ORIGINAL ARTICLE

Value of Dupilumab in Egyptian Cases of Chronic Rhinosinusitis with Nasal Polyps

Sameh M. Zamzam [a,*], Ahmed M. Seleim [b], Rania G. Hanafy [c], Osama A. Hassan [a]

[a] Department of E.N.T, Kasr Alainy Hospital, Cairo university, Cairo, Egypt
[b] Department of E.N.T, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt
[c] Department of E.N.T, Railway Hospital, Ramsis, Egypt

Abstract

Introduction: ***Dupilumab is a biologic agent and a monoclonal antibody that blocks receptors on IL4,13. It's indicated in specific cases of CRSwNP, it decreases symptoms, polyps' size and opacification in CT.***

Aim: ***This study aimed to assess the effect of dupilumab on Egyptian patients with chronic rhinosinusitis with nasal polyps.***

Methods: ***This is a triple-centre prospective cohort study, conducted on 50 adult patients of both sexes with chronic rhinosinusitis with nasal polyps that fulfil EPOS 2020[7] criteria for case selection for biologic treatment at the otolaryngology departments of Cairo and Al-Azhar Universities and Railway hospital from October 2024 to May 2025. The study was approved by the ethical committee of the Faculty of Medicine, Cairo University, Egypt, with IRB number (N-396-2024).***

Results: ***Before treatment, most patients (58%) had a maximum score of 24, with no patients scoring below 14. After six months, the most common post-treatment score was 16, recorded in 44% of patients, with a highly significant difference compared to baseline (P < 0.0001).***

Conclusion: ***Dupilumab is an effective biologic treatment for chronic rhinosinusitis with nasal polyps with type 2 inflammation. It showed a significant decrease in the CT scoring system in all sample sizes, with improved quality of life.***

Keywords: CRSwNP; Dupilumab; EPOS 2020; SNOT-22; Lund Mackay score

1. Introduction

Chronic rhinosinusitis with nasal polyps (CRSwNP) is one of the most common nasal and sinus problems worldwide. It's a type 2 inflammatory process mediated by different types of interleukins (IL-4, IL-5, IL-13) and cytokines. Patients develop a cascade of symptoms entailing nasal obstruction, mucoid discharge, anosmia, and sleep apnea that may affect life quality. Treatment clues include medical treatment in the form of systemic and topical steroids up to functional endoscopic sinus surgery in resistant cases, but unfortunately, some cases couldn't receive systemic steroids, and not all patients can accept surgical treatment or are unfit for general anaesthesia. [1,2,3]

Immunotherapy or biologic treatment is one of the recently emerged worldwide treatments for different cases of allergic diseases like asthma and chronic skin eczema. Immunotherapy is a medicine that interferes with the inflammatory process of allergy. Dupilumab is an immunotherapeutic agent and a monoclonal antibody. It blocks receptors of IL4,13. It's indicated in specific cases of CRSwNP, it decreases symptoms, polyps' size and opacification in CT. [4,5,6]

This study aimed to assess the value of dupilumab in Egyptian patients with chronic rhinosinusitis with nasal polyps.

Accepted 20 July 2025.
Available online 31 August 2025

* Corresponding author at: E.N.T, Kasr Alainy Hospital, Cairo university, Cairo, Egypt.
E-mail address: samehzamzam@cu.edu.eg (S. M. Zamzam).

https://doi.10.21608/aimj.2025.394383.2570

2. Patients and methods

This is a triple-centre prospective cohort study, conducted on 50 adult patients of both sexes with chronic rhinosinusitis with nasal polyps that fulfil EPOS 20207 criteria for case selection for biologic treatment at the otolaryngology departments of Cairo and Al-Azhar Universities and Railway Hospital from October 2024 to May 2025. The study was approved by the ethical committee of the Faculty of Medicine, Cairo University, Egypt, with IRB number (N-396-2024).

Sample size included in this study fulfils EPOS 2020[7] criteria, considering biologics in patients that are uncontrolled despite good medical treatment and previous successful sinus surgery, and fulfil at least 3 of the following five criteria:

A presence of type 2 inflammation: the blood eosinophils ≥150 cells/mL. or serum IgE ≥ 100 IU/mL

Regular need for systemic corticosteroids: ≥ 2 courses per year or long-term "≥ 3 months" low-dose steroids.

SNOT-22 ≥ 40

Loss of smell

Comorbid asthma: proven cases of bronchial asthma on regular use of inhaled corticosteroids.

