



CHARACTERISTICS OF CHRONIC RHINOSINUSITIS PHENOTYPES IN PATIENTS UNDERGOING FUNCTIONAL ENDOSCOPIC SINUS SURGERY: AN OBSERVATIONAL COHORT RETROSPECTIVE STUDY

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SUMMARY – This study analyzed the characteristics of chronic rhinosinusitis patients with and without nasal polyps failing conservative treatment and undergoing functional endoscopic sinus surgery as part of their treatment for chronic inflammatory sinonasal disease. The aim of this retrospective single-institution cohort study conducted at a university hospital tertiary referral center was to evaluate the characteristics of patients with both disease phenotypes in whom conservative treatment was unsuccessful. Patients who were surgically treated with functional endoscopic sinus surgery performed by two rhinology surgeons during a one-year period (2016) were enrolled in the study. Patient data collection included demographics, risk factor exposure, diagnosis, and type of endoscopic surgical procedure performed. In total, 185 patients were included in the study. Patients with malignant disease and those with incomplete data were excluded from the study. In the group of patients with nasal polyps, mean age, male gender, presence of allergy (34.9%), asthma (21.4%), aspirin sensitivity (6.3%), cystic fibrosis (1.6%), and previous nasal surgery rates (36.5%) were significantly higher as compared with the group of patients with chronic rhinosinusitis without nasal polyps. Septal deviation was more prevalent in the chronic rhinosinusitis group (55%) as compared to the group with nasal polyps (25%). The ethmoid (17%) and maxillary sinus (13%) were most frequently involved, but most of the patients who needed surgery had involvement of multiple or all sinuses (40%). The reasons for conservative treatment failure in chronic rhinosinusitis are multifactorial, but identifying the most prevalent characteristics in patients treated surgically may be helpful in identifying patients who would benefit most from surgery.

Key words: *Chronic rhinosinusitis; Nasal polyps; Functional endoscopic sinus surgery; Patient characteristics*

Introduction

Chronic rhinosinusitis (CRS), in its various forms, constitutes one of the most common conditions encountered in medicine and requires attention of a wide range of clinicians, including primary care physicians,

pulmonologists, allergologists and otorhinolaryngologists¹. Due to the heterogeneity of the disorder and its diagnostic variability, the accurate prevalence of CRS remains speculative. In surveys of chronic conditions, CRS was found to affect 15.5% of the total adult population^{2,3}. Additional endoscopic signs of nasal polyps, mucopurulent discharge or mucosal obstruction, or computed tomography (CT) changes that demonstrate mucosal edema within the ostiomeatal complex must be noted when establishing a diagnosis. CRS is further divided into chronic rhinosinusitis with nasal polyps (CRSwNP) and chronic rhinosinusitis without

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nasal polyps (CRSsNP)⁴. Nasal septal deformity is a common disorder that presents in up to 62% of the population, and its role in the pathogenesis of chronic sinusitis remains uncertain. Nasal septal deviation may either cause ostiomeatal obstruction or interfere with proper airflow and result in sinusitis⁵. Allergy-related CRS investigation has suggested that atopy with allergic inflammation has a role in its development. Swelling of the nasal mucosa in atopic patients may compromise ventilation and obstruct the sinus ostia, leading to mucus retention and infection⁶. Failure to address allergy as a contributing factor to CRS diminishes the probability of success of sinus surgery⁷. The goal of treatment in CRS is to reduce mucosal inflammation, control infection, and to restore mucociliary clearance within the sinuses⁸. Management of CRS should be individualized. For those patients suffering from allergy, pollution, or mold exposure, environmental control is an important modality. Sinus surgery is generally reserved for patients who remain symptomatic despite maximal medical therapy⁹. One of the most important benefits of surgery is the ability to deliver medications (sprays, rinses, nebulized drugs) to the lining of the sinuses after they have been opened. Therefore, sinus surgery is done in addition to, and is not a replacement for proper medical treatment of the sinuses¹⁰. It is important to note that surgery is rarely successful in long-term disease control in patients who have recurrent nasal polyps associated with severe asthma. For many patients, surgery may not be a definitive cure, but it is an important option in managing both phenotypes of chronic sinus disease¹¹.

The aim of this study was to evaluate the characteristics of patients failing conservative treatment and undergoing functional endoscopic sinus surgery (FESS).

