

## Original Article

# Preventing sino-nasal polyposis recurrence after functional endoscopic sinus surgery: a multicentric study

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**Abstract:** Background: Chronic rhinosinusitis with nasal polyps (CRSwNP) frequently recurs after functional endoscopic sinus surgery (FESS), particularly in patients with eosinophilic inflammation or aspirin-exacerbated respiratory disease (AERD). Optimizing postoperative medical regimens based on disease severity may reduce recurrence rates. The aim of this study was to evaluate the impact of severity-based postoperative medical regimens on recurrence rates following FESS in patients with CRSwNP. Methods: This prospective multicentric cohort study included 144 patients with CRSwNP who underwent FESS between 2021 and 2023. Patients were stratified into five groups based on eosinophilia, AERD status, and radiologic/endoscopic severity using the Modified Lund-Mackay (MLM) and Modified Lund-Kennedy (MLK) scores. Each group received a tailored postoperative medical regimen. Patients were followed for two years, with recurrence assessed via nasal endoscopy and scored using MLK. Results: The overall recurrence rate at two years was 10.4%. Recurrence rates increased progressively from 0% in Group 1 (non-eosinophilic) to 33.3% in Group 5 (AERD). The trend was statistically significant (Cochran-Armitage test,  $Z = 3.48$ ,  $P < 0.001$ ). A significant association between follow-up group and recurrence was found (Chi-square,  $P = 0.006$ , Cramér's  $V = 0.316$ ). Blood eosinophilia and elevated IgE levels were strongly correlated ( $P < 0.001$ ,  $OR = 3.15$ ). Conclusion: Postoperative recurrence in CRSwNP can be significantly reduced by tailoring medical regimens based on clinical, radiologic, and immunologic severity. Group-based stratification provides a feasible model for personalizing care, especially in settings where biologics are unavailable.

**Keywords:** Nasal polyps, rhinosinusitis, eosinophilia, postoperative care, recurrence

## Introduction

Chronic rhinosinusitis (CRS) has been classified in many ways, most commonly according to phenotypes and endotypes. Phenotypically, it is clinically distinguished between CRS with nasal polyposis (CRSwNP) and CRS without nasal polyposis (CRSsNP); endotypically, it is classified into type 2 and non-type 2 inflammation, according to its pathophysiology [1-3]. Endotyping CRS is challenging due to mixed endotypes in some patients and unclear optimal anatomical sites. EPOS combines endotypes, phenotypes, and anatomic distributions for tailored treatments [4].

There are numerous treatment modalities for CRSwNP. Corticosteroids are extensively utilized, both intranasally and systemically, and

they constitute the initial therapeutic approach in numerous clinical settings. However, topical corticosteroids primarily alleviate symptoms, and systemic corticosteroids offer only transient benefits due to the necessity of limiting their use to short-term periods to mitigate adverse effects [5]. Other medical treatment methods include the use of antibiotics, leukotriene modifiers, aspirin desensitization (in those with aspirin-exacerbated respiratory disease), and novel biological treatments [6].

With the advancement in understanding the pathophysiology of CRS, biologics have been developed to modulate the immune system, thereby inhibiting chronic inflammation and aiding in the management of comorbidities that complicate the treatment of CRS (e.g., asthma). However, these treatments have notable limita-

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tions. They are expensive, restricted to use in chronic rhinosinusitis with type 2 inflammation, and are typically reserved for cases where other therapeutic approaches have proven ineffective [7].

