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Original Article

Effectiveness of mometasone, indacaterol, glycopyrronium (once daily single inhaler triple therapy) in the management of severe asthma: a prospective observational study

Abhishek Krishna[1], Sandeep[2], Shaiju Dharan[3], Lal Prasanth[4], Dhanya Dharman[5*]

[1]Department of Clinical Pharmacy, KIMS Health, Trivandrum.
[2]Department of Pulmonology, NIMS Medicity, Neyyattinkara, Trivandrum, Kerala, India.
[3]Department of Pharmaceutics, Ezhuthachan College of Pharmaceutical Sciences, Trivandrum, Kerala, India.
[4]Department of Pharmaceutical Chemistry, Dr Moopen's College of Pharmacy, Wayanad, Kerala, India.
[5]Department of Pharmacy Practice, Dr Moopen's College of Pharmacy, Wayanad, Kerala, India.

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***Corresponding Author:**
Dr. Dhanya Dharman
Email: dhanyadharman07@gmail.com
Phone : +919526591767

ABSTRACT

Background: Severe asthma is a type of difficult-to-treat asthma that refers to the asthma that is uncontrolled regardless of maximized optimum high-dose Inhaled Corticosteroid-Long-Acting β2-Agonist (ICS-LABA) treatment. When a long-acting muscarinic antagonist (LAMA) was introduced in patients with poorly controlled asthma who were already on inhaled glucocorticoids and LABAs, it gradually prolonged the time to the first severe exacerbation and provided sustained, adequate bronchodilation. The effectiveness of once-daily single-inhaler triple therapy consisting of Indacaterol (LABA), Mometasone (ICS), and Glycopyrronium (LAMA) in the treatment of severe asthma is assessed in this study. **Objectives**: The primary aim of the study was to assess the effectiveness of once-daily single-inhaler triple therapy in the management of severe asthma. **Methods**: A prospective observational study was conducted from November 2023 to April 2024 with a sample size of 60 in the pulmonology department of a tertiary care hospital. The study assessed medication adherence to previous asthma medication using a questionnaire, assessed lung function using a pulmonary function test, and analyzed the impact of SITT using an asthma control questionnaire after 3 months. **Results**: The SITT significantly improved the lung function in all 60 subjects. When compared, parameters such as FEV1, FEV1/FVC, FVC, and FEF25-75% before and after SITT showed significant improvement in lung function. The impact of the SITT on patients was assessed using an asthma control questionnaire, which showed substantial improvement in their condition. **Conclusion**: The study underscores the effectiveness and potential benefits of single-inhaler triple therapy in the management of severe asthma. By combining ICS, LABA, and LAMA agents into a single device, this treatment approach offers simplicity, convenience, and improved symptom control for patients facing the challenges of severe asthma.

1. INTRODUCTION

The prevalence of asthma shows wide variation across countries and even within regions of the same nation due to differences in geography and socioeconomic status (Agrawal et al., 2013) The Indian

Study on Epidemiology of Asthma, Respiratory Symptoms, and Chronic Bronchitis in Adults (INSEARCH) reported a national prevalence of 2.05%, which corresponds to about 17.23 million cases (Song et al., 2022).In comparison, the Global Burden of Disease (GBD, 1990–2019) estimated that 34.3 million people in India are affected, accounting for 13.09% of the global burden (Wang et al., 2023).

Severe asthma is described as asthma that remains uncontrolled despite the use of optimized high-dose inhaled corticosteroid (ICS)-long-acting beta-agonist (LABA) therapy, even after addressing modifiable risk factors (Lommatzsch & Virchow, 2014). This phenotype is difficult to treat and tends to worsen if high-dose treatment is reduced. According to GINA guidelines, none of the asthma patients achieved complete control, 60% had partial control, and 40% remained uncontrolled (Salvi et al., 2015).

Asthma is a major global health problem that affects people of all ages. When patients using medium-dose ICS/LABA continue to experience symptoms and frequent exacerbations, the standard step-up approach is to increase the ICS dose. However, long-term use of high-dose ICS may raise the risk of adverse effects due to cumulative exposure (Beasley et al., 2019; Fujiki et al., 2023). Evidence suggests that adding a long-acting muscarinic antagonist (LAMA) to ICS/LABA therapy provides additional bronchodilation, delays the time to first severe exacerbation, and reduces airflow limitation (Evans et al., 2015; Kew & Dahri, 2016).

