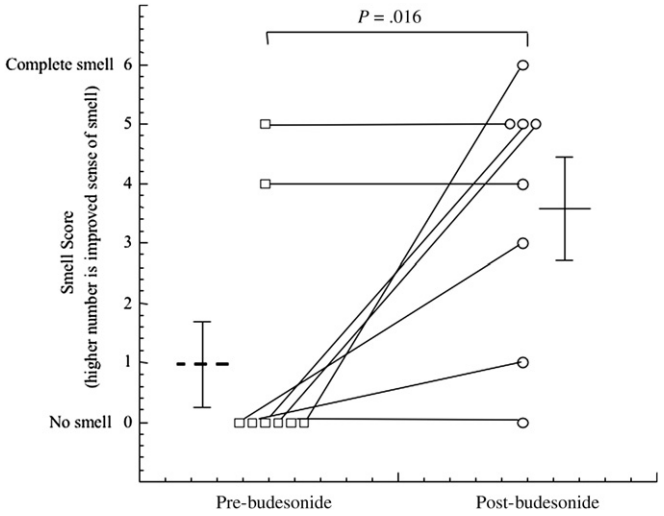

FIG E2. Patient perception of sense of smell after budesonide nasal irrigation. Using a VAS, subjects were asked to assess their sense of smell before and after nasal irrigation. The VAS was converted to a digital scale rated 0 (no smell) to 6 (no impairment in ability to smell). Each *dot* represents an individual with a *line* connecting the prebudesonide and postbudesonide scores, and the *lines* to the side of the data points indicate the means ± SEMs ($P < .05$ for prebudesonide compared with postbudesonide sense of smell).

Patient Name:
Date of Visit:
Diagnosis:

ENDOSCOPIC FINDINGS

(IF NONE PRESENT, CIRCLE=0)
(IF PRESENT, CIRCLE=1)

1: CRUSTING	0	1	
2: ERYTHEMA	0	1	
3: SWELLING	0	1	
4: SCAR BAND	0	1	
5: PURULENT DRAINAGE	0	1	
6: THICK MUCOUS	0	1	

(IF NO POLYP PRESENT, CIRCLE=0)
(IF POLYP PRESENT IN MIDDLE MEATUS, CIRCLE=1)
(IF POLYP PRESENT OUTSIDE MIDDLE MEATUS, CIRCLE=2)

7: POLYPS	0	1	2

FIG E3. Endoscopic scoring system. Modified from Lund VJ, Kennedy DW. Staging for rhinosinusitis. Otolaryngol Head Neck Surg 1997;117:S35-S40.[E7]

None – None to occasional symptoms
Mild – Steady symptoms but easily tolerated
Moderate – Symptoms hard to tolerate, may interfere with activities of daily living/ sleep
Severe – Symptoms are so bad, person can not function virtually all the time

	None	Mild	Moderate	Severe
Example			X	
Shortness of breath				
Wheezing				
Cough				
Sputum/ phlegm production				
Chest tightness				
Exercise-induced shortness of breath				

FIG E4. VAS for asthma symptoms. Each subject was asked to rate each of 6 symptoms.

TABLE E1. Baseline demographics and subject characteristics

Patients	Sex	Age	Race	SPT+ Yes/No	Asthma Yes/No	AERD Yes/No
1	F	52	W	Yes	No	No
2	F	50	W	Yes	Yes	No
3	F	77	W	Yes	Yes	No
4	F	48	B	Yes	Yes	Yes
5	M	59	W	Yes	Yes	No
6	M	53	W	Yes	Yes	Yes
7	F	59	W	Yes	Yes	Yes
8	M	47	W	Yes	Yes	Yes

AERD, Aspirin-exacerbated respiratory disease; *B,* black; *F,* female; *M,* male; *SPT,* skin prick test; *W,* white.

TABLE E2. Prebudesonide and postbudesonide suspension clinical characteristics

	Asthma control		Asthma score		Rhinoscopy score		Polyp score	
Patient	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
1	NA	NA	NA	NA	ND	ND	ND	ND
2	Uncontrolled	Well	17	12	6	4	1	0
3	Very poorly controlled	Well	24	10	0	2	0	0
4	Uncontrolled	Uncontrolled	12	12	5	4	1	0
5	Well	Well	12	12	4	0	0	0
6	Well	Well	2	2	2	ND	0	0
7	Well	Well	16	22	3	1	1	2
8	Very poorly controlled	Well	24	10	3	2	1	0

NA, Not asthmatic; *ND*, not determined.