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Outcomes of Sinus Surgery in Ambulatory Patients with Immune Dysfunction

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Abstract

Background—Previous outcomes studies of patients with chronic rhinosinusitis (CRS) have mostly excluded subjects with immunodeficiency or autoimmune disease. While expert opinion suggests these patients are often refractory to therapy, outcomes following endoscopic sinus surgery (ESS) are not well delineated.

Objective—We evaluated improvement in objective and quality of life (QoL) measures following endoscopic sinus surgery in adult patients treated in the ambulatory setting with immune dysfunction including immunodeficiency and autoimmune diseases.

Methods—Patients with CRS associated with immune dysfunction (n=22) were evaluated and matched 1:1 with control subjects from a prospective cohort in a nested case-control design. Preoperative computed tomography (CT) and pre/postoperative endoscopic findings were recorded. Disease-specific QoL instruments (Rhinosinusitis Disability Index (RSDI) and Chronic Sinusitis Survey (CSS)) were administered pre- and postoperatively.

Results—Mean postoperative follow-up was similar for both cases (18.6±6.6 months) and controls (18.4±8.7 months). Preoperative CT and endoscopy scores (i.e. disease severity) were similar in both cases and controls. Post-operative endoscopy scores were significantly improved for both cases (p<0.001) and controls (p=0.012). Both groups had similar preoperative and postoperative scores on the CSS, however control subjects reported significantly worse RSDI baseline scores. Immunodeficiency and autoimmune cases and CRS controls experienced significant improvement in QoL after surgery (p≤0.041).

Conclusion—Immunodeficiency and autoimmune cases, in the ambulatory setting, present with similar severity of disease as compared to controls with CRS. We found similar improvements in both objective and QoL outcomes for case subjects and control subjects, suggesting that patients with immune dysfunction may experience similar benefit from ESS.

Keywords

immunodeficiency; autoimmune; chronic rhinosinusitis; quality-of-life; outcomes; sinusitis; endoscopic surgery; ambulatory; endoscopy

Introduction

Recent literature has demonstrated that endoscopic sinus surgery (ESS) is associated with improvement in disease symptoms, patient quality of life (QoL), and intranasal endoscopy

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scores for medically recalcitrant chronic rhinosinusitis (CRS).^{1–4} However, the majority of studies have focused on CRS associated with classic comorbidities such as allergy, aspirin intolerance, asthma and nasal polyposis, and have excluded, for the most part, patients with *immune dysfunction* either in the form of immunodeficiency or autoimmune disease.^{5–7}

Immune dysfunction can be broadly classified into two basic categories: immunodeficiency and autoimmune disease. These diseases represent two ends of the spectrum of immune dysfunction but share a common dysregulation of the host immune system which can manifest as a relative hypo- vs. hyperfunction of host immunity.

Rhinosinusitis is a clinical manifestation of immune dysfunction and while rhinologists are familiar with the overt presentation of the hospitalized patient with immune dysfunction and severe sinusitis, many patients present in the ambulatory setting with subclinical immune dysfunction often diagnosed only following many failed treatment regimens.^{8,9} Although the effects of CRS on QoL have been well documented in the general population, QoL in patients with immune dysfunction and CRS is relatively unknown. The purpose of our study was to characterize objective and QoL measures, both prior to and following endoscopic sinus surgery, in ambulatory CRS subjects with comorbid immune dysfunction in the form of either autoimmune disease or immunodeficiency.

Methods

All study subjects were prospectively enrolled and followed in the ambulatory clinic setting at an academic tertiary care center utilizing a trained research coordinator. The Institutional Review Board at the Oregon Health and Science University provided approval for all investigational protocols. All subjects were assured participation was voluntary and informed consent was obtained for all participants meeting inclusion criteria.

Study Population and Inclusion Criteria

Enrollment criteria included English speaking, adult subjects (≥ 18 years) presenting with diagnostic criteria for CRS, as outlined in the 2003 Rhinosinusitis Task Force.¹⁰ Subjects were invited to participate in this investigation after failing medical management and electing ESS as the next treatment alternative.

