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Real-World Evaluation of Asthma Severity Following Endoscopic Sinus Surgery in Chronic Rhinosinusitis Patients

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Abstract

Objective. This study aimed to evaluate the impact of endoscopic sinus surgery (ESS) on asthma severity up to 12 months after surgical intervention.

Study Design. Retrospective cohort.

Setting. Tertiary care center.

Methods. Patients with a history of asthma and Chronic Rhinosinusitis (CRS) who underwent ESS between 2013 and 2023 were included. Asthma severity was assessed according to current Global Initiative for Asthma (GINA) guidelines, classifying patients into mild, moderate, and severe based on medication requirements. Asthma severity was evaluated up to 3 months prior to ESS and 1-year post-ESS. Patients with aspirin-exacerbated respiratory disease (AERD) were excluded. Statistical analysis was performed using McNemar test and Wilcoxon signed-rank test to assess differences in asthma severity, medication doses, and number of medications.

Results. Sixty-five patients were included, of which 44 (67.7%) had CRS with nasal polyps (CRSwNP) and 21 (32.3%) had CRS without nasal polyps (CRSsNP). No significant differences were found in asthma severity pre- and post-ESS ($P = .175$). Similarly, no differences were found in ICS doses ($P = .999$), total number of prescribed medications ($P = .157$) or presence of exacerbations before and after ESS ($P = .078$). However, a significant increase in time from last rescue inhaler use was noted after ESS, increasing from a median of 6.71 to 23.1 weeks ($P = .004$).

Conclusion. This study is the first to assess the impact of ESS on asthma severity in a real-world setting. Our findings suggest that ESS does not impact asthma severity classification. However, it might provide relief of asthma symptoms in the early postoperative period.

Keywords

asthma, chronic rhinosinusitis, endoscopic sinus surgery, rhinosinusitis, sinusitis

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Chronic rhinosinusitis affects up to 12% of the global population, while asthma impacts around 300 million individuals worldwide.[1–3] These prevalent inflammatory diseases are believed to be linked, according to the unified airway disease (UAD) theory, which suggests a common pathogenic origin based on anatomic, histologic, and immunological similarities among CRS, asthma, and allergic rhinitis (AR) conditions.[4–7] There is strong evidence supporting the association between asthma and CRS, as 20% to 40% of asthmatics have a diagnosis of CRS with nasal polyps (CRSwNP), and the majority of patients with nasal polyposis are reported to have increased severity of asthma.[7] This link is so well described that the most recent International Consensus of Allergy and Rhinology (ICAR) publication recommended that patients with CRSwNP be screened for asthma and potentially undergo diagnostic testing such as pulmonary function test (PFT) regardless of active asthma symptoms.[8]

Chronic rhinosinusitis in its most simplistic form can be divided into CRS with and without polyps, however, the underlying pathophysiology is quite heterogeneous.[9] Several studies have looked at clinical asthma outcomes after endoscopic sinus surgery for CRSwNP and most have found a positive response using asthma symptoms scores and objective respiratory testing.[10] In fact, many studies have noted a reduction in inhaled corticosteroids after ESS for nasal polyps.[11] There is, however, limited

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data on the effect of ESS on asthma severity in patients with CRS as a whole. Specifically, CRSsNP has not been independently studied in relation to asthma at nearly the rate of those with CRSwNP.

The Global Initiative for Asthma (GINA) was formed in 1993 based on the need to better understand and guide treatment algorithms for asthma.[12] Prior to 2009, the classification had four categories: intermittent, mild persistent, moderate persistent, and severe persistent. However, this classification was primarily designed as a guide for treatment in patients who had not received inhaled corticosteroid (ICS) treatment.[12] More recently, the GINA guidelines have focused on determining the effectiveness of treatment and providing improved assessments of asthma control. The current classification system categorizes asthma as mild, moderate, or severe, based on the level of treatment required to control symptoms and prevent adverse outcomes.[2] This allows clinicians to determine the appropriate level of treatment and consider the dynamic changes in asthma severity over time. To date, there are no studies using this classification system to determine the impact of ESS on changes in asthma control.