Cases were excluded from the study: chronic rhinosinusitis without polyps (CRSsNP), patients younger than 18 years, who did not meet 3 out of 5 of EPOS 2020 criteria, and didn't undergo medical or surgical treatment unless contraindicated or refused. Prior failure or reaction to biologic treatment, or refusal by patients to participate in the study.

Steps in detail:

Pre-administration of the Dubilumab

Diagnosis of cases of chronic rhinosinusitis with nasal polyps clinically and radiologically.

Blood eosinophilic level.

Serum IgE level.

SNOT-22 score. [8]

Assessment of CT findings by the Lund Mackay scoring system. [9]

Administration of the drug (Dupilumab prepared syringe 300mg/2ml = 1 shot) 1

Loading dose: 2 shots SC once in the deltoid region (Day Zero)

Maintenance doses: 1 shot after day zero by 2 weeks to be repeated every 2 weeks until the end of the sixth month. (12 shots).

Re-assessment by CT and the Lund-Mackay scoring system at the end of the sixth month.

Reducing dose: to 1 shot monthly during follow-up

Statistical analysis:

Statistical analysis has been carried out with SPSS 27®, Graph Pad Prism® and Microsoft Excel 2016. All qualitative data were presented as Frequency (N) and percentages (%), and all comparisons were performed by using the chi-square test and Fisher's Exact test. The significance level was set at P ≤0.05.

3. Results

This study included 50 cases, 45 males and 5 females with age range 34-63 years.

The data in Table 1 demonstrates the prevalence of EPOS 2020 criteria among the study population. Notably, 100% of patients reported regular use of systemic corticosteroids, loss of smell, and a SNOT-22 score of ≥ 40. Elevated serum IgE levels (>100 IU/ml) were found in 94% of patients. Additionally, a high eosinophilic count (>150 cells/mcL) was observed in 98% of cases. Asthma was present in 78% of patients, a lower proportion compared to other criteria, and this difference was statistically significant as P = 0.0005, figure 1.

Table 1. EPOS 20 criteria for patients' selection in the sample size

EPOS 2020 CRITERIA	NUMBER OF PATIENTS (N=50)	PERCENTAGE	P VALUE
ELEVATED SERUM IGE > 100 IU/ML	47 [a]	94.00%	0.0005*
HIGH EOSINOPHILIC LEVEL > 150 CELLS/MCL	49 [a]	98.00%	
REGULAR USE OF SYSTEMIC CORTICOSTEROIDS	50 [a]	100.00%	
LOSS OF SMELL	50 [a]	100.00%	
SNOT-22 ≥ 40	50 [a]	100.00%	
ASTHMA	39 [b]	78.00%	

*Significant difference as P ≤ 0.05.

N with different superscript letters were significantly different as P ≤ 0.05.

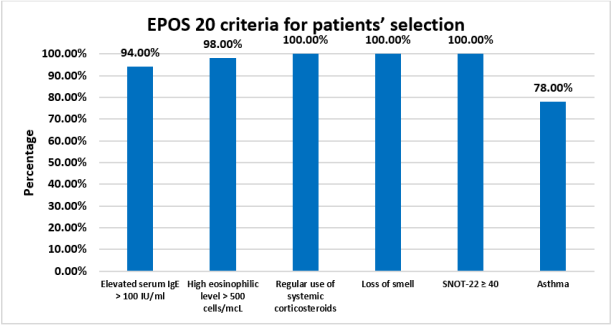

Figure 1. bar chart showing EPOS 20 criteria for patients' selection in the sample size.

The data presented in Table 2 describes the distribution of Lund-Mackay scores. A Lund-Mackay score of 24, representing 58% of patients, which was statistically significant (P < 0.0001) the highest. Other scores, including 23, 20, 18, 16, and 14, were found in 12%, 12%, 8%, 6%, and 4% of patients respectively, indicating they were significantly less frequent than the score of 24, figure 2.

Table 2. Lund-Mackay score pre-administration of Dupilumab in the sample size

LUND MACKAY SCORE	NUMBER OF PATIENTS	PERCENTAGE	P VALUE
24	29	58.00%	<0.0001*
23	6	12.00%	
20	6	12.00%	
18	4	8.00%	
16	3	6.00%	
14	2	4.00%	

*Significant difference as P ≤ 0.05.