The 2021 GINA guidelines recommend adding a LAMA for patients whose asthma remains uncontrolled despite medium- to high-dose ICS/LABA. A once-daily single-inhaler triple therapy (SITT) containing Indacaterol (LABA), Mometasone (ICS), and Glycopyrronium (LAMA) has been developed to address this need. Indacaterol, known as an ultra-LABA, provides more than 24 hours of bronchodilation with a once-daily dose. Glycopyrronium is a selective LAMA with a rapid onset and prolonged action, acting via M3 receptor antagonism. Mometasone, in combination with Indacaterol, exerts synergistic bronchodilatory effects. Together, this combination offers a promising therapeutic option for patients with severe asthma (Agusti et al., 2022).

This study evaluates the clinical effectiveness of once-daily SITT with Indacaterol, Mometasone, and Glycopyrronium in the management of severe asthma.

2. METHODOLOGY

2.1 Study Design and Setting

A prospective observational study was conducted in the Pulmonology Department of a tertiary care hospital in South Kerala from November 2023 to April 2024. The study aimed to evaluate the efficacy of single-inhaler triple therapy in patients with severe asthma. A total of 60 participants meeting the inclusion criteria were enrolled.

2.2 Ethical Considerations

The study was approved by the institutional ethics committee (Ref No: ECR EC/NEW/INST/2022/KL/0068), and all participants provided written informed consent before enrollment. The study adhered to the principles of the Declaration of Helsinki.

2.3 Study Population

2.3.1 Inclusion Criteria

- Adults aged 18–60 years.
- Diagnosed with severe asthma and previously treated with standard asthma therapies, including inhaled corticosteroids and long-acting β2 agonists (LABAs).
- Adherent to prior asthma treatment as assessed using the Adherence to Asthma Medication Questionnaire (AAMQ-13).

2.3.2 Exclusion Criteria

- Presence of other significant respiratory conditions, such as COPD or bronchiectasis.
- Pregnancy or lactation.
- Serious comorbid conditions (e.g., severe cardiovascular disease).
- Unwillingness to provide consent or participate in the study.

2.4 Data Collection and Baseline Assessment

Baseline demographic data, including age, gender, height, weight, and body mass index (BMI), were recorded. Adherence to prior asthma treatment was assessed using the AAMQ-13. Lung function tests were performed at baseline using spirometry, measuring the following parameters:

- Forced Expiratory Volume in 1 second (FEV1)
- Forced Vital Capacity (FVC)
- FEV1/FVC ratio

- Forced Expiratory Flow 25–75% (FEF25–75%)

2.5 Intervention

Participants received once-daily single-inhaler triple therapy containing Indacaterol, Glycopyrronium, and Mometasone. The treatment duration was 3 months, with adherence monitored throughout the study period.

2.6 Follow-Up and Outcome Measures

After 3 months of therapy, participants were reassessed for lung function using the same spirometric parameters. Asthma control was evaluated using the Asthma Control Questionnaire (ACQ-7). The primary outcomes were improvements in lung function parameters and asthma control scores.

2.7 Statistical analysis

Data were analyzed using SPSS software (version 22.0). Continuous variables were presented as mean ± standard deviation. Pre- and post-treatment comparisons were performed using paired t-tests, while subgroup analyses were conducted using independent t-tests. A p-value of <0.05 was considered statistically significant.

3. RESULTS AND DISCUSSION

A total of 60 subjects were included in the study. Out of 60 participants, 40 (66.7%) were females and 20 (33.3%) were males, indicating a predominance of females in the study population (Table 1). The majority of participants (20; 33.3%) belonged to the 30–40 years age group, followed by 12 (20.0%) each in the 40–50 years and 50–60 years groups. Ten participants (16.7%) were aged 60–70 years, while only 6 (10.0%) were in the 20–30 years group. This data shows that most of the study population were middle-aged adults (30–60 years, 73.3%). Most participants (58; 96.7%) had a BMI within the normal range (18.5–24.9), while only 2 (3.3%) were overweight (BMI ≥25). The study population was predominantly female, middle-aged, and within the normal BMI category.