Demographic and Objective Measures

Demographic data and a detailed medical history were collected and recorded at the initial enrollment visit. Factors and comorbidities of interest included age, gender, race/ethnicity, asthma, aspirin triad, nasal polyposis, tobacco use, history of depression, prior sinus surgery, and allergy. A diagnosis of autoimmune disease was made by a rheumatologist following a clinical history, physical examination, and objective data using an autoimmune panel consisting of a complete blood count with platelets, differential, sedimentation rate, c-ANCA, p-ANCA, antineutrophil antibody, rheumatoid factor, and other indicated studies at their discretion. Immunodeficiencies were diagnosed by an allergist/ immunologist using clinical history, physical examination, and objective data from an immunodeficiency panel including serum levels of the following immunoglobulins: IgA, IgE, IgG, and IgG I subclasses, as well as the IgG II–V subclasses.

The Principal Investigator (PI) performed baseline examinations of all subjects included standard bilateral nasal endoscopy and assessment of current CT imaging. Endoscopic examinations were quantified using the Lund-Kennedy scoring system (score range: 0–20) while the CT scans were assessed utilizing the Lund-Mackay scoring system (score range: 0–24).^{11,12} In order to provide an objective measure of change following surgery, endoscopic

examinations were performed again during postoperative follow-up evaluations by the PI. The PI was blinded to QoL responses for the duration of the study.

Quality of Life Measures

Subjects completed two validated disease-specific QoL instruments: the Rhinosinusitis Disability Index (RSDI) and the Chronic Sinusitis Survey (CSS).^{13,14} To measure change in QoL status, subjects were asked to complete both surveys pre- and postoperatively.

Nested Case Control Design

Case subjects with comorbid immunodeficiency or autoimmune disease were matched 1:1 on potential confounding variables (gender, race, and age) to control subjects from the remaining cohort without comorbid immunodeficiency or autoimmune disease. For both cases and controls, patients were required to have at least 6 months of postoperative follow-up to be evaluated in the analyses.

Statistical Analysis

All data was recorded on standardized clinical research forms, transcribed, scored, and entered into a secure MS FoxPro (Microsoft Corp., Redmond, WA.) database. All analyses were conducted utilizing statistical software (SPSS Inc., Chicago, IL). Comparisons of continuous, descriptive variables were accomplished utilizing the Mann-Whitney U test. Contingency tables (2×2) and χ^2 -tests were used to examine differences in comorbidity frequency counts between cases and controls. Fisher's exact test was used for small sample cell sizes. The average magnitude of improvement in both endoscopy and disease-specific QoL scores between pre- and postoperative time points was assessed with the Wilcoxon signed-rank test. Mann Whitney U tests were utilized to assess differences between both preoperative and postoperative disease-specific QoL scores, as well as differences in absolute improvement between cases and controls.

Comparisons between case groups were also performed to determine if either autoimmune or immunodeficiency patients were disproportionately responsible for a greater degree of improvement in objective or QoL measures. Because of the fact that depression is a potential confounder of QoL outcomes and is found in higher prevalence among those with immunodeficiency and autoimmune disease, simple linear regression analysis was used to examine confounding of effect estimates for the main outcome of interest (postoperative change in QoL).^{15–17} If depression was introduced into linear models and altered the case effect estimate >10%, depression was considered a confounding variable. Means and standard deviations ($\pm$ SD) were reported for descriptive analyses and an alpha level of 0.05 was considered statistically significant for all bivariate analyses without adjusting for multiple comparisons.

Results

Subject presentation

Demographic characteristics and case descriptions are included in Table 1. Subjects with CRS and comorbid immune dysfunction (immunodeficiency or autoimmune disease) met inclusion criteria for the case group (n=22) and were matched 1:1 by age, sex, and race/ethnicity with control subjects from the CRS cohort. Immunodeficiency subjects (n=10) consisted of chronic immunosuppression secondary to prior organ transplant, splenectomy, immunoglobulin A deficiency, IgG-4 deficiency, chronic lymphoblastic leukemia, end stage renal disease, primary biliary cirrhosis, and acute lymphocytic leukemia. Autoimmune subjects (n=12) consisted of celiac disease, Crohn's disease, multiple sclerosis, sarcoidosis, Sjogren's syndrome, and

rheumatoid arthritis (Table 2). Baseline comparisons demonstrated no differences between cases and controls in terms of patient demographics ($p \geq 0.750$) or CRS cofactors ($p \geq 0.728$). There were also no appreciable differences between cases and controls in terms of comorbid conditions ($p \geq 0.210$).

