

## Original Research Article

# Role of leukotriene receptor antagonist in improvement of symptoms after functional endoscopic sinus surgery for chronic rhinosinusitis with or without sinonasal polyposis

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## ABSTRACT

**Background:** Chronic rhinosinusitis is one of the common ENT diseases encountered daily. Due to its chronicity, it leads to patient morbidity and decreased quality-of-life of the patient. Although various medical and surgical management options are available, none can manage the condition effectively. So, the aim of the study is to evaluate the efficacy of the montelukast in the subjective and objective improvement after the FESS for patients with chronic rhino sinusitis.

**Methods:** This randomized controlled trial was conducted among 50 patients diagnosed with chronic rhino sinusitis. All the patients underwent FESS, and after that, they were divided into two groups; one group received the Montelukast tablet in addition to the standard post-operative regimen, and the other group received the standard post-operative medications only. The subjective and objective measurements were made using SNOT-22 and Lund-Kennedy endoscopic scores during the pre- and post-operative periods.

**Results:** The study showed a significant reduction in the various parameters of SNOT-22, viz runny nose ( $p=0.013$ ), cough ( $p=0.003$ ), post-nasal discharge ( $p=0.037$ ), thick nasal discharge ( $p=0.013$ ), ear fullness ( $p=0.021$ ), difficulty in falling asleep ( $p=0.018$ ), walking up at night ( $p<0.001$ ), reduced concentration ( $p=0.001$ ) in Group-A than in Group-B. The study also showed a significant reduction in the overall SNOT-22 score in the Group-A. The Lund-Kennedy endoscopic score ( $p=0.006$ ) also showed a significant reduction during the postoperative period in Group-A.

**Conclusion:** The Montelukast positively affects the reduction of the various domains in the SNOT-22 and the Lund-Kennedy endoscopic score. It can be used as adjuvant therapy during the post-operative period in patients operated with FESS for CRS.

**Keywords:** Chronic rhinosinusitis, SNOT-22, Lund-Kennedy score, Post-operative

## INTRODUCTION

Chronic rhinosinusitis is one of the common clinical entities in the ENT practice, diagnosed by subjective and objective sinonasal inflammation. It is defined as the inflammatory outgrowth of the sinonasal tissue of unknown aetiology.<sup>1</sup> The prevalence of the disease varies between 0.2% to 4.3%.<sup>2</sup> According to the Indian National

Institute of Allergy and Infectious Diseases (NIAID), about 134 million Indians suffer from chronic rhino sinusitis.<sup>3</sup> There are two significant phenotypes of CRS present, viz, chronic rhinosinusitis with polyps (CRSwNP) and chronic rhinosinusitis without nasal polyps (CRSsNP).<sup>4</sup> The nasal polyps are primarily benign, occur bilaterally, and develop during adulthood. The unilateral polyposis should be evaluated for the

underlying malignancy.<sup>5</sup> The polyps can lead to nasal obstruction, decreased sense of smell, and frequent infections, affecting people's quality of life.<sup>6</sup> Nasal polyposis is mainly associated with bronchial asthma. The pathogenesis of the development of nasal polyposis depends upon two mechanisms, infectious and non-infectious.<sup>7</sup>

The results in both the mechanism of the expression of the various inflammatory mediators such as cytokines and interleukins and causing a complex interaction between the sinonasal epithelium and the host immune response, which promotes the development of the chronic inflammation and leading to nasal polyposis.<sup>8</sup>

Often, there is a difference between the occurrence of the symptoms and the development of the diseases in the case of CRS. Because the patients are precisely defined most of the time, but not all the symptoms are. Hence, the European Position paper on rhinosinusitis and nasal polyps recommends the subjective assessment of the symptoms using the validated questionnaire, and the Sinonasal Outcome Test-22 (SNOT-22) is one of its kind.