Numerous studies have investigated the impact of ESS on asthma; however, most have focused on evaluating the improvement of objective parameters such as PFT and asthma control scores. The current body of literature has sufficient evidence to conduct 2 systematic reviews and meta-analysis on asthma and chronic rhinosinusitis.[11,13] Interestingly, these reviews had differing conclusions regarding the impact of ESS on PFT. However, they both concluded that additional studies are needed to address the effect of surgery on asthma control. Real-world studies of asthma severity have been performed to try and better understand the impact of medical therapy on asthma severity.[10,14] This type of study is invaluable to a better understanding of the effect of medical and surgical interventions associated with asthma, especially because of the known poor adherence and compliance to ICS therapy in the asthma population. To date, the evidence regarding the real-world effect of ESS in asthma remains inconclusive. This study aims to examine the real-life impact of ESS on asthma severity and the trends in asthma treatment up to twelve months after surgery.

Methods

Data Source

This is a Mayo Clinic Institutional Review Board (IRB: 19-009198) approved retrospective observational study including patients with CRS and comorbid asthma who underwent ESS between 2013 and 2022 in Arizona, Florida, or Minnesota. Data were collected from EPIC electronic medical records (EMR) and stored in a secure web-based database system for research (REDCap).[15]

Study Population

This study included patients with CRS undergoing ESS who had been diagnosed with asthma prior to the date of surgery. CRS diagnosis and indications for surgery followed the ICAR guidelines.[8] Inclusion criteria required, information about medication usage and asthma exacerbations up to 3 months prior surgery, as well as a detailed documentation from the postoperative period, up to a year after surgery. Only participants who fulfilled all these criteria were included in the final analysis. Patients (1) who did not have a CRS diagnosis, (2) did not undergo ESS, (3) had concomitant diagnosis of acute exacerbated respiratory disease (AERD), (4) were under 18 years of age, or (5) had incomplete documentation regarding their asthma evaluation, CRS medical therapies, use of asthma medications and last asthma exacerbation were excluded. Patient demographics, past medical history, smoking history, and asthma and rhinologic history were obtained through a chart review.

Variable Definitions

Asthma severity was assessed according to the GINA 2024 guidelines.[2] Using medical records up to 3 months before and up to 12 months after endoscopic sinus surgery, patients were initially categorized into 1 of the 5 steps of treatment, based on current asthma medical therapy. Patients were subsequently identified as having mild, moderate, or severe asthma. Mild asthma included patients receiving steps 1 or 2 level of treatment, moderate asthma included those treated with steps 3 or 4 level of therapy, and severe asthma were those with step 5 level of treatment.

We adhered to the GINA definition of controller and reliever medications. Controller medications are those meant to be used daily as a maintenance medication. Reliever medication is a rescue inhaler used to alleviate acute asthma symptoms.[2]

The GINA guidelines outline 2 tracks for treatment of asthma. In the preferred track, Steps 1 and 2 involve using a low-dose inhaled corticosteroid (ICS)-formoterol on an as needed basis. Step 3 requires a low-dose maintenance ICS, Step 4 includes a medium-dose maintenance ICS-formoterol, while Step 5 requires a high-dose ICS-formoterol, along with an expert evaluation and the need for extra medications.[2] In the alternative approach, Step 1 includes using ICS whenever SABA is taken, Step 2 involves low-dose maintenance ICS, Step 3 requires a medium dose ICS combined with a long-acting beta-agonist (LABA). For Step 4, the patient required a medium/high dose of ICS-LABA while Step 5 involves adding a long-acting muscarinic antagonist (LAMA) and an expert evaluation.[2] We considered both tracks for this study.

For the purpose of this study, asthma exacerbation was defined as asthma symptoms requiring a visit to the emergency department or hospitalization. In addition, we also collected the time in weeks since the last use of a reliever inhaler.

Statistical Analysis

The Shapiro-Wilk test evaluated the normal distribution of the data. Descriptive statistics were used to report baseline characteristics of the population.

Statistical analysis was performed using McNemar test and Wilcoxon signed-rank tests to assess paired differences in asthma severity, step of treatment, presence of exacerbation, and time since last use of a reliever.

All statistical analyses were performed using R statistical software and RStudio environment version 2023.06.0 + 421. The significance level was set at $P < .05$.[16] The outcomes were reported with 95% confidence interval (CI) and effect size when appropriate.