The current study assessed the impact of triple therapy on lung function and found highly significant improvements ($P = 0.001$) across all parameters, demonstrating both physiological and clinical relevance. FEV1/FVC ratio improved from 76.72 ± 11.29 to 96.63 ± 5.06 (Table 2). This increase suggests enhanced airway patency and reduced airflow obstruction, which is a hallmark improvement in obstructive airway diseases such as asthma or COPD.FEV1 rose from 47.27 ± 10.40 to 75.93 ± 7.72. Since FEV1 reflects the degree of airway obstruction and is a key marker of disease severity, this substantial improvement indicates a strong therapeutic response, with better expiratory flow and reduced bronchospasm.FVC increased from 58.97 ± 14.24 to 80.00 ± 5.78, signifying greater lung capacity and improved ability to inhale and exhale maximally, consistent with reduced lung hyperinflation. FEF25–75% increased from 57.97 ± 21.66 to 91.90 ± 9.11. This parameter reflects small airway function explicitly, which is often impaired early in obstructive airway diseases. The marked improvement highlights the therapy's effectiveness in targeting both central and peripheral airways. Triple treatment produced significant improvements in both large (FEV1, FVC) and small airway function (FEF25–75%), reflecting bronchodilation, reduced airway resistance, and better lung compliance. The improvement in FEV1/FVC ratio confirms the reversal of airflow limitation. These findings provide strong evidence that triple therapy enhances pulmonary function and supports its role as an effective therapeutic strategy in patients with chronic obstructive airway disease.

Asthma control was assessed using the Asthma Control Questionnaire (ACQ7) before and after therapy. The mean ACQ7 score decreased from 0.91 ± 0.13 (controlled asthma) to 0.42 ± 0.19 (well-controlled asthma) following treatment (Table 3). This difference was statistically significant ($t = 7.98$, $p = 0.001$), indicating a substantial improvement in asthma control.

The reduction in ACQ7 scores reflects a significant improvement in patient-reported asthma symptoms, including daytime and nighttime symptoms, activity limitation, and rescue medication use. A score of 0.42 falls within the "well-controlled" range, demonstrating that the intervention effectively enhanced symptom management and overall disease control. The large t-value and very low p-value indicate that the observed improvement is unlikely to be due to chance, confirming the therapy's efficacy in achieving clinically meaningful asthma control. Improved ACQ7 scores correlate with the observed improvements in objective lung function parameters (FEV1, FVC, FEV1/FVC, and FEF25–75%), suggesting that the therapy not only improves airway physiology but also translates into better patient-perceived outcomes. This result aligns with prior studies showing that interventions improving airway function are associated with better asthma control scores, highlighting the therapy's dual benefit on both objective and subjective measures of disease.

Table 1:Demographic details of the Study participants

Demographic Details		N	%
Gender	Female	40	66.66
	Male	20	33.34
Age	20-30	6	10
	30-40	20	33.3
	40-50	12	20
	50-60	12	20
	60-70	10	16.7
BMI	18.5 – 24.9	58	96.7
	>= 25	2	3.3

Table 2: Comparison of lung function test before and after triple therapy

LUNG FUNCTION	BEFORE TRIPLE THERAPY		AFTER TRIPLE THERAPY	
	MEAN SCORE	NDARD DEVIATION	EAN SCORE	DARD DEVIATION
FEV1/FVC	76.72	11.29	96.63	5.06
	P-value (P<0.05) = 0.001			
FEV1	47.27	10.40	75.93	7.72
	P-value (P<0.05) = 0.001			
FVC	58.97	14.24	80.00	5.78
	P-value (P<0.05) = 0.001			
$FEF_{25-75\%}$	57.97	21.66	91.90	9.11
	P-value (P<0.05) = 0.001			

The effect of triple therapy on airway obstruction was evaluated using the FEV1/FVC ratio. The mean ratio increased significantly from 76.72 ± 11.29 before treatment to 96.63 ± 5.06 after treatment ($p = 0.001$), indicating a marked improvement in airway patency (Figure 1). FEV1/FVC is a key indicator of airflow limitation in obstructive airway diseases. The substantial increase observed post-therapy reflects reversal of airway obstruction, likely due to bronchodilation, reduced airway inflammation, and improved lung compliance. The decrease in variability (smaller SD after therapy) suggests a consistent treatment effect across the study population. The significant improvement in FEV1/FVC correlates with enhanced expiratory airflow and reduced airway resistance, which is clinically meaningful for patients with obstructive lung disease. These findings support the efficacy of triple therapy in improving both physiological and functional measures of pulmonary performance, complementing improvements in other lung function parameters (FEV1, FVC, FEF25–75%) and patient-reported outcomes (ACQ7).