In addition to pharmacological interventions, surgical procedures, particularly endoscopic sinus surgery (ESS), are employed in the management of CRSwNP, especially in cases where medical treatments alone prove ineffective. The primary objectives of ESS in the context of CRSwNP include the excision of diseased mucosa and nasal polyps, enhancement of intranasal treatment delivery to the sinuses, and subsequent reduction of the inflammatory burden associated with the disease [8]. While surgical intervention effectively addresses mucosal abnormalities and restores airway patency, it is insufficient as a standalone measure to prevent recurrence. Literature indicates that the recurrence rates of CRSwNP following ESS can reach up to 60% within a 4-year postoperative period. Furthermore, the likelihood of recurrence is elevated in patients with comorbid conditions such as asthma or aspirin sensitivity [9]. Given this high recurrence rate, it is imperative for surgeons to consider individualized treatment approaches. These may include varying surgical techniques tailored to the extent of the disease or implementing similar surgical procedures with distinct postoperative medical regimens specific to the disease type. For surgical techniques or postoperative regimens to be individualized, patients require stratification based on the severity of their conditions and the presence of known risk factors for recurrence.

The primary aim of this study is to evaluate the effectiveness of different postoperative medical regimens given after functional endoscopic sinus surgery. The secondary aim is to use the existing data in the literature to classify patients based on their clinical, endoscopic, and radiologic disease severities.

### Materials and methods

#### Study design

This prospective cohort study was conducted to evaluate different postoperative medical regimens after Functional Endoscopic Sinus Surgery (FESS) for CRSwNP. It enrolled 144 patients who had undergone FESS in four centers.

#### Settings

The study was conducted from 2021 to 2023, and the corresponding author gathered all information and performed all surgeries.

#### Participants

Inclusion criteria: Patients with CRSwNP (Chronic Rhinosinusitis with Nasal Polyps) were included. Among the patients were those undergoing primary or secondary surgery, and those with Aspirin-Exacerbated Respiratory Disease (Allergy, Aspirin Sensitivity, and Sinonasal Polyps) [10].

Exclusion criteria: (1) Patients with ciliary dyskinesia were excluded using the Sweat Chloride Test [11]. (2) Patients who underwent FESS less than six months before presenting with recurrence. (3) Patients not compliant with the allocated follow-up visits.

The inclusion and exclusion criteria are better visualized in **Figure 1**.

#### Variables

The study assessed multiple variables, including: (1) Primary outcome: Recurrence rate of nasal polyposis among different follow-up groups. (2) Predictors: Presence of eosinophilia, AERD, and endoscopic and radiologic disease severity. (3) Potential confounders: Patient demographics and surgical history. (4) Diagnostic criteria: Severity was determined using the Endoscopic Modified Lund-Kennedy Score (MLK) and the Radiologic Modified Lund-Mackay Score (MLM) for CT scans.

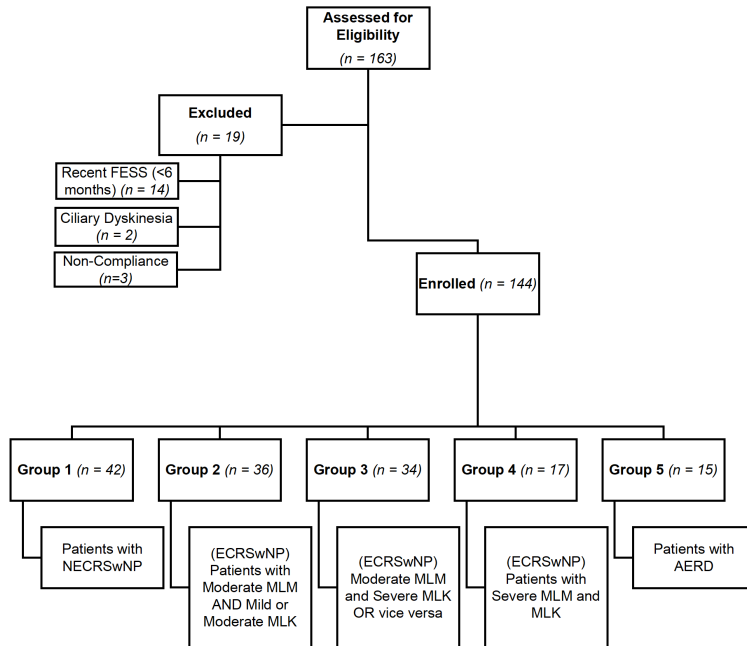
#### Data sources and measurement

Anamnesis, clinical examination, and nasal endoscopy were performed for all patients. All underwent necessary blood tests, including blood eosinophil count (to diagnose eosinophilia) and IgE count, as well as a CT scan of the nose and paranasal sinuses prior to surgery. Through blood eosinophilia, patients were classified into ECRSwNP and NECRSwNP (this was later confirmed by postoperative polyp histopathology).