Objectively assessing the functional endoscopic sinus surgery was done by endoscopic evaluation based on the modified Lund-Kennedy score, which is more popular and easier to use.<sup>9</sup> The diagnosis of CRS is based on well-defined criteria, consisting of a combination of specific signs and symptoms confirmed by endoscopic and radiological findings.<sup>4</sup>

The management of nasal polyposis depends upon surgical and medical management and avoiding allergen exposure. Montelukast is an orally active antagonist against the leukotriene receptor, inhibiting the cysteinyl leukotriene, a product of arachidonic acid pathway.<sup>10</sup> Although the montelukast was approved by the Food and Drug Administration in 1998, its use for treating conditions such as allergic rhinitis and asthma has already been established.

The effect of montelukast in managing chronic rhinosinusitis with nasal polyposis and the post-operative cases of functional endoscopic surgery for the above conditions has been studied less. So, this study has been planned to evaluate the efficacy of the montelukast in the subjective and objective improvement after the FESS for patients with chronic rhino sinusitis with or without polyposis.

## METHODS

### Study design

This randomized controlled trial was conducted among the patients undergoing Functional Endoscopic Sinus Surgery (FESS) at the ENT department of Sri Venkateswara Medical College Hospital and Research Centre, Puducherry, from July 2023 to December 2023.

### Sampling technique

All the patients with the symptoms of the CRS during the study period were included in the study. And the patients were selected using a convenient sampling technique.

### Inclusion criteria

All the patients during the period with age greater than 18 years, with a confirmatory diagnosis of chronic rhinosinusitis with or without nasal polyps, and willing to undergo FESS were included in the study.

### Exclusion criteria

Patients with uncontrolled diabetes mellitus, hypertension, invasive fungal rhinosinusitis, immunocompromised state, diagnosed with allergic rhinitis, patients with a history of surgery, and hypersensitive to Montelukast were excluded from the study.

### Intervention

All the patients were evaluated with detailed history and clinical examination followed by all the blood investigations, diagnostic nasal endoscopy (DNE), X-ray, and computed tomography (CT) of paranasal sinuses. The patients had been subjected to the preoperative sinonasal outcome test 22 and were scored preoperatively. After getting anesthesia clearance, the patients were taken up for FESS and the intraoperative findings were noted. All the patients were uniformly packed with merocel nasal packing and were removed uniformly on the 2nd postoperative day.

Then, the block randomization technique divided the patients into two groups. In Group A, all the patients were provided with a Montelukast tablet of 10 mg at night for three months, along with other routine medications such as antibiotics, analgesics, antacids, and nasal douching. In Group B, the patients will receive the routine medications only. All the patients were followed up for three months. They were evaluated with the SNOT 22 score and endoscopic evaluation based on the Lund-Kennedy scoring system at the end of the 3rd, 6th and 12th post-operative week.

### Sino nasal outcome test – 22 (SNOT-22) score

The sino nasal outcome test–22 (SNOT-22) is a validated, self-administered questionnaire which can be used to assess patients with CRS. It provides a subjective assessment of the various symptoms of the patients. It consists of 22 parameters, each rated from 0 to 5.

Zero means no problem at all, and 5 means the worst possible symptom. And the possible total score ranges from 0 to 110.<sup>11</sup> A higher SNOT-22 score means the worse the symptoms the patients face. The total 22

parameters were divided into five domains, nasal domain, ear/facial domain, sleep domain, function domain and emotion domain. In the nasal domain, parameters include Need to blow nose, nasal blockage, sneezing, runny nose, cough, post-nasal discharge, thick nasal discharge, and decreased sense of smell/taste. The ear/facial domain consisted of ear fullness, dizziness, ear pain, and facial pain/pressure. The sleep domain consists of difficulty falling asleep, waking up at night, lack of a good night's sleep and waking up tired; the function domain consists of fatigue, reduced productivity, and reduced concentration and the emotion domain consists of frustrated/restless/irritable, sad and embarrassed.<sup>12</sup>

### Modified Lund-Kennedy endoscopy score

The well-known Lund-Kennedy endoscopic score is a validated outcome measure. It is an objective measurement to stage the inflammatory burden in patients with sinonasal diseases. It comprises five domains: polyp in or outside the middle meatus, oedema, discharge, scarring and crusting.