Objective measures

Baseline preoperative Lund-MacKay CT scores were similar in the immune dysfunction group as compared with CRS controls ($p=0.706$; Table 3). Similarly, there were no appreciable differences in preoperative mean endoscopy scores for cases as compared to controls (9.8 ± 6.6 vs. 11.0 ± 6.7 ; $p=0.605$). As outlined in Table 3, postoperative mean endoscopy scores also did not differ significantly between cases and controls (3.8 ± 3.9 vs. 4.1 ± 4.3 ; $p=0.748$). Postoperative endoscopy scores significantly improved for both cases ($p<0.001$) and controls ($p=0.012$). In evaluating the degree of change between pre- and postoperative endoscopy scores, both cases and controls demonstrated a similar degree of significant improvement (3.0 ± 4.9 ; $p<0.001$ vs. 3.1 ± 3.7 ; $p=0.012$, Table 4).

Disease Specific QoL Measures

Case subjects presented with similar mean preoperative CSS total scores as compared to control patients (Table 3). The baseline scores for the RSDI were significantly worse in the functional, emotional and total RSDI scores in the matched controls ($p < 0.010$). Postoperative scores were mostly similar for both cases and controls with the exception of control subjects reporting worse scores on the RSDI emotional subscale ($p=0.025$).

Both the subjects with immune dysfunction and their matched controls experienced significant improvement in QoL and objective outcomes after ESS ($p \leq 0.041$), with the exception of the control subgroup responses on the CSS medication subscale ($p=0.143$; Table 4). Postoperative improvements on both RSDI and CSS instruments were similar for cases and controls ($p \geq 0.391$), indicating that both groups experience and describe similar benefit in QoL after surgical intervention for CRS. Depression was not found to be a significant confounding variable with any of the QoL outcome models.

Case Comparisons

Comparisons between immunodeficiency ($n=10$) and autoimmune case types ($n=12$) revealed no significant differences in baseline demographics ($p \geq 0.314$), cofactors ($p \geq 0.135$), or comorbidity ($p \geq 0.571$). Similar to the total case group, no appreciable differences in preoperative CT scores ($p \geq 0.755$) and endoscopy scores ($p \geq 0.481$) were found between case subgroups and matched controls.

There were no appreciable differences in baseline scores on either the CSS or RSDI between case groups and their matched controls. Both subgroups with immune dysfunction had similar RSDI scores at baseline with significantly lower scores found in matched controls. Both subgroups also noted significant improvement in the QoL scores with a similar degree of improvement noted between each subgroup and their matched controls.

Discussion

This study evaluated the effectiveness of ESS for CRS in adult patients in the ambulatory setting with comorbid immune dysfunction, either in the form of immunodeficiency or autoimmune disease. Interestingly, we noted that subjects with immune dysfunction had similar baseline CT and endoscopy scores as matched controls with CRS. Improvement in postoperative endoscopic examination was also similar for both cases and controls. Our data suggest that ambulatory, adult CRS subjects with immune dysfunction experience significant

improvement in sinonasal symptoms and QoL following endoscopic sinus surgery. Moreover, the degree of improvement is similar to that experienced by matched control subjects with CRS and it is maintained for at least one year postoperatively.

Immune dysfunction presents in a highly varied fashion across a spectrum of disease that includes immunodeficiency, or relative hypofunction of the immune system, and autoimmune illness, or a relative hyperfunction of the immune system. In addition, immune dysfunction can present with widely varying disease severity. While the hospitalized patient with severe immune dysfunction is a well known and challenging clinical scenario, those with more subtle or subclinical forms of immune disease are often treated in the ambulatory setting and overlooked in the study of CRS outcomes.

Patients with subtle immunodeficiency have been shown to have increased risk for refractory CRS.^{5,18} There are various definitions of “refractory CRS” in the literature, making it difficult to compare the prevalence of immunodeficiency in clinical outcomes research. Chee et al. defined “refractory CRS” as at least one previous ESS and three episodes of CRS within the previous year.¹⁹ This study assessed immune function in 79 refractory patients and found that 10–15% had abnormal immune function tests, most commonly CVID followed secondly by decreased levels of immunoglobulin. Vandergle also reported that 22% of CRS subjects (n=307) had humoral immunodeficiency, with the majority of these as IgG subclass deficits.²⁰ Overall, the most common immunoglobulin deficiency in adults that has been linked to recurrent sinopulmonary infections is the IgG3 subclass deficiency.^{21–23} These studies highlight the prevalence of subclinical immunodeficiency and suggest that immune dysfunction may play a role in refractory CRS.