#### Surgical intervention

Surgery was performed under general anesthesia in the reverse Trendelenburg position with

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**Figure 1.** Flow diagram illustrating inclusion and exclusion criteria and subsequent stratification of the 144 enrolled patients into five treatment groups based on disease phenotype, radiologic and endoscopic severity, and presence of AERD. NECRSwNP patients were assigned to Group 1, while patients with ECRSwNP were classified into Groups 2-4 according to MLM and MLK scores. Group 5 included all patients with AERD, regardless of severity (NECRSwNP: Non-eosinophilic chronic rhinosinusitis with nasal polyps; ECRSwNP: Eosinophilic chronic rhinosinusitis with nasal polyps; AERD: Aspirin-exacerbated respiratory disease; MLM: Modified Lund-Mackay score; MLK: Modified Lund-Kennedy score; FESS: Functional Endoscopic Sinus Surgery).

a rigid video endoscope (Karl Storz GmbH, Tuttlingen, Germany), which included a 4K camera system, a monitor, four scope angles (0, 30, 45, and 70 degrees), and a shaver system. The scopes were 4 mm in diameter and 18 cm in length.

Preparation involved mopping the nasal cavity with one Merocel divided into six pieces (three per nasal cavity), soaked in a solution of 4 mL of adrenaline and 8 mL of normal saline. Surgery began with the removal of intranasal polyps, which were sent for histopathology to detect eosinophil count and confirm eosinophilia. Full-house functional endoscopic sinus surgery was then performed [12]. Both nasal cavities were irrigated with warm normal saline to remove remaining clots and shaved bone. Finally, another Merocel was used for nasal packing, divided into six pieces (three per nasal cavity), soaked with an ampoule of dexamethasone (8 mg in 2 mL), and bound to a silk suture

(1/0) for ease of removal. The packing remained for one week for hemostasis [13].