Recently, Psaltis et al, modified the Lund Kennedy endoscopic score by removing the scarring and crusting, including only mucosal oedema, discharge, and polyp subdomains. Each domain has a score from 0 to 2. And the score should be measured for each nostril separately and added together. And the score ranges from 0 to 12. The higher the score, the worse the disease. This Lund-Kennedy has been validated and gave improved correlation with patient-reported outcome measures, regardless of the operative status of the patient.<sup>13</sup>

### Statistical analysis

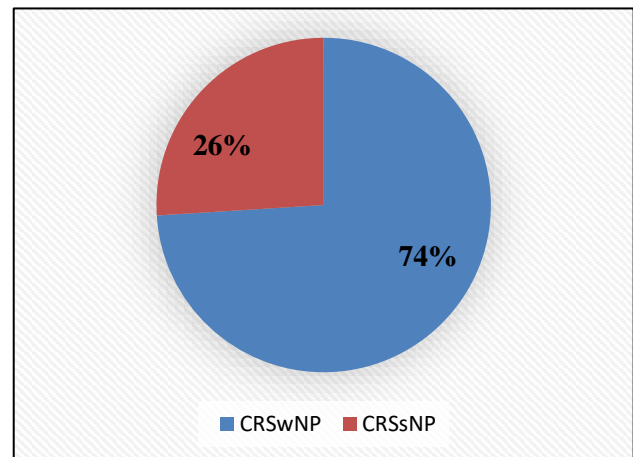
All the data were analyzed through SPSS software version 23. The repeated measures ANOVA was used to determine the significant difference between the groups and the p value of less than 0.05 was considered significant.

## RESULTS

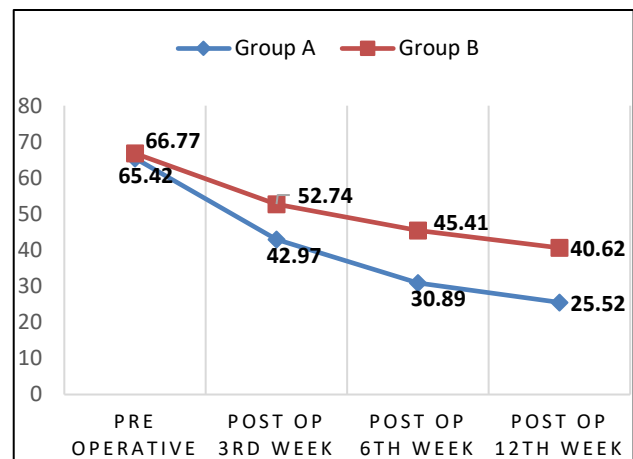
Fifty patients diagnosed with chronic rhino sinusitis with or without nasal polyposis undergoing FESS participated in the study. About 42% of the patients were in the 30 to 40 age group, followed by 34% in the 40 to 50 age group and 16% in the younger age group. And only 8% in the over-50 age group. The male patients comprised 58%, whereas 42% were female. Most of the patients, 78%, were non-smokers and from rural areas 70%.

The socioeconomic status of the patient reveals that the majority of the patient belongs to class IV socioeconomic (Rs 1130-Rs. 2259 per month), followed by 32% in class III (Rs. 2260-Rs. 3765 per month) group as per modified BG Prasad Scale.<sup>14</sup> Regarding the comorbidities, 66% had allergic rhinitis, followed by 38% had asthma. Furthermore, 22% had previous FESS

operation, 95% had bilateral polyposis, and only 5% had unilateral disease, as in (Table 1).



**Figure 1: Distribution of the patient based on the diagnosis.**



**Figure 2: Comparison of overall SNOT-22 score between the groups.**

Among the patients, 74% had chronic rhinosinusitis with nasal polyps, and only 26% had chronic rhinosinusitis without nasal polyps, as in (Figure 1). The SNOT-22 score was used to assess the subjective outcome of the patients based on the 22 parameters. The scores were analyzed preoperatively, during the 3rd, 6th and 12<sup>th</sup> post-operative week, and between the groups. A significant difference had been noted in the reduction of the various symptoms of SNOT-22 parameters such as runny nose ( $p=0.013$ ), cough ( $p=0.003$ ), post-nasal discharge ( $p=0.037$ ), thick nasal discharge ( $p=0.013$ ), ear fullness ( $p=0.021$ ), difficulty in falling asleep ( $p=0.018$ ), waking up at night ( $p<0.001$ ), reduced concentration ( $p=0.001$ ) in group A than in group B.