N with different superscript letters were significantly different as P ≤ 0.05.

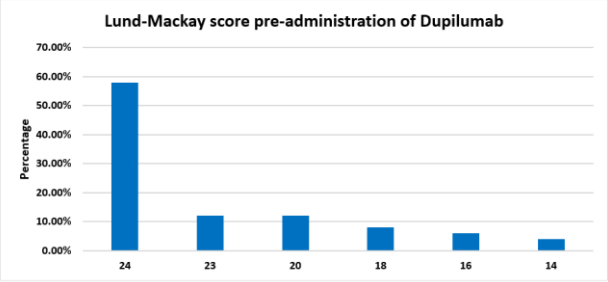

Fig. 2: bar chart showing Lund-Mackay score pre-administration of Dupilumab.

The data in Table 3 reveal significant changes in Lund-Mackay scores following six months of Dupilumab treatment in the study cohort using Fishers Exact test which revealed that:

Before treatment, most patients (58%) had a maximum score of 24, indicating severe radiological disease, with no patients scoring below 14.

After six months, none of the patients retained the highest scores (24, 23, 20, or 18). The most common post-treatment score was 16, recorded in 44% of patients, with a highly significant difference compared to baseline (P < 0.0001), figure 3

Additionally, lower scores of 12, 10, 8, 7, 6, and 4 emerged after treatment, which were absent before therapy, demonstrating a shift toward milder disease categories, figures 6-12.

Table 3. Lund-Mackay score comparison pre and post administration of Dupilumab in the sample size

	PRE-ADMINISTRATION		POST 6 MONTHS		P VALUE
LUND MACKAY SCORE	Number of patients	Percentage	Number of patients	Percentage	
24	29	58.00%	0	0	-----
23	6	12.00%	0	0	-----
20	6	12.00%	0	0	-----
18	4	8.00%	0	0	-----
16	3	6.00%	22	44.00%	<0.0001*
14	2	4.00%	2	4.00%	1.00
12	0	0	11	22.00%	-----
10	0	0	9	18.00%	-----
8	0	0	2	4.00%	-----
7	0	0	2	4.00%	-----
6	0	0	1	2.00%	-----
4	0	0	1	2.00%	-----

*Significant difference as P ≤ 0.05.

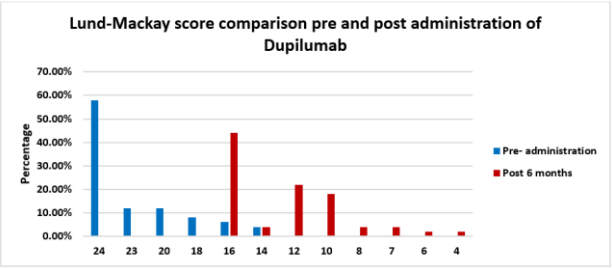

Figure 3. bar chart showing Lund-Mackay score comparison pre and post administration of Dupilumab.

After 6 months of Dupilumab administration, significant clinical and laboratory improvements were observed across multiple EPOS 2020 criteria and presented in table 4, all comparisons were performed by using Chis square test which revealed that:

Elevated Serum IgE: At baseline, 47 patients (94%) had elevated serum IgE levels (>100 IU/ml). After 6 months of Dupilumab administration, 43 patients (91.5%) showed improvement, and among them, 4 cases (8.5%) achieved normalization of their IgE levels. This reduction was statistically significant with a P value of <0.0001.

High Eosinophilic Level: Initially, 49 patients (98%) presented with high blood eosinophil counts (>150 cells/mcL). Post-treatment, 45 cases (91.8%) demonstrated improvement, with 2 cases (4.2%) returning to normal values. This change was also statistically significant, with a P value of <0.0001.

Regular Use of Systemic Corticosteroids: Before Dupilumab, all 50 patients (100%) were dependent on regular systemic corticosteroids. After 6 months of therapy, none of the patients required systemic corticosteroids, maintaining a 100% cessation rate. As no variation occurred, no P value was applicable.

Loss of Smell: All 50 patients (100%) suffered from anosmia before treatment. After 6 months of Dupilumab, all 50 cases (100%) reported improvement in their sense of smell, reflecting a complete response in this parameter.

SNOT-22 scores: Pre-administration, all 50 patients (100%) had SNOT-22 scores ≥40, indicating significant symptom burden. Post-treatment, all cases (100%) showed a reduction in their SNOT-22 scores to less than 40, denoting marked symptomatic relief.