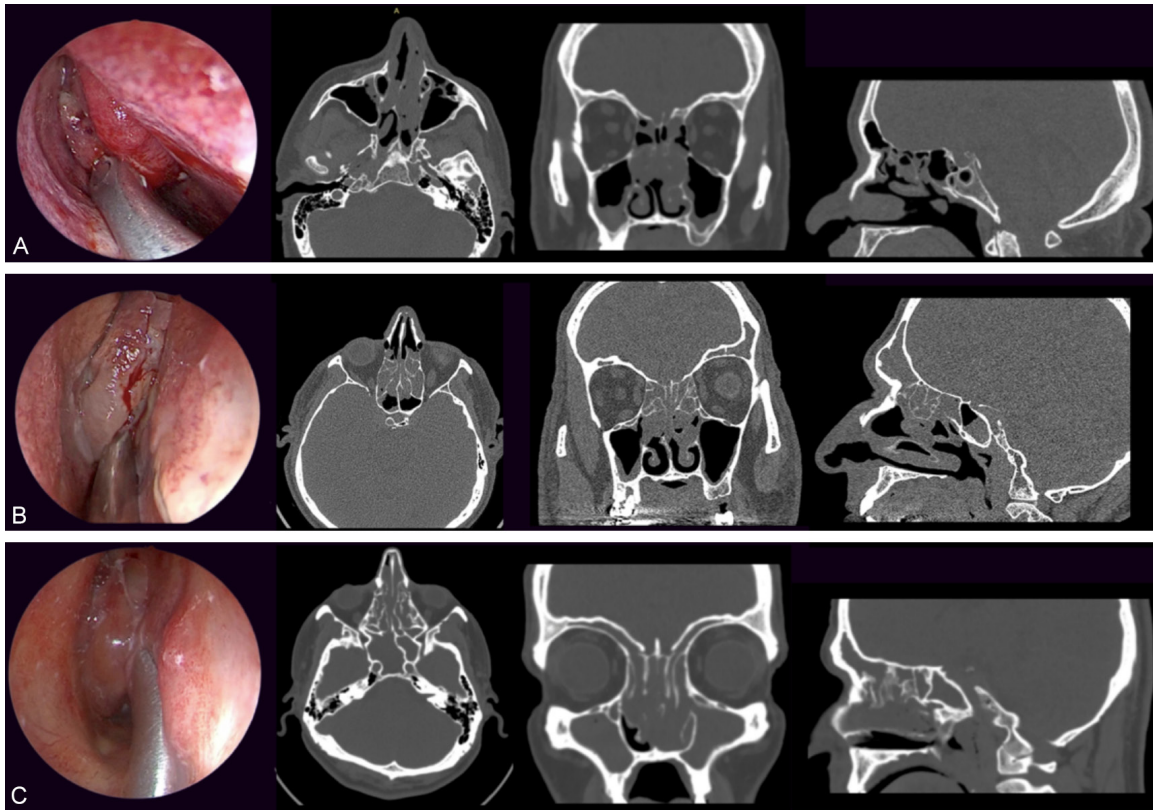
### Follow-up groups

Patients were grouped based on the presence of eosinophilia and AERD, risk of recurrence, and Modified Lund-Mackay (MLM) and Modified Lund-Kennedy (MLK) Scores [14, 15]. The MLM Score, ranging up to 54, was divided into three severity groups: 1-18 (mild), 19-36 (moderate), and 37-54 (severe CRS). The MLK Score (max 6) was classified as 1-2 (mild), 3-4 (moderate), and 5-6 (severe CRS). No patients had a score of 0 pre-operatively; all had polyposis and were classified accordingly. Group 1 and Group 5 were classified independent of MLM/MLK: Group 1 included all non-eosinophilic patients, while Group 5 included patients with AERD, regardless of their severity scores.

The full grouping methodology, including the inclusion and exclusion criteria and patient distribution across the five treatment groups, is illustrated in **Figure 1**.

**Figure 2** provides representative endoscopic and radiologic examples of the MLK and MLM scores used to classify patients by disease severity.

Each follow-up group received a distinct medical regimen: (1) Group 1 (42 patients, NECRSwNP): 250 mg clarithromycin once daily for 3 months and nasal irrigation with normal saline for 6 months. (2) Group 2 (36 patients, mild ECRSwNP): Lifelong nasal irrigation with 500 mL normal saline plus 0.5 mg budesonide, 20 mL per nasal cavity, twice daily. (3) Group 3 (34 patients, moderate ECRSwNP): Same as Group 2 plus 10 mg montelukast daily for 3 months. (4) Group 4 (17 patients, severe ECRSwNP): Same as Group 3 plus 250 mg clarithromycin daily for 3 months and oral prednisolone (1 mg/kg) for 10 days with dose tapering. (5) Group 5 (15 patients, AERD): Same treatment as Group 4.



**Figure 2.** Representative examples of patient stratification using the Modified Lund-Kennedy (MLK) and Modified Lund-Mackay (MLM) scores. A. Patient with mild MLK (score = 2) and moderate MLM (score = 24); B. Patient with moderate MLK (score = 4) and moderate MLM (score = 28); C. Patient with severe MLK (score = 5) and severe MLM (score = 54). These combinations illustrate how patients were classified into mild, moderate, or severe ECRSwNP.

All patients were instructed on proper irrigation techniques and equipment hygiene. They were followed up eight times: two weeks postoperatively, every two months in the first year, and at two years. At each visit, patients underwent nasal endoscopy and debridement under local anesthesia. Recurrence was scored at two years postoperatively using the Modified Lund-Kennedy Score. **Table 1** summarizes the stratification methodology and assigned treatments.