In contrast, no significant difference was noted in the parameters such as need to blow the nose ( $p=0.199$ ), sneezing ( $p=0.107$ ), blockage/congestion of the nose ( $p=0.269$ ), loss of sense of taste/smell ( $p=0.177$ ),

dizziness ( $p=0.661$ ), ear pain ( $p=0.193$ ), facial pain or pressure ( $p=0.153$ ), lack of good night's sleep ( $p=0.116$ ), waking up tired ( $p=0.205$ ), reduced productivity ( $p=0.156$ ), frustrated/restless/irritable ( $p=0.149$ ), sad ( $p=0.166$ ) and embarrassed ( $p=0.122$ ), as in table 2. It is noted that there was a significant reduction in the nasal, ear/facial, sleep, and function domains. However, no significant difference was noted in the emotion domain of the SNOT-22 score. On comparing the mean value of the overall score of the SNOT-22 score, on comparing both

the groups, Group A showed a more significant reduction of the SNOT-22 score during the post-operative period than group B with a significant  $p$  value of 0.016, as in (Figure 2). On comparing the endoscopic grading between the two groups using the modified Lund Kennedy Score, the group A patients showed more significant improvement in the endoscopic findings in the nasal cavities during the post-operative period than the group B with a significant  $p$  value of 0.006, as in (Table 3).

**Table 1: Demographic details of the patient.**

Demographic details	Frequency	%
<b>Age (in years)</b>		
18-30	8	16
30-40	21	42
40-50	17	34
>50	4	8
<b>Gender</b>		
Male	29	58
Female	21	42
<b>Smoking status</b>		
Non-smoker	39	78
Smoker	11	22
<b>Locality</b>		
Rural	15	30
Urban	35	70
<b>Socio-economic status</b>		
More than Rs 7533 per month (Class I)	4	8
Rs 3766-Rs 7533 per month (class II)	9	18
Rs. 2260 – Rs 3765 per month (class III)	16	32
Rs 1130 – Rs 2259 per month (class IV)	21	42
<b>Co-morbidities</b>		
Asthma	19	38
Allergic rhinitis	33	66
Acetylsalicylic acid intolerance	4	8
<b>History of previous FESS surgery</b>		
Yes	11	22
No	39	78
<b>Polyp nature</b>		
Unilateral	5	10
Bilateral	45	90

**Table 2: Comparison of individual parameters of SNOT-22 score between the groups.**

S. no.	SNOT-22 parameters	Groups	Mean score				P value
			Pre-operative	Post-operative			
				3 <sup>rd</sup> Week	6 <sup>th</sup> Week	12 <sup>th</sup> Week	
1	Need to blow nose	Group A	4.12	2.22	1.35	0.30	0.199
		Group B	3.94	3.11	3.01	2.95	
2	Sneezing	Group A	3.88	2.11	2.00	1.04	0.107
		Group B	4.56	3.89	3.50	3.50	
3	Runny nose	Group A	4.45	1.95	1.02	0.56	0.013
		Group B	4.67	3.01	2.56	1.95	
4	Blockage/congestion of the nose	Group A	4.56	2.01	1.45	1.01	0.269
		Group B	4.12	3.56	2.75	2.75	

Continued.