Asthma Control: Among the cohort, 39 patients (78%) had concomitant asthma. After 6 months, 16 cases (41.1%) were able to stop using steroid inhalers following improvement, while 23 cases (58.9%) continued with inhaler therapy but with notable symptomatic improvement. This change, however, did not reach statistical significance, with a P value of 0.13, figures 4,5.

Table 4. EPOS 2020 criteria comparison pre and post administration of Dupilumab in the sample size

2020 CRITERIA	PRE-ADMINISTRATION		POST 6 MONTHS OUTCOME			P VALUE
	Number of patients	Percentage (%)		Number of patients	Percentage (%)	
ELEVATED SERUM IGE > 100 IU/ML	47	94	Improved	43	91.5	<0.0001*
			Normalized	4	8.5	
HIGH EOSINOPHILIC LEVEL > 150 CELLS/MCL	49	98	Improved	45	91.8	<0.0001*
			Normalized	2	4.2	
REGULAR USE OF SYSTEMIC CORTICOSTEROIDS	50	100	Not received within 6 months	50	100	------
LOSS OF SMELL	50	100	Improved	50	100	------
SNOT-22 ≥ 40	50	100	Score less than 40	50	100	------
ASTHMA	39	78	Improved, stopped inhaler	16	41.1	0.13
			Improved, continued inhaler	23	58.9	

*Significant difference as P ≤ 0.05.

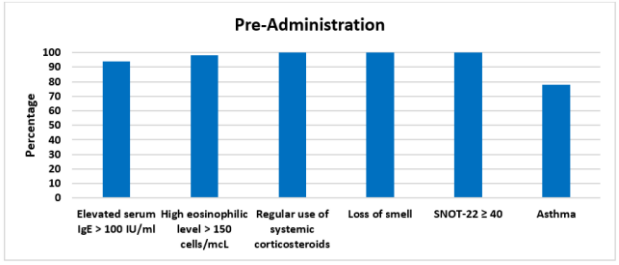

Figure 4. bar chart showing EPOS 2020 criteria pre administration of Dupilumab.

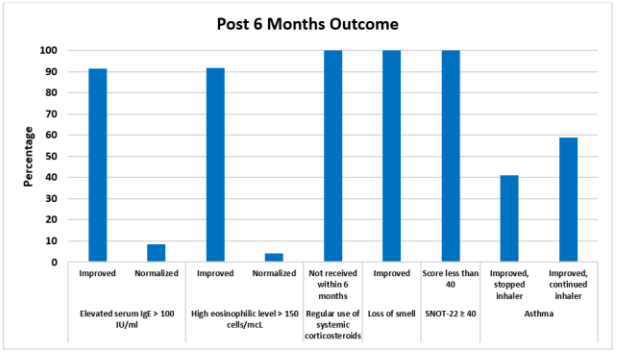

Figure 5. bar chart showing EPOS 2020 criteria post administration of Dupilumab.

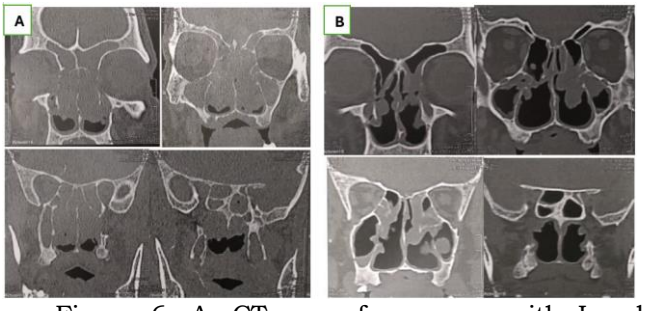

Figure 6. A: CT scan for a case with Lund Mackay score 24 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 8 after 6 months of administration of dupilumab

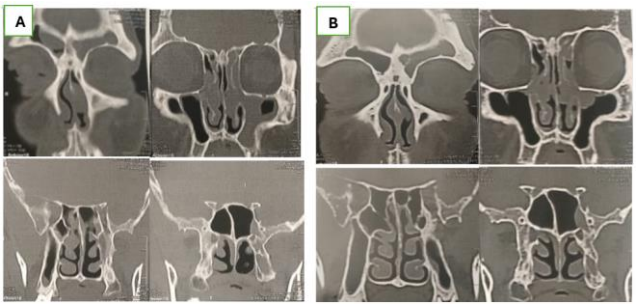

Figure 7. A: CT scan for a case with Lund Mackay score 14 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 8 after 6 months of administration of dupilumab