#### *Bias control*

To reduce bias, the same surgeon performed all MLM and MLK scorings and conducted all surgeries.

#### *Study size*

The sample size of 144 patients was justified based on feasibility and comparison to prior similar studies.

#### *Data administration and statistical analysis*

All data were collected and organized in Microsoft Excel, Version 16.93.1 (25011917). Statistical analysis was performed using JASP (version 0.19) and R Console (R 4.4.2 GUI 1.81 Big Sur Intel build, 8462). Normality of continuous variables was assessed using the Kolmogorov-Smirnov test. Age and Modified Lund-Mackay Total Scores were normally distributed; all other continuous variables were not. Descriptive statistics were used to summarize demographics and clinical characteristics. The Chi-square test assessed associations between recurrence and categorical predictors (eosinophilic vs. non-eosinophilic phenotype, presence of AERD, and treatment group). The Cochran-Armitage trend test was applied to examine trends in recurrence across severity-based treatment groups. Cramér's V measured effect size, interpreted as:  $\leq 0.1$  (weak), 0.1-0.3 (moderate), 0.3-0.5 (strong), and  $> 0.5$  (very strong). Statistical significance was defined as

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**Table 1.** Overview of grouping criteria and tailored postoperative therapies

Groups	Diagnosis	Diagnosis Methodology	Post-FESS Treatment
Group 1	NECRSwNP	All patients with non-eosinophilic polyps	- Clarithromycin tablet - Nasal irrigation with normal saline
Group 2	Mild ECRSwNP	- Patients with eosinophilic polyps - Moderate MLM score (19-36) AND mild or moderate MLK score (1-4)	- Nasal irrigation with a solution of normal saline and budesonide
Group 3	Moderate ECRSwNP	- Patients with eosinophilic polyps AND - Moderate MLM score (19-36) and severe MLK (5-6) score OR severe MLM (37-54) score and moderate MLK score (3-4)	- Montelukast tablet - Nasal irrigation with a solution of normal saline and budesonide
Group 4	Severe ECRSwNP	- Patients with eosinophilic polyps AND - Severe MLM score (37-54) AND Severe MLK score (5-6)	- Clarithromycin tablet - Prednisolone tablet - Montelukast tablet - Nasal irrigation with a solution of normal saline and budesonide
Group 5	AERD	Patients with the triad of allergy, aspirin sensitivity and sinonasal polyps	- Clarithromycin tablet - Prednisolone tablet - Montelukast tablet - Nasal irrigation with a solution of normal saline and budesonide

Summary of patient stratification into five groups based on disease phenotype, radiologic and endoscopic severity scores, and presence of AERD. Eosinophilic and non-eosinophilic CRSwNP were differentiated using blood eosinophil count and confirmed by postoperative polyp histopathology. Aspirin-exacerbated respiratory disease (AERD) was diagnosed based on patient anamnesis. Each group received a tailored postoperative treatment regimen corresponding to recurrence risk. Abbreviations: NECRSwNP, non-eosinophilic chronic rhinosinusitis with nasal polyposis; ECRSwNP, eosinophilic chronic rhinosinusitis with nasal polyposis; AERD, aspirin-exacerbated respiratory disease; MLM, Modified Lund-Mackay score; MLK, Modified Lund-Kennedy score.

$P < 0.05$ . All analyzed data can be made available upon formal request from the corresponding author. The STROBE guidelines were followed in reporting this study.

### *Ethics statement*

This study was conducted in accordance with national guidelines and the Declaration of Helsinki. Ethical approval was granted by the committee of the primary affiliation (approval number 139) during the 15th committee meeting on 22/6/2021. Patient consent for publication was not required as no identifying information was included.

### *Data availability*

All data, including analyses, can be made available upon formal request from the corresponding author.