S. no.	SNOT-22 parameters	Groups	Mean score				P value
			Pre-operative	Post-operative			
				3 <sup>rd</sup> Week	6 <sup>th</sup> Week	12 <sup>th</sup> Week	
5	Loss of sense of taste/smell	Group A	3.23	2.02	1.56	1.20	0.177
		Group B	3.11	2.56	2.22	1.95	
6	Cough	Group A	2.98	2.22	1.95	1.75	0.003
		Group B	2.87	2.30	2.11	1.89	
7	Post-nasal discharge	Group A	3.12	1.52	1.12	0.44	0.037
		Group B	3.55	3.10	2.34	1.98	
8	Thick nasal discharge	Group A	3.11	1.98	1.54	1.23	0.013
		Group B	2.93	2.00	1.98	1.56	
9	Ear fullness	Group A	2.98	1.67	1.34	1.34	0.021
		Group B	2.56	1.78	1.58	1.50	
10	Dizziness	Group A	1.67	1.30	1.31	1.23	0.661
		Group B	1.12	1.02	1.00	0.95	
11	Ear pain	Group A	1.98	1.50	1.34	1.24	0.193
		Group B	1.78	1.65	1.45	1.34	
12	Facial pain/pressure	Group A	2.11	1.96	1.70	1.66	0.153
		Group B	1.87	1.87	1.67	1.56	
13	Difficulty falling asleep	Group A	1.64	1.45	1.32	0.97	0.018
		Group B	2.01	1.89	1.45	1.34	
14	Walking up at night	Group A	2.76	1.99	1.45	1.44	<0.001
		Group B	2.53	1.89	1.35	1.33	
15	Lack of a good night's sleep	Group A	2.45	1.79	1.65	1.34	0.116
		Group B	2.79	1.70	1.70	1.56	
16	Waking up tired	Group A	3.11	2.98	1.76	1.56	0.205
		Group B	3.01	2.95	2.54	2.01	
17	Fatigue	Group A	4.48	2.99	2.65	1.90	0.005
		Group B	4.98	2.87	2.46	2.22	
18	Reduced productivity	Group A	2.86	1.89	1.45	1.23	0.156
		Group B	3.33	2.95	2.45	2.33	
19	Reduced concentration	Group A	2.95	2.01	1.67	1.32	0.001
		Group B	3.55	2.79	2.43	2.11	
20	Frustrated/restless/irritable	Group A	3.11	2.22	1.65	1.11	0.149
		Group B	2.87	2.27	1.71	1.26	
21	Sad	Group A	1.78	1.40	1.24	0.89	0.166
		Group B	1.73	1.54	1.32	1.22	
22	Embarrassed	Group A	2.09	1.79	1.37	0.76	0.122
		Group B	2.89	2.04	1.83	1.36	

Table 3: comparison of the mean Lund Kennedy score for the endoscopic findings.

Parameter	Groups	Mean score				P value
		Pre-operative	Post-operative			
			3 <sup>rd</sup> Week	6 <sup>th</sup> Week	12 <sup>th</sup> Week	
Modified Lund Kennedy score	Group A	8.31	2.34	1.12	0.81	0.006
	Group B	9.21	4.52	4.32	2.88	

## DISCUSSION

Chronic rhinosinusitis with or without nasal polyposis is a prevalent disease worldwide, representing a diffuse inflammatory process due to multiple causes, affecting everyone irrespective of age and sex. It significantly impacts the person's quality of life and indirectly affects the country's economic burden.<sup>15</sup> The main symptoms

due to the disease were nasal obstruction, sneezing, itching post-nasal drip and smell disturbances.<sup>7</sup> Managing chronic rhinosinusitis with or without nasal polyposis includes medical and surgical management.<sup>16</sup> post-operative management also plays a vital role in preventing infection and recurrence.<sup>17</sup> Although surgical management and steroids are the main strays of treatment in the management of chronic rhino sinusitis, many of the



patients end up with recurrence and post-operative infection. This study evaluates the leukotriene antagonist in the subjective and objective improvement after the FESS for patients with chronic rhino sinusitis with or without polyposis. This used the SNOT-22 score for the subjective improvement measurement and the Lund-Kennedy score for the objective improvement of the symptoms. In this study, about 42% of the patients were 30 to 40 years old, and 34% were 40 to 50 years old, followed by 16% between the 18 to 30 years old age category. About 58% of the people were males, whereas 42% of the patients were females with chronic rhino sinusitis who participated in the study. This supports the epidemiology of the CRS, affecting all age groups irrespective of sex.<sup>18</sup> It is surprising to see in our study that 78% of the people affected with CRS were non-smokers. At the same time, many studies have shown that the CRS is more familiar to smokers than non-smokers.<sup>19</sup>