Table 3: Comparison of ACQ 7 after 3 months with asthma severity

ACQ7	Well Controlled	Controlled
Mean Score	0.42	0.91
SD	0.19	0.13
Independent t-value	7.98	
Significant value	.001* (p<0.05)	

The effect of triple therapy on forced expiratory volume in 1 second (FEV1) was assessed to evaluate significant airway function. The mean FEV1 increased significantly from 47.27 ± 10.40 before

treatment to 75.93 ± 7.72 after treatment (p = 0.001), indicating a pronounced improvement in expiratory airflow. FEV1 is a primary indicator of airway obstruction and disease severity in obstructive pulmonary conditions (Figure 2). The substantial post-treatment increase reflects effective bronchodilation, reduced airway resistance, and improved ventilatory function. Additionally, the lower standard deviation after therapy suggests that the response was consistent across the study population. The significant improvement in FEV1 demonstrates that triple therapy markedly improves large-airway function, which likely contributes to better symptom control, reduced airflow limitation, and improved exercise tolerance. This improvement is consistent with parallel gains observed in FVC, FEV1/FVC, and small airway function (FEF25–75%), supporting the overall efficacy of the treatment.

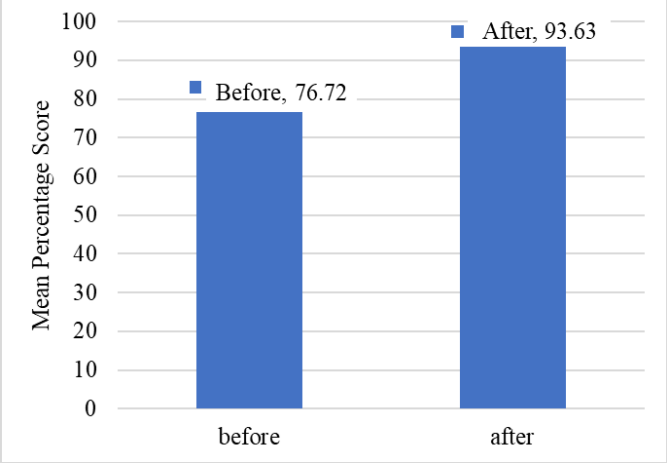

Figure 1: Comparison of FEV1/FVC before and after triple therapy.

The effect of triple therapy on lung capacity was evaluated using forced vital capacity (FVC). The mean FVC increased significantly from 58.97 ± 14.24 before treatment to 80.00 ± 5.78 after treatment (p = 0.001), indicating a substantial improvement in pulmonary volume. FVC represents the total volume of air exhaled during a forced breath and reflects both large airway patency and overall lung compliance (Figure 3). The observed post-treatment increase suggests enhanced lung expansion, reduced air trapping, and improved ventilatory mechanics, likely due to bronchodilation and decreased airway obstruction. The reduction in standard deviation indicates a consistent therapeutic response among participants.

The significant improvement in FVC demonstrates that triple therapy effectively restores lung volume and capacity, complementing the observed enhancements in FEV1, FEV1/FVC ratio, and FEF25–75%. Collectively, these findings indicate that the therapy improves both large- and small-airway function, leading to better pulmonary performance and symptomatic relief in patients with obstructive airway disease.

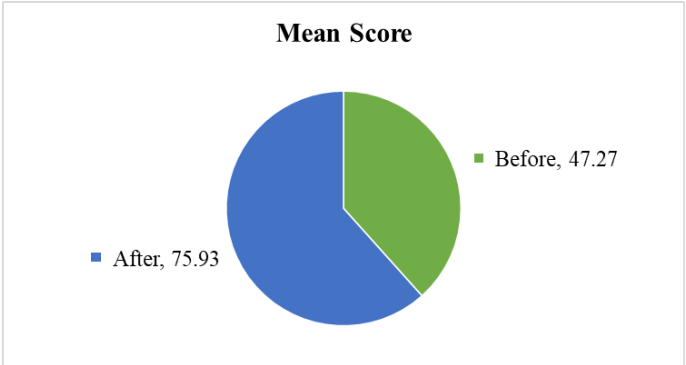

Figure 2: Comparison of FEV1 before and after triple therapy.