### **Results**

A total of 144 patients with CRSwNP were enrolled, of whom 75 (52.1%) were female. The age range was 21 to 73 years, with a mean of

37.4±10.7 years. Baseline clinical characteristics are detailed in **Table 2**. Preoperative disease severity was assessed using the Modified Lund-Kennedy (MLK) and Modified Lund-Mackay (MLM) scores. Among patients with ECRSwNP (Groups 2 to 4), 71.3% had moderate MLK scores, and 50.6% had severe MLM scores. The mean MLK score was 4.1±0.75, and the mean MLM score was 37±5.6. All patients had nasal polyps at baseline, thus no patients had a score of 0 preoperatively. Two years after surgery, 105 patients (72.9%) had no endoscopic evidence of recurrence (MLK score = 0), and the mean postoperative MLK score was 0.65±1.4. The total recurrence rate was 10.4%. Recurrence at two years varied across the five follow-up groups (**Table 3**). No patients in Group 1 had recurrence. Recurrence rates were 11% in Group 2, 8.8% in Group 3, 17.6% in Group 4, and 33.3% in Group 5. This trend is illustrated in **Figure 3**. A statistically significant association was observed between group stratification and recurrence rate (Chi-square test,  $P = 0.006$ ; Cramér's  $V = 0.316$ , 95% Percentile CI: 0.2151-0.5303; 95% BCa CI: 0.1845-0.4565). A Cochran-Armitage test

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**Table 2.** Baseline characteristics and clinical parameters

Categorical Variable		Frequency (n)
Age Groups	18-24	20 (13.9%)
	25-34	37 (25.7%)
	35-44	54 (37.5%)
	45-54	21 (14.6%)
	55-64	10 (6.9%)
	65 and above	2 (1.4%)
Sex	Male	69 (47.9%)
	Female	75 (52.1%)
Asthmatic	Yes	39 (27.1%)
	No	105 (72.9%)
Allergy to Aspirin	Yes	15 (10.4%)
	No	129 (89.6%)
AERD (Aspirin-Exacerbated Resp. Dis.)	Yes	15 (10.4%)
	No	129 (89.6%)
Past Surgical History	Yes	21 (14.6%)
	No	123 (85.4%)
Blood Eosinophil Count	Less than $0.44 \times 10^9/L$	42 (29.2%)
	More than or Equal to $0.44 \times 10^9/L$	102 (70.8%)
Blood IgE Count	Less Than or Equal to 100 IU/mL	61 (42.4%)
	More than 100 IU/ml	83 (57.6%)
Postoperative Tissue Eosinophil Count	Less Than 10%	42 (29.2%)
	More Than or Equal to 10%	102 (70.8%)
Pre-Operative MLK		
Mild (1-2)		1 (1.1%)
Moderate (3-4)		62 (71.3%)
Severe (5-6)		24 (27.6%)
Pre-Operative MLM		
Mild (1-18)		0 (0%)
Moderate (19-36)		43 (49.4%)
Severe (37-54)		44 (50.6%)
Post-Operative MLK		
Score = 0		105 (72.9%)
Mild (1-2)		24 (16.7%)
Moderate (3-4)		8 (5.5%)
Severe (5-6)		7 (4.9%)
Continuous Variables		Mean ( $\pm$ SD)
Age		37.4 $\pm$ 10.7
TNSS		4.7 $\pm$ 2.1
Pre-Operative MLK		4.1 $\pm$ 0.75
Pre-Operative MLM		37 $\pm$ 5.6
Post-Operative MLK		0.65 $\pm$ 1.4
Total		144 (100%)