Material and Methods

This was a retrospective cohort study on patient data collected at the Department of Otorhinolaryngology and Head and Neck Surgery in a tertiary university hospital setting, enrolling 189 patients diagnosed with CRS that underwent FESS during a one-year period (2016). Data were collected from patient electronic medical charts that contain records of patient comorbidities and previous medical history. The data included disease phenotype, age, sex, sinuses involved, previous operations, and risk factor exposure; septal deformity (if presenting with unilateral nasal obstruction), allergy (proven sensitization to airborne allergens, symptom-

atic allergic rhinitis or both), asthma (only if currently treated and diagnosed by a pulmonologist), history of cystic fibrosis, and smoking. Septal deformity was considered significant if the patient complained of continuous nasal obstruction regardless of topical medication administered on the side of the nose where an anatomic deformity was observed endoscopically.

This study and its protocol were designed and conducted in line to the Helsinki Declaration of 1983, and informed consent was obtained from all patients. Inclusion criteria were complete medical documentation and undergoing surgical treatment. Out of 246 patients with CRS who were admitted to the ENT department in 2016, a total of 189 patients underwent endoscopic sinus surgery by two rhinology surgeons and had complete medical records available. Patients with malignant disease were excluded from the study (4 patients), alongside patients with antrochoanal polyps and mucoceles. All study patients underwent FESS either as a primary or revision surgery. None of the patients had any other type of sinus surgery previously, such as open procedures. The decision to perform surgery was based on persistence of CRS symptoms after maximal doses of intranasal corticosteroids used for a minimum of six months failed to provide control of the disease symptoms. At least two of the following symptoms needed to persist for more than six months: nasal blockage/obstruction/congestion or nasal discharge (anterior/posterior nasal drip), facial pain/pressure, and reduction or loss of smell.

Statistical analysis was performed using MedCalc software (version 11.2. 1993–2010, MedCalc Software bvba Software, Mariakerke, Belgium). Associations between variables were assessed using Mann-Whitney U test and Kruskal-Wallis test for non-parametric samples. All tests of statistical significance were performed using a two-sided 5% type I error rate.

Results

A total of 185 patients were enrolled in the study, 113 (61.1%) male and 72 (38.9%) female, male to female ratio 1.57 (Fig. 1).

The patients were divided into two main groups according to disease phenotype; 69% of the participants were diagnosed with CRSwNP while 31% were diagnosed with CRSsNP. Interestingly, 74 patients with CRSwNP were affected bilaterally and 52 unilaterally, whereas only 10 patients with CRSsNP were affected bilaterally and most CRSsNP patients (n=49) were affected unilaterally.

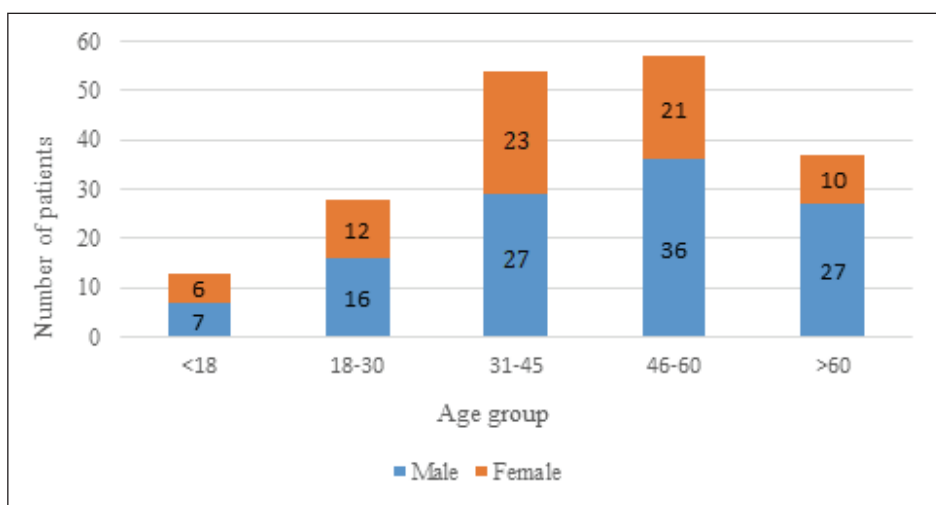


Fig. 1. Patient distribution according to age and gender.

The variables included demographic view and risk factor exposure, as well as previous endoscopic sinus surgeries performed (Table 1).