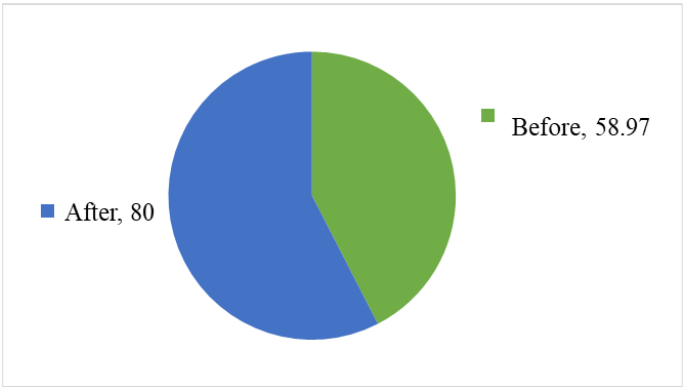

Figure 3: Comparison of FVC before and after triple therapy.

The effect of triple therapy on small airway function was evaluated using FEF25–75%. The mean FEF25–75% increased significantly from 57.97 ± 21.66 before therapy to 91.90 ± 9.11 after therapy (p = 0.001), indicating a substantial improvement in mid-expiratory flow (Figure 4). FEF25–75% reflects airflow in the small distal airways and is often the earliest indicator of small airway obstruction in obstructive pulmonary diseases. The marked increase after therapy suggests effective bronchodilation, decreased peripheral airway resistance, and improved ventilation in the distal lung regions. The reduction in standard deviation post-therapy indicates a consistent response among participants. Improvement in FEF25–75% demonstrates that triple therapy not only restores large airway function (as seen in FEV1 and FVC) but also significantly enhances small airway performance. This comprehensive improvement in both central and peripheral airway function is likely responsible for

better overall pulmonary performance and clinical symptom control, as corroborated by parallel improvements in ACQ7 scores.

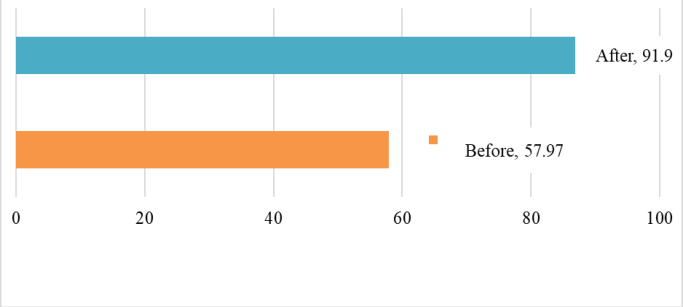

Figure 4: Comparison of $FEF_{25-75\%}$ before and after triple therapy.

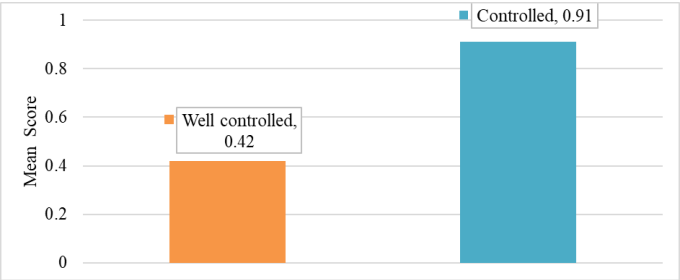

Figure 5: Comparison of ACQ 7 after 3 months with asthma severity.