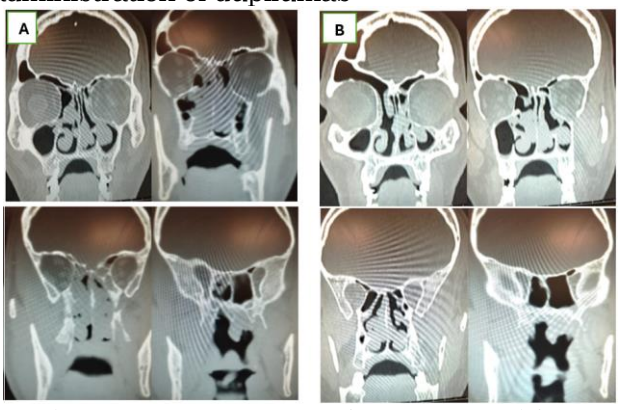

Figure 8. A: CT scan for a case with Lund Mackay score 14 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 6 after 6 months of administration of dupilumab

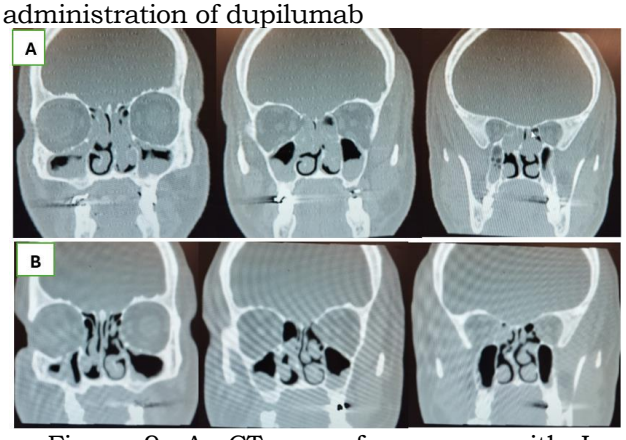

Figure 9. A: CT scan for a case with Lund Mackay score 23 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 7 after 6 months of administration of dupilumab

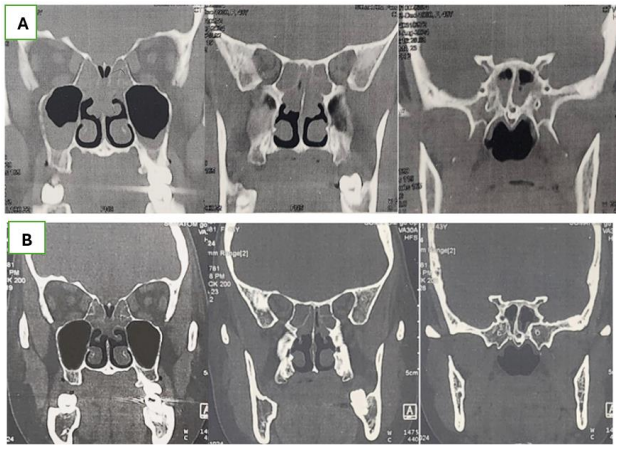

Figure 10. A: CT scan for a case with Lund Mackay score 16 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 10 after 6 months of administration of dupilumab

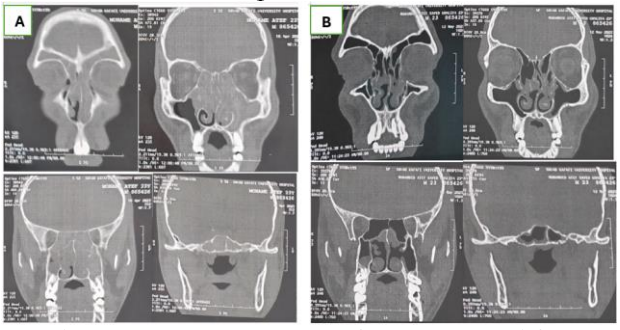

Figure 11. A: CT scan for a case with Lund Mackay score 18 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 10 after 6 months of administration of dupilumab