Results

Population Characteristics

A total of 65 patients met inclusion criteria for the study. The mean age of the population was 55.8 years (SD 12.8) with a 2.09:1 M:F ratio. Of the total participants, 67.7% had CRSwNP and 32.3% had CRSsNP. Asthma severity groups were evenly distributed, with 22/65 (33.8%) having mild, 24/65 (37%) having moderate, and 19/65 (29.3%) having severe asthma. The most prevalent comorbidities included allergic rhinitis (AR) in 68.8% of the population, followed by gastroesophageal reflux disease (GERD) and obesity in 42.2% and 29.7% respectively. **Table 1** details baseline characteristics of the population. The mean duration of follow up after ESS was 8.37 months (SD = 2.8).

Asthma Severity After ESS

Table 2 demonstrates the differences preoperatively and postoperatively in disease severity and trends of treatment. There were no significant differences in asthma severity after ESS in any of the asthma groups. The number of patients with mild asthma decreased from 22 to 17 cases ($P = .130$). The total number of patients in the moderate asthma group increased slightly from 24 to 25 ($P = .999$). In addition, the number of patients with severe asthma increased from 19 to 23, which was not statistically significant ($P = .288$).

ESS Versus Trends in Treatment

No significant differences were observed for the steps of treatment following ESS. However, each step of treatment had a small reduction in the number of patients in it after surgery, except for steps 3 and 5. The total number of patients in step 5 increased from 19 patients pre-ESS to 24 post-ESS without reaching statistical significance ($P = .182$).

Table 1. Baseline Characteristics of Asthma-CRS Patients

	Total n = 65	Mild asthma n = 22	Moderate asthma n = 24	Severe asthma n = 19	*P* value
Age[a]	55.80 (12.80)	56.82 (12.25)	53.0 (14.65)	58.16 (10.76)	.787
Sex					
Male	34 (52.3)	10 (54.5)	12 (50)	12 (63.20)	.506
Female	31 (47.7)	12 (45.5)	12 (50)	7 (38.7)	
Race					
White	61 (93.8)	22 (100)	22 (91.7)	17 (89.5)	.577
Black	1 (1.5)	-	1 (4.2)	-	
Other	3 (4.7)	-	1 (4.2)	2 (10.5)	
CRS subtype					
CRSwNP	44 (67.7)	17 (77.3)	16 (66.7)	11 (57.9)	.413
CRSsNP	21 (32.3)	5 (22.7)	8 (33.3)	8 (42.1)	
Smoking					
Former	18 (27.7)	8 (36.4)	4 (16.7)	6 (31.6)	.297
Never	47 (72.3)	14 (63.6)	20 (83.3)	13 (68.4)	
Past medical history					
BMI[a]	29.4 (5.56)	29.01 (5.85)	29.73 (5.35)	29.66 (5.9)	.326
Allergic rhinitis	44 (68.8)	16 (72.7)	18 (75.0)	10 (55.6)	.357
GERD	27 (42.2)	8 (36.4)	9 (37.5)	10 (55.6)	.398
Obesity	19 (29.7)	7 (31.8)	6 (25)	6 (33.3)	.812
Anxiety	18 (28.1)	7 (31.8)	8 (33.3)	3 (16.7)	.475
OSA	16 (25.0)	5 (22.7)	6 (25)	5 (27.8)	.937
Diabetes	9 (14.1)	2 (9.1)	4 (16.7)	3 (16.7)	.734

Abbreviations: BMI, body mass index; CRS, chronic rhinosinusitis; CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; ESS, endoscopic sinus surgery; GERD, gastroesophageal reflux disease; OSA, obstructive sleep apnea; -, No data.

[a]Mean (standard deviation).

Table 2. Asthma Severity and Trends of Treatment Pre- and Post-ESS

	Pre-ESS	Post-ESS	*P* value
Asthma severity			**.175**
Mild asthma	22	17	.130
Moderate asthma	24	25	.999
Severe asthma	19	23	.288
Asthma step of treatment			
Step 1	14	10	.220
Step 2	9	7	.723
Step 3	5	7	.723
Step 4	18	17	.999
Step 5	19	24	.182
ICS dose			
Low ICS	12	13	.999
Moderate ICS	22	26	.999
High ICS	16	16	.999
Number of medications prescribed			
Total medications	3.11 (1.55)	3.39 (1.65)	.157
Asthma disease control			
Time since last use of reliever [a,b]	6.71 (0.34-41.3)	23.1 (16.5-36)	.004
Exacerbation	16	12	.078
SNOT 22	43 (29.5-51)	17 (9.5-32)	<.001

Abbreviations: ESS, endoscopic sinus surgery; ICS, inhaled corticosteroid.
[a]Median (interquartile range).
[b]in weeks.