Table 1. Patient characteristics

Variable	CRSwNP	CRSsNP
Sex, male/female	83/43	30/29
Mean age (yrs)	49	38
Septal deformity	33 (25%)	32 (55%)
Allergy	44 (34.9%)	18 (31%)
Asthma	27 (21.4%)	2 (3.4%)
Aspirin sensitivity	8 (6.3%)	0
Smoking	30 (23.8%)	19 (32.7%)
Cystic fibrosis	2 (1.6%)	0
Previous ESS	46 (36.5%)	10 (17%)
ESS + septal reconstruction	20 (16%)	23 (40%)

CRSwNP = chronic rhinosinusitis with nasal polyps; CRSsNP = chronic rhinosinusitis without nasal polyps; ESS = endoscopic sinus surgery

In the CRSwNP group, 25% of patients had septal deformity, and 16% had simultaneous endoscopic sinus and septal surgery. In the CRSsNP group, 32 (55%) had septal deformity and 40% had simultaneous endoscopic sinus and septal surgery. Patients with

CRSsNP had a statistically higher incidence of septal deformity (Mann-Whitney U test, $p=0.03$).

When analyzing risk factors, 44 (34.9%) patients with CRSwNP and 18 (31%) patients with CRSsNP had allergy, but significantly more CRSwNP patients had asthma, i.e. 27 (21.4%) *vs.* only 2 (3.4%) CRSsNP patients (Mann-Whitney U test, $p=0.002$). Aspirin sensitivity was found in 8 (6.3%) CRSwNP patients and none of the patients in the CRSsNP group. When analyzing smoking, 30 (22.9%) CRSwNP patients were smokers *vs.* 19 (32.7%) patients with CRSsNP.

A total of 46 (36.5%) CRSwNP patients and 10 (17%) CRSsNP patients had at least one previous surgery (Kruskal-Wallis test, $p=0.023$). Out of these, 35 patients had previously undergone one ESS procedure, including 28 (80%) CRSwNP patients and 7 (20%) CRSsNP patients, whereas 8 CRSwNP patients and 1 CRSsNP patient had two procedures. Eight patients with CRSwNP had 3-5 previous operations and 4 patients had more than 5 operations, with the highest number of procedures *per* patient being 21.

Involvement of ethmoid sinus alone was found in 17%, maxillary sinus alone in 13%, and involvement of both ethmoid and maxillary sinuses in 19% of cases. Frontal sinus and sphenoid sinus by themselves were diseased in 2% of study patients each. Involvement of multiple sinuses or different combinations was found in 31%, whereas 16 (8%) patients had all sinuses affected (pansinusitis). There were no statistical differences in sinus involvement according to disease phenotype (Fig. 2).

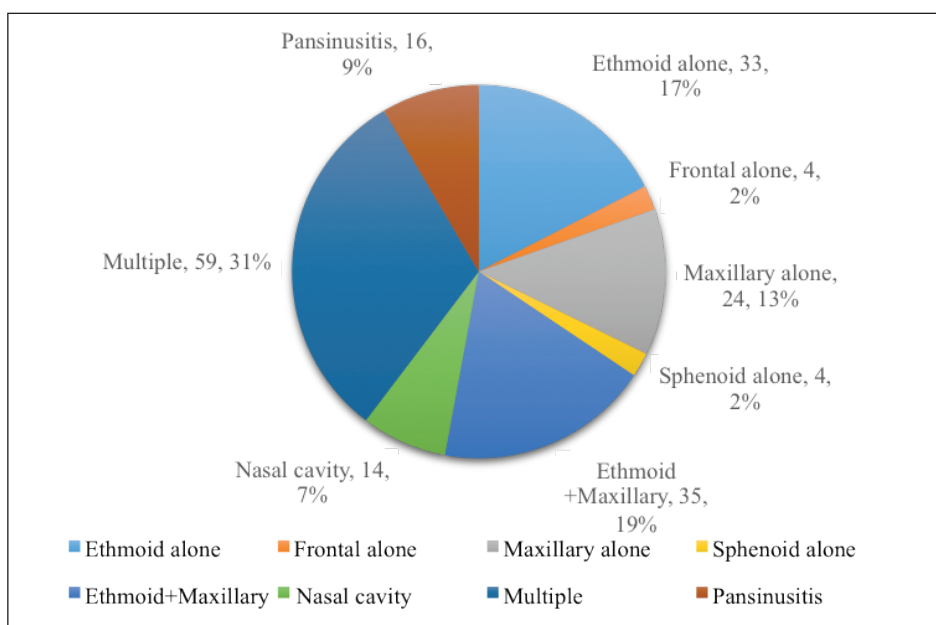


Fig. 2. Sinuses affected in patients undergoing functional endoscopic sinus surgery.