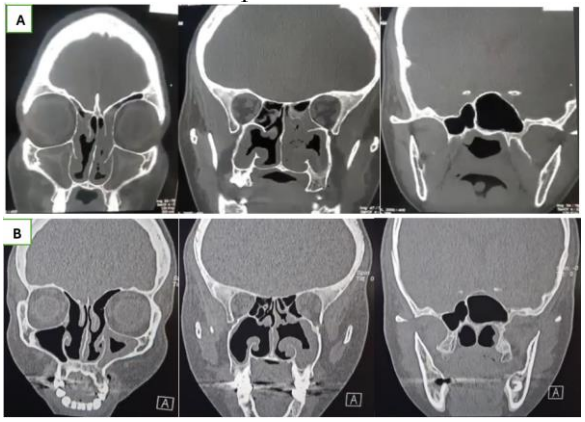

Figure 12. A: CT scan for a case with Lund Mackay score 20 before administration of dupilumab. B: CT scan for the same case with Lund Mackay score 4 after 6 months of administration of dupilumab

4. Discussion

In this study, the authors faced a dilemma regarding “study duration and follow-up period”; however, there is no clear established rule about “when to stop biological treatment?”[10-13], the authors thought that from an ethical perspective, it is necessary to follow up this group of patients routinely with administration of the reduced dose of dupilumab. But every study should have an end. The authors thought to evaluate the effect of dupilumab at the end of the sixth month by CT “Lund-Mackay scoring system” to publish the results of this study.

Biologic is a treatment option for chronic rhinosinusitis with nasal polyposis (CRSwNP), particularly those who are of type 2 inflammatory reaction. Different types of biologics are available worldwide nowadays: dupilumab, mepolizumab, and omalizumab have shown promising results in reducing polyp size, improving smell, and improving quality of life. CRSwNP is type 2 immunity and is often characterised by elevated levels of cytokines and IL-4, IL-5, and IL-13. Dupilumab works on blocking IL-4Ra, a receptor for IL-4 and IL-13, Mepolizumab inhibits IL-5, Omalizumab neutralises IgE, all three types of biologics potentially reducing the severity of type 2 inflammation and CRSwNP.[14]

In the current study, patients were asked to stop routine medications for nasal polyps, with no nasal surgeries being done during the study duration. Authors noticed a significant response to the all-sample size, especially those with high Lund Mackay scores, but no case reached a score of zero. All cases showed a decrease in serum IgE and eosinophils with improved QoL and smell.

The current study agrees with a study on dupilumab in 2016 on 60 patients, which demonstrated that dupilumab provided a significant decrease in nasal polyp score of approximately 2 points, out of a maximum score of 8.[15]

Other studies also declared that dupilumab is highly effective in reducing the CT-scan-based Lund Mackay-Score, improving smell function and quality of life, and changes in the Sinonasal Outcome Test (SNOT-22).[16-17]

In the current study, we noticed no adverse effect unless a few cases developed a reaction at the injection site; on the other hand, another study noticed nasopharyngitis and headache.[18]

A study on mepolizumab in 105 subjects over 25 weeks showed a reduction in the need for surgery for CRSwNP, with a significant reduction of symptom scores, nasal polyp score and SNOT-22, with no longer required surgery.[19]

A study included more than 700 adult patients allocated into two groups: dupilumab vs. topical nasal steroid spray over 1 year. The outcome was a significant decrease in Lund-Mackay CT in the dupilumab group compared to the topical steroid group at 24 weeks .[10]

A retrospective cohort study over 5 years on 2208 patients, 89.8% received dupilumab, mepolizumab in 5.3%, omalizumab in 4.8%, during the 24 months after biologic initiation,

patients showed a decrease in oral corticosteroid use by 65% and sinus surgery by 7%.[20]

Another study over one year on 642 patients (58% male, mean age 48 years), 89% are asthmatics, the authors noticed that these patients had high oral steroids 68.8% and less sinus surgery 11.6%.[21]

Scientific studies should mention its drawbacks: it's very difficult to afford biologic in some countries as it's very expensive, that's why the study sample size is small although it was collected from 3 centers, also we suggest future studies on some ideas like combination of 2 or 3 biologics, and use of biologics with routine anti-allergic treatment and topical and systemic steroids, also follow up on the long run is highly recommended.

4. Conclusion

Dupilumab is an effective biologic in controlling chronic rhinosinusitis with nasal polyps with type 2 inflammation. It showed a significant decrease in the CT scoring system in all sample sizes, especially those who have high scores, with improved quality of life and smell.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

Funding

No Funds : Yes

Conflicts of interest

There are no conflicts of interest.

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