Sinonasal pathology is common in autoimmune disease with profound inflammation of the mucosa leading to a host of symptoms often similar to CRS, including mucopurulent drainage, crusting, and bloody mucoid secretions. The severe inflammation often mimics classic CRS and given the similarities, it is important to consider autoimmune etiologies when signs and symptoms of systemic diseases are present. A recent study by Lund's group reported that patients with Wegener's granulomatosis demonstrated sinonasal symptoms similar to subjects with CRS, and often had delays in their diagnosis of systemic disease.²⁴ Previous studies have recommended both aggressive topical therapies and systemic steroids in the treatment of CRS with comorbid autoimmune disease.

Limited data exists with regards to postoperative QoL outcomes and endoscopic improvement in patients with CRS and immune dysfunction. Some previous clinical outcomes studies of patients with CRS have specifically excluded subjects with a diagnosis of immunodeficiency or autoimmune disease. Interestingly, our study found a similar degree of postoperative improvement in subjects with CRS as compared to subjects with CRS and comorbid immune dysfunction in both endoscopy exam and QoL. Our study showed that subjects with immune dysfunction have significantly better baseline RSDI scores as compared to their matched controls. This may be as a result of the fact that our subjects with immune dysfunction perceive their CRS as less severe relative to their systemic immune diseases. Our study also highlights that immune dysfunction in ambulatory CRS patients can be nonspecific in presentation, suggesting that patients with recalcitrant CRS be evaluated for immune deficiency or autoimmune disease as a diagnostic consideration.

There are a number of caveats to consider with this investigation. All patients were enrolled in the outpatient clinic setting and therefore represent a unique, non-hospitalized cohort with immune dysfunction. Consequently, these results should be not be generalized to the inpatient population who likely suffer more profound immune dysfunction. Limited sample size may inhibit our ability to detect significant differences between cases and controls, as well as prevent

further subgroup analyses. Due to the infrequency of clinical presentation by patients with CRS and comorbid immune dysfunction, however, accumulating outcomes data for a larger prospective cohort of these patients can be challenging. Further generalizability of QoL improvement is limited due to the fact that all subjects underwent surgical intervention by the same surgeon in the same geographic area. Additionally, we classified subjects with immunodeficiency and autoimmune disease using a dichotomous measure and therefore may lack the appropriate level of discrimination for accurately measuring differences in endoscopy, CT, and QoL scores outcomes for different severities of immune dysfunction. Despite these limitations, this investigation represents one of the largest case-control outcome studies following sinus surgery in this particular patient population.

Conclusions

In summary, immunodeficiency and autoimmune cases with CRS in the ambulatory setting present with similar severity of disease as compared to controls with CRS. This study noted a similar degree of improvement in both objective and QoL measures for case subjects as compared to matched controls suggesting that ambulatory patients with immunodeficiency or autoimmune diseases experience similar benefit from ESS.

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Table 1

Preoperative patient demographics, disease severity, and comorbidity prevalence for cases and controls.

	Cases (n=22)	Matched controls (n=22)	
Demographics:	(mean ± SD)	(mean ± SD)	p-value
Age (yrs.)	49.4 ± 12.9	48.2 ± 11.5	0.750
Follow-up (mos.)	18.6 ± 6.6	18.4 ± 8.7	0.938
Gender	n (%)	n (%)	
Male	7 (31.8)	7 (31.8)	
Female	15 (68.2)	15 (68.2)	>0.999
Race/ethnicity			
White	20 (90.9)	20 (90.9)	
African American	1 (4.5)	1 (4.5)	
Asian	1 (4.5)	1 (4.5)	>0.999
CRS Cofactors:			
Nasal polyposis	2 (9.1)	8 (36.4)	0.069
Septal deviation	2 (9.1)	3 (13.6)	>0.999
Prior sinus surgery	17 (77.3)	16 (72.7)	0.728
Comorbid conditions:			
Asthma	10 (45.5)	6 (27.3)	0.210
Allergic rhinitis	11 (50.0)	9 (40.9)	0.545
Aspirin triad	2 (9.1)	5 (22.7)	0.412
Depression	3 (13.6)	6 (27.3)	0.457
Current smoking	1 (4.5)	2 (9.1)	>0.999

Case subjects with follow-up (n=22) were matched 1:1 on age and gender with controls without immunodeficient or autoimmune disease. SD = standard deviation. CRS = chronic rhinosinusitis. $p \leq 0.05$ is statistically significant.