Asthma control after 3 months of therapy was evaluated using the ACQ-7 score and stratified by baseline asthma severity. Patients with well-controlled asthma achieved a mean ACQ7 score of 0.42 ± 0.19, while those classified as controlled had a mean score of 0.91 ± 0.13 (Figure 5). The difference was statistically significant ($t = 7.98$, $p = 0.001$), indicating substantial improvement in patient-reported outcomes. The ACQ7 is a validated tool that quantifies asthma symptoms, activity limitation, and rescue medication use. The significant reduction in scores post-therapy demonstrates improved symptom control and enhanced quality of life, reflecting effective management of airway inflammation and obstruction. The difference between severity groups highlights that the therapy effectively benefits patients across varying baseline disease severities. The improvement in ACQ7 scores aligns with observed gains in objective lung function parameters (FEV1, FVC, FEV1/FVC, and FEF25–75%), confirming that triple therapy produces both physiological and clinically meaningful improvements. This dual effect underscores the therapy's efficacy in optimizing pulmonary function and patient-perceived asthma control across different severity categories. All subjects showed significant improvements in lung function after SITT, with increased FEV1, FEV1/FVC, FVC, and FEF25-75% values. Similar studies, such as Kerstjens et al., reported a 139-170 mL increase in peak FEV1 after introducing LAMA in patients with severe asthma (GINA steps 4 and 5). They also assessed asthma symptoms using ACQ-7, confirming significant improvement (Kerstjens et al., 2012).

A preliminary retrospective cohort study by Fujiki et al. (2023) demonstrated that SITT significantly improved disease control, particularly nighttime symptoms. They concluded that adding LAMA to ICS/LABA provided a faster response than doubling the dose of inhaled corticosteroids with LABA. The study conducted by Lai et al. (2019) also found that single-inhaler triple therapy for COPD patients can result in lower rates of moderate or severe exacerbations, as well as improved lung function and quality of life, compared with dual therapy with LABA/LAMA or ICS/LABA. The study by Busse & Abbott (2022) examined patient adherence and persistence with single-inhaler triple therapy compared with multiple-inhaler triple therapy for asthma management. The findings underscore a crucial aspect of asthma control treatment adherence, which directly influences symptom control, exacerbation frequency, and overall quality of life.

Our study contributes to the growing body of evidence supporting the effectiveness of once-daily single-inhaler triple therapy. Combining ICS, LABA, and LAMA in a single inhaler enhances asthma control and lung function. The results align with previous research demonstrating the efficacy of triple therapy in severe asthma. Notably, adding LAMA to standard ICS/LABA treatment provides superior bronchodilation and anti-inflammatory effects, particularly in patients with inadequately controlled symptoms. Single-inhaler triple therapy offers simplicity, convenience, and improved treatment adherence, reducing medication errors. By targeting both inflammatory and bronchospastic components of asthma pathophysiology, triple therapy may provide comprehensive symptom control and minimize rescue medication and healthcare utilization. However, this study has limitations, including a small sample size and a short follow-up period (3 months).

Additionally, potential side effects were not assessed. Cazzola et al. (2022) reviewed the clinical characteristics of patients on multiple-inhaler triple therapy and found that adherence often declines with increasing treatment complexity. Their analysis revealed that patients using multiple inhalers experience reduced persistence and higher rates of treatment errors compared to those on single-inhaler regimens. The findings support simplifying therapy to

enhance compliance and improve overall disease control.

In contrast, Virchow et al. (2019) provided robust clinical evidence from two phase 3 randomized controlled trials, demonstrating that single-inhaler extrafine triple therapy significantly improves lung function and reduces exacerbation rates in patients with uncontrolled asthma. The extrafine formulation ensures optimal drug deposition in both large and small airways, contributing to superior symptom relief and improved control. Complementing these results, Cella et al. (2021) conducted an ethnic sensitivity study that confirmed the pharmacokinetic and safety consistency of the extrafine single-inhaler triple therapy (beclomethasone dipropionate, formoterol fumarate, and glycopyrronium bromide) across Japanese and Caucasian populations. Their findings highlight the global applicability and tolerability of this formulation.

4. CONCLUSION

This investigation highlights the therapeutic efficacy and clinical benefits of single inhaler triple therapy (SITT) in the management of severe asthma, demonstrating improved symptom control and enhanced patient outcomes. By integrating inhaled corticosteroids (ICS), long-acting beta agonists (LABA), and long-acting muscarinic antagonists (LAMA) into a single inhaler device, SITT offers a streamlined treatment approach that simplifies disease management, enhances treatment adherence, and reduces the likelihood of medication errors. Although further research is warranted to elucidate long-term safety profiles and optimize dosing regimens, the present study provides significant insights into the therapeutic potential of SITT in severe asthma, underscoring its potential as a valuable treatment option for patients with inadequately controlled symptoms.

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Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this manuscript.

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