Discussion

A number of published studies have demonstrated that FESS in patients can result in a prolonged reduction of nasal symptoms and improvement in the quality of life. Dalziel *et al.* evaluated 33 articles published between 1978 and 2001¹¹. The review included three studies comparing FESS with Caldwell-Luc or other endonasal procedures (n=240), three nonrandomized studies comparing different surgical approaches (n=2699), and 27 case series (n=8208). Seven studies included only patients with nasal polyps and 26 included CRS patients with and without polyps. Patients found their symptoms to be 'improved' or 'greatly improved' in 75% to 95% of surgical treatments. The percentage of overall complications was low (1.4% for FESS compared to 0.8% for traditional open procedures). The implications of this review are that FESS is safe and effective treatment for the great majority of patients¹².

The efficacy of FESS in CRSwNP patients is comparable to patients with CRSsNP. There is evidence that a significantly higher rate of recurrent surgery is required in patients with nasal polyposis than those without polyps¹³. In our study, patients with CRSwNP were significantly younger than those with CRSsNP (average age 38 *vs.* 49 years). The rates of CRSwNP and CRSsNP in our study (68% CRSwNP and 32% CRSsNP) match the results in the largest study to

date, the UK National Sinonasal audit, with prospective data from 87 hospitals and 298 UK otorhinolaryngologists on patients having undergone FESS (n=3128)¹².

Despite successful surgical treatment in CRSsNP patients, CRSwNP patients with refractory disease have a tendency to undergo repeated surgeries even after prolonged attempts at medical intervention, and a lower success rate (54.3%) in avoiding revision surgery compared to CRSsNP patients (93.7%)^{13,14}. In our study, 56 patients had at least one previous FESS procedure, including 46 CRSwNP patients and only 10 CRSsNP patients. However, revision surgery is not necessarily viewed as treatment failure, reflecting the results of the National Audit study in UK, which did not show surgical outcomes between CRSwNP and CRSsNP to differ significantly in terms of subjective improvement in long-term observation¹². It is important to identify patients that may benefit from repeated surgical treatment.

When analyzing the extent of FESS in CRS patients, the ethmoid and maxillary sinus were the only localizations involved by the disease in 17% and 13% of surgeries, respectively. They were both involved in 19% of cases. In our patient cohort, almost one-third of patients presented with unilateral CRSsNP, based on combined CT and intraoperative endoscopic results. We considered intraoperative endoscopy to be

the gold standard, leading to a higher percentage of unilateral disease patients compared to CT findings alone. Literature data report that CRS with or without nasal polyposis is the most common cause of unilateral sinus disease in 60.3% of patients, presenting with single-sinus disease, and fungal sinusitis being the second most common etiology. The unilateral character of CRS does not influence the quality of life scores¹⁴. We observed that isolated involvement of the sphenoid and frontal sinus was quite rare, 2% each. However, surgery on multiple sinuses/all sinuses (pansinusitis) was necessary in 40% of patients, especially revision cases. Most patients with CRS have involvement of more than one sinus, with maxillary sinus (99%) being the most commonly involved sinus, followed by anterior ethmoids (89%), frontal (64%), posterior ethmoids (61%), and sphenoid sinus (31%)^{15,16}.

Allergy is more prevalent in CRSwNP compared with CRSsNP. Several studies demonstrated an increased prevalence of perennial allergies in patients with CRSwNP compared with controls, with reports varying between 45% and 77.4%¹⁷⁻¹⁹. In our study, 34.9% (n=44) of patients with CRSwNP and 31% (n=18) of patients with CRSsNP had allergies, but there were no significant differences between the phenotypes. There is a high prevalence of CRS among patients with asthma, and the presence of CRS is associated with poor asthma outcomes, especially with CRSwNP²⁰. Moreover, comorbid asthma is an important risk factor for resistance to therapeutic interventions for CRS, such as FESS²¹. In our study, 21.4% (n=27) of patients with CRSwNP had asthma, whereas in the CRSsNP group of patients, 3.4% (n=2) were diagnosed with asthma. In CRSwNP, there is an increase in Th2 cytokines such as interleukin (IL)-4, IL-5 and IL-13, and the presence of eosinophils in the tissues of these patients is markedly increased alongside co-existing asthma or positive allergy skin tests²²⁻²⁴. In our study, 8 (6.3%) patients with CRSwNP had aspirin intolerance in comparison to none of the CRSsNP group patients.

A total of 65 (35%) patients with CRS had septal deformity (33 in the CRSwNP group and 32 in the CRSsNP group). There are several theories explaining the relationship between nasal septal deformity and CRS, mostly referring to the accumulation of secretion in the sinuses as a result of narrowing of the ostiomeatal complex²⁵.