Table 3. Phenotype Distribution of the Population

	CRSwNP n = 44	CRSsNP n = 21	*P* value
Age[a]	56.05 (12.37)	55.29 (12.25)	.825
Sex			
Male	26 (59.1)	8 (38.1)	.187
Female	18 (40.9)	13 (61.9)	
Race			
White	41 (93.2)	20 (100)	.742
Black	1 (2.3)	-	
Other	2 (4.6)	1 (2.3)	
Smoking			
Former	32 (72.7)	15 (71.4)	.999
Never	12 (27.3)	6 (28.6)	
BMI[a]	29.51 (5.76)	29.34 (5.25)	.639
Allergic rhinitis	30 (69.8)	14 (66.7)	.999
GERD	17 (42.2)	10 (47.6)	.730
Obesity	14 (32.6)	5 (23.8)	.669
Anxiety	10 (23.3)	8 (38.1)	.246
OSA	11 (25.6)	5 (23.8)	.999
Diabetes	4 (9.3)	5 (23.8)	.140

Abbreviations: BMI, body mass index; CRS, chronic rhinosinusitis; CRSsNP, chronic rhinosinusitis without nasal polyps; CRSwNP, chronic rhinosinusitis with nasal polyps; ESS, endoscopic sinus surgery; GERD, gastroesophageal reflux disease; OSA, obstructive sleep apnea.
[a]Mean (standard deviation).
[b]Median (interquartile range).

No significant differences in ICS-dose were observed among groups in our study. The number of patients receiving low-ICS dose prescription decreased after ESS ($P = .999$). However, in the moderate ICS group there was a small incremental increase from 22 to 26 ($P = .999$).

ESS Versus Asthma Control of Disease

No significant differences were found in the impact of surgery on the number of asthma exacerbations ($P = .078$). Regarding asthma symptom control, a significant improvement in the weeks since the last use of a reliever medication was observed. We found a statistically significant decrease in the use of reliever medications after ESS, from a median of 6.71 weeks pre-ESS (IQR = 0.34-41.3) to 23.1 weeks post-ESS (IQR = 16.5-36), *P*-value of 0.004. In addition, a significant improvement in quality of life and burden of CRS diseases was observed postoperatively, with SNOT-22 scores decreasing from a median of 43 (IQR = 29.5-51.5) to 17 (IQR = 9.5-32) up to 12 months after surgery ($P < .001$).

CRS Phenotypes

Tables 3 and **4** present the demographic and perioperative characteristics of the study population according to the CRS phenotype. In the CRSwNP group (n = 44) no significant differences were found among groups in the univariate analysis. Regarding the asthma severity after ESS, the number of patients with mild asthma significantly decreased from 17 to 11 ($P = .041$), postoperatively. However, no statistically significant changes were observed in the moderate (16-18) and severe (11-15) asthma categories ($P = .772$ and $P = .288$, respectively). The use of reliever medications showed a statistically significant reduction following ESS, from 6.14 weeks (IQR = 0.57-27.9) preoperatively to 22 weeks (IQR = 16.6-44.4) postoperatively ($P = .018$). While the number of exacerbations did not show differences preoperatively and postoperatively ($P = .085$).

In the CRSsNP, no significant differences were observed in asthma severity among the groups ($P = .999$). There was no significant reduction in medication use preprocedure and postprocedure ($P = .821$) nor were there differences in the number of exacerbations preoperatively and postoperatively ($P = .085$). Although the use of reliever medication did decrease after ESS from 7.29 weeks (IQR = 0.29-45.3) preoperatively to 24.29 weeks (IQR = 14.9-35.7) postoperatively, this difference did not reach statistical significance.