Table 2

Patients with immune dysfunction either in the form of immunodeficiency or autoimmune disease

Immunodeficiency (n=10)		Autoimmune (n=12)	
Diagnosis:	n	Diagnosis:	n
Post transplant immunosuppression	3	Sarcoidosis	7
Splenectomy	1	Crohn's disease	1
IgA deficiency	1	Multiple sclerosis	1
End stage renal disease	1	Sjogren's syndrome	1
Primary biliary cirrhosis	1	Rheumatoid arthritis	1
Acute lymphocytic leukemia	1	Celiac disease	1
IgG4 deficiency	1		
Chronic leukemia	1		

Table 3

Comparisons between cases and controls for preoperative and postoperative measures.

	Cases (n=22)	Matched controls (n=22)	
Preoperative measures:	mean ± SD	mean ± SD	p-value
Objective:			
Endoscopy score	6.8 ± 4.6	7.2 ± 4.5	0.706
CT score	9.8 ± 6.6	11.0 ± 6.7	0.605
Quality of Life:			
RSDI functional	12.0 ± 5.7	17.6 ± 6.6	0.008
RSDI physical	17.2 ± 8.6	19.7 ± 5.5	0.397
RSDI emotional	9.5 ± 6.3	15.4 ± 6.4	0.002
RSDI total	38.6 ± 18.3	52.8 ± 15.2	0.010
CSS symptom	37.9 ± 31.8	30.7 ± 24.6	0.498
CSS medication	36.7 ± 24.6	43.2 ± 22.8	0.309
CSS total	37.3 ± 22.1	36.9 ± 18.1	0.887
Postoperative measures:			
Objective:			
Endoscopy score	3.8 ± 3.9	4.1 ± 4.3	0.748
Quality of Life:			
RSDI functional	8.1 ± 6.6	11.7 ± 7.8	0.126
RSDI physical	11.6 ± 8.7	14.3 ± 7.1	0.184
RSDI emotional	6.1 ± 6.6	10.5 ± 6.5	0.025
RSDI total	25.7 ± 20.1	36.5 ± 19.7	0.065
CSS symptom	57.9 ± 37.6	59.8 ± 28.9	0.878
CSS medication	54.2 ± 27.8	57.6 ± 20.9	0.643
CSS total	56.1 ± 28.8	58.7 ± 21.0	0.860

SD = standard deviation. CT = computed tomography. RSDI = Rhinosinusitis Disability Index. CSS = Chronic Sinusitis Survey. $p \leq 0.05$ is statistically significant.

Table 4

Absolute mean improvement in objective and quality of life measures for both cases and controls.

Absolute mean improvement		
Cases:	mean $\pm$ SD	p-value
Objective:		
Endoscopy score	3.0 $\pm$ 4.9	<0.001
Quality of Life:		
RSDI functional	4.0 $\pm$ 5.2	0.007
RSDI physical	5.6 $\pm$ 8.4	0.041
RSDI emotional	3.4 $\pm$ 5.7	0.019
RSDI total	12.9 $\pm$ 16.1	0.017
CSS symptom	20.1 $\pm$ 29.4	0.004
CSS medication	17.4 $\pm$ 24.2	0.041
CSS total	18.7 $\pm$ 21.9	0.019

Matched Controls:		
Objective:		
Endoscopy score	3.1 $\pm$ 3.7	0.012
Quality of Life:		
RSDI functional	5.9 $\pm$ 9.1	0.041
RSDI physical	5.5 $\pm$ 6.6	0.007
RSDI emotional	4.9 $\pm$ 5.9	0.004
RSDI total	16.3 $\pm$ 18.9	0.017
CSS symptom	29.1 $\pm$ 34.9	0.003
CSS medication	14.4 $\pm$ 26.5	0.143
CSS total	21.8 $\pm$ 25.4	0.027

SD = standard deviation. RSDI = Rhinosinusitis Disability Index. CSS = Chronic Sinusitis Survey. $p \leq 0.05$ is statistically significant.