Mucociliary clearance is grossly impaired in cystic fibrosis (CF) because of alterations in the transepithelial

passage of anions (chloride and bicarbonate) caused by genetic mutations in the cystic fibrosis transmembrane conductance regulator. Disturbances in anion transport result in viscous secretions that obstruct sinus ostia and create hypoxic conditions with increased edema, secondary ciliary dyskinesia, and subsequent bacterial overgrowth. Patients with classic CF have a high incidence of CRS approaching 100%. CF patients have a high incidence of nasal polyposis associated with CRS (7%-48%)²⁶. In our study, 2 CF patients aged 9 diagnosed with CRSwNP had undergone FESS.

Tobacco smoke exposure is considered an important negative prognostic factor for CRS, and smoking has been demonstrated to increase the risk of CRS²⁷. In our patient group, 23.8% of CRSwNP patients and 32.7% of CRSsNP patients were smokers. We could not identify smoking as an independent risk factor, but the impact of tobacco smoke exposure on FESS outcomes has been investigated, with smokers displaying a less favorable response to surgery²⁸. It has been reported that both secondhand smoke-sensitive and non-sensitive individuals had increased symptoms of rhinorrhea, nasal congestion, and headache following passive smoke exposure²⁹.

The authors are aware of the weaknesses of the retrospective study design. Analyzing epidemiologic data on CRS patients who were successfully treated medically and those who were treated surgically would yield more information on the factors leading to surgery, and recognizing the risk factors and comorbidities predisposing to unsuccessful medical treatment outcomes. This would require quality of life questionnaires filled out by all patients both preoperatively and postoperatively, and appropriate regression statistics³⁰. Instead, the main focus of our paper was to analyze the characteristics of patients with the two CRS phenotypes that were selected to undergo FESS. These data might also be of relevance to clinical practitioners in identifying patients that might benefit from FESS.

Conclusions

The reasons for conservative treatment failure in CRS are multifactorial, but identifying the most prevalent characteristics in patients treated surgically may be helpful. The CRSwNP patients undergoing surgery had lower mean age, increased male gender prevalence, presence of allergy, asthma, aspirin sensitivity, and a higher number of prior surgeries when compared to the CRSsNP patients.

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Sažetak

ZNAČAJKE FENOTIPA KRONIČNOG RINOSINUSITISA U BOLESNIKA LIJEČENIH ENDOSKOPSKOM SINUSNOM KIRURGIJOM: OPSERVACIJSKA KOHORTNA RETROSPEKTIVNA STUDIJA

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U ovom istraživanju analizirana su svojstva bolesnika s oba fenotipa kroničnog rinosinusitisa u kojih konzervativno liječenje nije bilo uspješno pa su potom liječeni funkcionalnom endoskopskom sinusnom kirurgijom. Cilj ovog istraživanja bio je procijeniti karakteristike bolesnika u oba fenotipa bolesti kod kojih konzervativno liječenje nije bilo uspješno. Istraživanje je provedeno kao retrospektivna kohortna studija u referentnom centru tercijarne sveučilišne bolnice. U studiju su uključeni bolesnici koji su kirurški liječeni funkcionalnom endoskopskom sinusnom kirurgijom u razdoblju od godinu dana (2016.). Prikupljeni su podaci o demografiji, izloženosti riziku, supostojećim bolestima i tipu izvedenog kirurškog zahvata. U studiju je uključeno 185 bolesnika. Isključeni su bolesnici s malignom bolešću nosa i sinusa te oni s nepotpunim podacima o liječenju (4 bolesnika). U skupini bolesnika s nosnim polipima su prosječna dob, muški spol, prisutnost alergije (34,9%), astme (21,4%), osjetljivost na aspirin (6,3%), prisutnost cistične fibroze (1,6%) i anamneza prethodnih kirurških zahvata na nosu i sinusima (36,5%) bili značajno viši u usporedbi sa skupinom s kroničnim rinosinusitisom bez nosnih polipa. Septalna devijacija bila je češća u skupini s kroničnim rinosinusitisom (55%) u usporedbi sa skupinom s nosnim polipima (25%). U većine bolesnika kojima je bila potrebna operacija zablježena je zahvaćenost više ili čak svih sinusa (40%). Razlozi za neuspjeh medikamentnog liječenja bolesnika s kroničnim rinosinusitisom su višestruki, ali prepoznavanje najčešćih karakteristika u kirurški liječenih bolesnika može pomoći u ispravnom odabiru bolesnika koji će od kirurškog liječenja imati najviše koristi.

Ključne riječi: *Kronični rinosinusitis; Nosni polipi; Funkcionalna endoskopska sinusna kirurgija; Karakteristike bolesnika*