Discussion

Our study examined the impact of endoscopic sinus surgery on asthma severity in a real-world setting. We did not find any significant differences in asthma severity, step of treatment, ICS doses, or asthma exacerbation among asthma groups before and after surgery. This indicates

Table 4. CRS Phenotypes and Asthma Severity

CRSwNP			
	Pre-ESS	Post-ESS	*P* value
Asthma severity			
Asthma mild	17	11	.041
Asthma moderate	16	18	.772
Asthma severe	11	15	.288
ICS dose			
Low ICS	9	10	.999
Moderate ICS	17	19	.683
High ICS	8	9	.999
Number of medications prescribed			
Total medications	2.89 (1.33)	3.09(1.52)	.161
Asthma disease control			
Last use of reliever	6.14 (0.57-27.9)	22 (16.6-44.4)	.018
Exacerbation	11	7	.085
SNOT-22	43 (26.8-50.5)	16 (8.7-30.2)	<.001
CRSsNP			
	Pre-ESS	Post-ESS	*P* value
Asthma severity			
Asthma mild	5	6	.999
Asthma moderate	8	7	.999
Asthma severe	8	8	.999
ICS dose			
Low ICS	3	3	.999
Moderate ICS	5	7	.617
High ICS	8	7	.999
Number of medications prescribed			
Total medications[a]	4 (3-5)	4 (3-5)	.821
Asthma disease control			
Last use of reliever[a,b]	7.29 (0.29-45.3)	24.29 (14.9-35.7)	.108
Exacerbation	5	5	.150
SNOT-22[a]	43 (40-57)	18 (10-39.5)	.001

Abbreviations: ESS, endoscopic sinus surgery; ICS, inhaled corticosteroid.
[a]Median (interquartile range).
[b]in weeks.

that the effect of ESS on decreasing asthma severity, de-escalating treatment, or preventing exacerbations may not be seen in daily practice. However, we did find a difference in the reliever medication use, noting that ESS did prolong the time between acute asthma symptoms requiring reliever medication. This change in medication use from on average every 6.7 to 23 weeks is consistent with previously published data but highlights the need for long-term follow-up with an asthma specialist.

Several studies have suggested that there is an immediate improvement in asthma symptoms after surgery. In a randomized controlled trial involving 43 participants with CRS and asthma, a significant reduction in bronchodilator inhaler usage was observed in the postoperative period. Consistent with our study, no changes in inhaled corticosteroid usage were reported.[17] In the same study, both ESS and medical therapy significantly improved the asthma control scores (ACS) at 6- and 12-month postsurgery.[17] Uri et al[18] also reported a significant reduction of bronchodilators use presurgery and postsurgery in 34 patients with CRSwNP. Additionally, they found a reduction in the need for oral corticosteroids after surgery. However, in contrast to the previous study, they did not find a difference in the mean asthma control score preoperative and postoperative. While in the Uri study, the mean follow-up was longer than ours, at 2.1 years, our study included a larger sample size of CRSwNP patients as well as those with CRSsNP.[18] Our real-world analysis adds to the current evidence which suggests that reliever medications are less necessary during the first 6 months after the after ESS.

In our study, we separately examined the CRS phenotypes and observed consistent trends in the results. There was no variation in asthma severity or disease control among groups, except for a decrease in the proportion of mild asthma patients postoperatively for the CRSwNP groups. This, we considered, could be the result of improved adherence to medical treatment during the postoperative period. The time without the need for reliever medication increased for both phenotypes after ESS. This finding is clinically relevant, suggesting that ESS may potentially reduce the need for reliever medication in the early postoperative period. Most of the current literature is focused on analyzing the asthma severity in CRSwNP patients. Ragab et al[19] analyzed asthma phenotypes using both clinical and diagnostic measures, reporting similar results to those found in our study. In their work, no difference was observed in clinically relevant parameters including use of medications, number of hospitalizations for asthma, overall asthma control score, exhaled Nitric Oxide (eNO), Forced Expiratory Volume in 1 second as a percentage of predicted value (FEV1 [% pred]), and peak Expiratory Flow (PEF). However, our study is unique in that it examines the requirement of reliever medications pre and post-ESS, which has not been previously described. This also highlights the need for future studies to determine the mechanism behind the unsustained improvement in asthma control, in the early postoperative period.