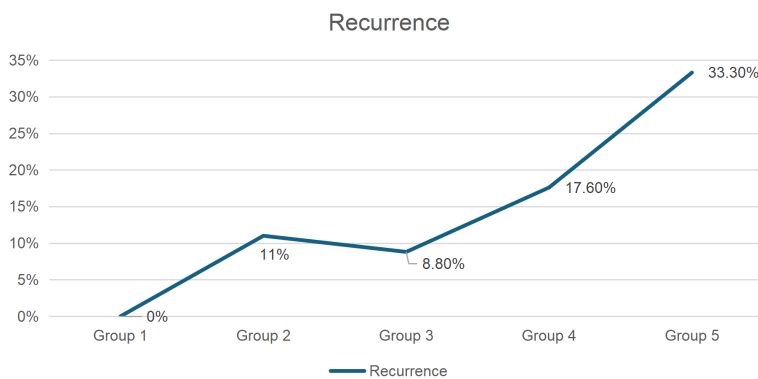
This table summarizes the demographic data, clinical characteristics, laboratory values, and radiologic/endoscopic scores for the 144 patients included in the study. Descriptive statistics were applied for categorical and continuous variables. The Modified Lund-Kennedy (MLK) and Modified Lund-Mackay (MLM) scores were used to assess endoscopic and radiologic severity, respectively. Blood eosinophilia and IgE levels were used to phenotype patients into ECRSwNP and NECRSwNP. Postoperative MLK scores at 2 years were used to assess recurrence.

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**Table 3.** Recurrence in follow-up groups

		Follow-Up Groups					P-Value
		Group 1	Group 2	Group 3	Group 4	Group 5	
2 Months Recurrence	Yes	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	N/A
	No	42 (100%)	36 (100%)	34 (100%)	17 (100%)	15 (100%)	
8 Months Recurrence	Yes	0 (0%)	0 (0%)	1 (3%)	1 (6.25%)	0 (0%)	0.35
	No	42 (100%)	36 (100%)	33 (97%)	16 (93.75%)	15 (100%)	
2 Years Recurrence	Yes	0 (0%)	4 (11%)	3 (8.8%)	3 (17.6%)	5 (33.3%)	0.006
	No	42 (100%)	32 (89%)	31 (91.2%)	14 (82.4%)	10 (66.7%)	

This table shows the number and percentage of patients with polyp recurrence at 2 months, 8 months, and 2 years after surgery across the five treatment groups. A Chi-square test was used to assess associations between follow-up groups and 2-year recurrence ( $P = 0.006$ ), and Cramér's V was calculated to determine effect size. A Cochran-Armitage test for trend confirmed a statistically significant linear increase in recurrence from Group 1 to Group 5 ( $Z = 3.48$ ,  $P < 0.001$ ), supporting the stratification model. See **Figure 3** for visual representation of the trend.



**Figure 3.** Postoperative recurrence rates at two years across all five treatment groups. Recurrence increased progressively with disease severity and phenotype, ranging from 0% in Group 1 (NECRSwNP) to 33.3% in Group 5 (AERD). This trend was statistically significant based on the Cochran-Armitage test for trend ( $Z = 3.48$ ,  $P < 0.001$ ).

for trend confirmed a statistically significant increase in recurrence from Group 1 to Group 5 ( $Z = 3.48$ ,  $P < 0.001$ ). Additionally, blood eosinophil count and serum IgE level were analyzed for correlation. High IgE ( $> 100$  IU/mL) was present in 94% of patients with eosinophilia, compared to 39% of those without (**Table 4**). The association was statistically significant (Chi-square test,  $P < 0.001$ ; OR = 3.15, 95% CI: 2.079-4.442; Cramér's V = 0.58).

### Discussion

This multicentric study evaluated recurrence rates of CRSwNP after FESS, stratified by disease phenotype and postoperative medical regimens. Overall, the study demonstrated a recurrence rate of 10.4% at two years, with increasing recurrence correlated to disease severity and phenotype. The recurrence-free

outcome in Group 1 underscores the generally favorable prognosis of non-eosinophilic CRSwNP following surgery and short-term topical therapy. In contrast, recurrence progressively increased from Group 2 to Group 5, which included patients with eosinophilic CRSwNP and/or aspirin sensitivity. This trend was statistically significant, as confirmed by both Chi-square analysis and Cochran-Armitage trend testing, reinforcing severity stratification and the clinical relevance of severity-specific postoperative care. The cur-

rent findings align with prior studies emphasizing the more aggressive and refractory nature of eosinophilic CRSwNP (ECSRwNP) and AERD-associated disease. Nakayama et al. previously highlighted that eosinophilic inflammation predicts poorer outcomes and a higher risk of recurrence after FESS [16]. Likewise, Likness et al. demonstrated that increased tissue eosinophilia is linked to early polyp recurrence and diminished corticosteroid responsiveness [11].