Exposure to environmental allergens, occupational irritants and passive smoking are also factors for the development of CRS, which were not explored in our study and the primary factor for the higher incidence of CRS in non-smokers in this study. The majority of the people affected with CRS belong to low socio-economic status because the people with low economic status are subjected to recurrent upper respiratory tract infections with poor quality of life.<sup>20</sup> The study by Philpott et al, also showed the prevalence of CRS in the same socio-economic background.<sup>21</sup> It is more commonly associated with allergic rhinitis in 66% of patients and asthma in 38% of patients, and 90% had bilateral disease; this explains the pathology of the disease.<sup>1</sup>

The study showed a reduction in the mean values of all the domains of the SNOT-22 scores and the Lund-Kennedy score. The SNOT-22 is a validated tool for evaluating patients' quality of life with CRS. It also measures the outcomes following the different management modes, such as surgical and medical management. This study's average preoperative SNOT-22 score ranges from 40 to 70, like many studies.<sup>22,23</sup>

Postoperatively, both groups positively impacted the reduction of the overall SNOT-22 score in our study. The montelukast group, Group A, showed a more significant reduction of the overall SNOT-22 score from the earlier weeks, compared with the other group, which had a significant p value. Not only reducing the overall SNOT-22 score, but the montelukast group also showed a significant reduction in many individual parameters such as runny nose, cough post-nasal discharge, thick nasal discharge, ear fullness, difficulty in falling asleep, waking up at night, fatigue and reduced concentration.

Although there is no significant reduction in other parameters, the group A scores are far less than the control group scores. Similar results were noted in the study by Schaper et al, where he found significant

improvement in all the outcome measures during the treatment with montelukast.<sup>24</sup> Another study by Vuralkan et al, compared the efficacy of the montelukast with the mometasone furoate nasal spray following the FESS. In this study, both groups showed significant improvement in SNOT-22 score. Still, the montelukast group has a higher polyp recurrence rate of 48% than the steroid group of 20%, and the study indicates the use of montelukast as adjuvant therapy with the other standard regimen.<sup>25</sup>

The study showed a significant reduction of the SNOT-22 score in four domains except the emotion domain. This may be because of the chronicity of the disease, which causes the patient to experience depression and low quality of life. It will take time to overcome this effect after the treatment. So, the emotion domain did not significantly reduce the score compared with other domains. The study by Davis et al, also showed that 25% of the patients with CRS presenting for sinus surgery are suffering from depression. In the same study, they found that 17% are experiencing anxiety.

On evaluating the objective measurement with the help of a modified Lund-Kennedy score, the average pre-operative score was between 8 and 9. The score reduction was noted in both groups in the postoperative period. Group A showed a more significant reduction than the other groups with a significant p value. The study by Yelverton et al, also showed similar results to ours and significantly reduced the Lund Kennedy score in the montelukast group compared to the control group.<sup>10</sup> It was noted that none of the patients in both groups developed any recurrence of polyp during the post-operative period, and none had developed any complications due to the drug.

The limitations of the study were that the study was conducted in a single centre and only a smaller population was included in the study. So, if the study were done in a multicenter and in a larger population, it would further help to confirm the study results.

## CONCLUSION

In today's world, CRS is one of the most common diseases encountered in day-to-day ENT practices. Although there are many treatment options available for the management of patients with the disease, many of them end up with recurrence of the disease and post-operative morbidity such as infection and persistence of the symptoms. This post-operative morbidity will end up creating a depression in the patients despite effective management and causing a reduction in the quality of life of the patients. This study showed the effect of the Montelukast underwent FESS and showed a positive reduction in many parameters measured in the SNOT-22 score and Lund-Kennedy endoscopic scoring system. Thus, the postoperative use of Montelukast will help in the subjective and objective

improvement of the patients during the postoperative period. The study also recommends that the montelukast be used as an adjuvant therapy with the standard post-operative medications after the successful FESS procedure. The study also recommends further, more extensive studies to prove montelukast's effect on improving post-operative patients' subjective outcomes.

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