Two systematic reviews and meta-analyses have summarized evidence on lung function improvement in patients with CRS and asthma.[11,13] The publication from 2013 concluded that ESS positively impacts symptom control, number of hospitalizations, and reduces the use of oral corticosteroids, ICS, and bronchodilators, with no significant difference in PFT (0.877).[11] Importantly, most of the treatment outcomes in the studies included in this review were based on patient reports.[20,21] In 2019, an updated systematic review was published and concluded that there was enough low-quality evidence to suggest that there is a positive association between sinus surgery and improved forced expiratory flow (FEF25-75%), forced expiratory volume at 1 second (FEV1), FEV1% predicted, and peak expiratory flow (PEF).[13] A study by Pellegrino et al,[22] concluded that an increase of ≥12% in FEV1 is considered a clinical improvement. Interestingly, only 1 of the manuscripts included in the most recent meta-analysis reported a ≥12% FEV1% improvement.[23] In this study, 70 patients with comorbid asthma and CRS were evaluated using PFTs and asthma symptoms and after surgery, FEV1% increased from 64% at baseline to 86%. However, this study did not report a p-value to determine the significance of the described changes. In our study, PFT differences after ESS could not be analyzed due to limited availability of pre- and post-surgery lung function tests.

Even with the relatively consistent improvement in clinical asthma symptoms seen after CRS, there is still no clear understanding why inconsistencies exist in results from postoperative lung function testing. Recently, the diagnosis of T2-low asthma has garnered more focus. This condition is associated with both type 1 and type 3 inflammation and is typically seen in late-onset adult asthmatics, females, obese patients, and those with frequent asthma exacerbations.[14] Patients with T2-low asthma also have less severe asthma and often do not respond to inhaled corticosteroids.[24] In our study, asthma severity did not significantly change after ESS. Despite this, there was a small increase in the number of moderate and severe cases during the postoperative period. We hypothesize that this finding may be related to re-establishment of asthma care or improved adherence to medication due to frequent follow-up visits. This unexpected finding reiterates the importance of a postoperative evaluation of asthma severity following ESS and need for future prospective studies in this area. Another possible explanation for the lack of change in asthma severity or treatment level is based on the hypothesis that CRS may directly act on the lower airway regardless of asthma status.[25] In their study on the association between bronchial wall thickening and CRS severity found that even in patients without asthma, CRS was positively correlated with an increase in bronchial wall-thickness and a decrease in FEV1. In general, decreasing the inflammation associated with the UAD may explain the short-term but consistent improvement in respiratory symptoms seen in our study and others.

Some limitations are inherent to the retrospective design of the study. First, asthma severity assessment and therapies were based on the information available in medical records. As a tertiary practice, patients often elect to receive their pulmonary care locally, limiting data retrieval. To minimize the risk of bias, and increase the validity and reliability of our results, we included only patients with information about asthma severity and treatments by allergy/immunology, pulmonology, internal medicine, anesthesiology, and otolaryngology. Additionally, our sample size was small due to the strict inclusion criteria we implemented. Given the limitations associated with real-world studies, we wanted to minimize the risk of recall bias and other confounders such as AERD patients. Finally, the patient's medical records lacked objective scores of symptom control, including the Asthma Control Test (ACT) that could have provided valuable additional insights on the impact of ESS on asthma severity.

Despite the acknowledged limitations, our findings present real-word practice evidence and highlights the importance of developing multidisciplinary guidelines for managing patients with comorbid asthma and CRS. Findings from this study also suggest that timely follow-up with an asthma specialist at key postoperative periods such as 3 and 6 months, may allow for optimization of medical therapy and minimize long-term exacerbations. Additional research on the long-term benefits of ESS and the underlying factors associated with the increased use of reliever medications for acute symptoms after 6 months is needed.

Conclusion

Our findings suggest that ESS does not impact asthma severity classification, step of treatment, ICS dose, or exacerbation occurrence. However, it might provide relief of asthma symptoms in the early postoperative period. Further research is needed to fully understand the long effect of ESS in CRS patients with comorbid asthma.

Author Contributions

Anyull D. B. Caballero, designed the study, collected data, ensured data quality, conducted the statistical analysis, drafted the manuscript, reviewed, and approved the final draft. **Estephania Candelo**, analyze the data, reviewed, and approved the final draft. **Karol Avila-Castano**, collected data, reviewed, and approved the final draft. **Alaa Alhalabi**, collected data, reviewed, and approved the final draft. **Angela M. Donaldson**, designed the study, analyzed data, drafted the manuscript, wrote the manuscript, reviewed, and approved the final draft, and revised it critically for important intellectual content.

Disclosure

Competing interests: Angela M. Donaldson, Advisor for Sanofi/Regeneron.

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