Postoperative modified Lund Kennedy scores decreased substantially across all groups, supporting the role of standardized endoscopic scoring systems in long-term monitoring. This modified system, which eliminates crusting and scarring scores, has been shown to correlate more strongly with patient-reported outcome measures than other systems, and its use in

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**Table 4.** The relationship between IgE and blood eosinophil count

	IgE Count		P-Value
	Less Than or Equal to 100 IU/mL	More Than 100 IU/mL	
Blood Eosinophil Count	Less than $0.44 \times 10^9/L$	37 (61%)	< 0.001
	More than or Equal to $0.44 \times 10^9/L$	24 (39%)	

This table displays the distribution of serum IgE levels in relation to blood eosinophil count, with eosinophilia defined as  $\geq 0.44 \times 10^9/L$ . A Chi-square test confirmed a statistically significant association ( $P < 0.001$ ,  $df = 1$ ), with a strong effect size (Cramér's  $V = 0.58$ ). Patients with eosinophilia were significantly more likely to have elevated IgE levels (OR = 3.15, 95% CI: 2.08-4.44). Notably, 6% of patients with high IgE did not exhibit elevated blood eosinophils, indicating partial but not complete overlap between these markers.

this study allowed consistent evaluation across phenotypes [10]. Also, serologic markers such as elevated IgE were significantly more prevalent in eosinophilic patients. While not used as grouping criteria, this correlation adds to the evidence base supporting IgE as a surrogate marker of type 2 inflammation in CRSwNP [17].

Patients with AERD (Group 5) had the highest recurrence rate at 33.3%. This finding aligns with the known challenges in managing AERD-associated CRSwNP [17]. Although aspirin desensitization has been shown to reduce recurrence following FESS in this patient population, it was not implemented in the present study due to the lack of specialized centers capable of offering this intervention in the study region. Future research may explore the potential benefit of combining this severity-based treatment approach with aspirin desensitization in AERD cases.

Although not a predefined objective, intraoperative observations highlighted several anatomical sites prone to residual disease if inadequately addressed. These included the lacrimal recess, axilla of the middle turbinate, Passavant space, Herzallah cell, Haller's cells, the olfactory cleft, the medial surface of the middle turbinate, and the periphery of the maxillary sinus ostium. Intraoperatively, if these regions are addressed carefully, it may lead to a reduction in the likelihood of recurrence. Additionally, stabilization of the middle turbinate and prevention of postoperative lateralization was found to be essential for maintaining the efficacy of postoperative topical steroid irrigation.

The findings in this study highlight the clinical utility of tailoring postoperative medical therapy based on disease severity and phenotype in CRSwNP. Stratifying patients by radiologic and endoscopic scores, eosinophilic status, and

aspirin sensitivity allowed for a targeted escalation of treatment, which appeared to reduce recurrence after FESS. This approach may be particularly valuable in settings where biologic agents are unavailable or unaffordable, offering a structured and accessible alternative through optimized use of steroids, irrigations, and oral corticosteroids. However, the study's non-randomized design and the absence of a control group not receiving postoperative therapy limit the strength of the conclusions. The exclusion of biologic therapy, due to its unavailability and lack of regulatory approval in the study setting, further restricts direct comparison with current guideline-based care. Despite these limitations, the statistically significant findings support the potential utility of this stratified model, and future randomized studies with larger cohorts may validate its effectiveness with greater precision.

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### Disclosure of conflict of interest

None.

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