ORIGINAL ARTICLE

Safety and Effectiveness of Indacaterol/Glycopyrronium/Mometasone Dry Powder Inhaler in Asthma: A Prospective Multicenter Phase IV Study

Saurabh Karmakar[1*], Amit S Bhate[2], C Prashanth[3], Dilip Kadam[4], Chintan B Patel[5], Akshay Budhraja[6], Utpal Nandy[7], Amogh Lotankar[8], Kundan Nivangune[9], Kamlesh Patel[10]

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Abstract

Background: Asthma remains a major public health challenge in India, characterized by high disease burden, poor adherence, and suboptimal control despite therapeutic advances. Fixed-dose combination therapy with indacaterol/glycopyrronium/mometasone furoate (IND/GLY/MF; DIFIZMA®), a single-inhaler triple therapy (SITT), offers the potential for improved symptom control and adherence through once-daily dosing. However, real-world and postmarketing surveillance data on the effectiveness and safety of IND/GLY/MF in Indian asthma patients remain limited, underscoring the need for local evidence to guide clinical practice.

Objectives: To evaluate the safety and effectiveness of once-daily IND/GLY/MF dry powder inhaler (DPI) in Indian adults with asthma inadequately controlled on inhaled corticosteroid (ICS)–long-acting β_2-agonist (LABA) therapy.

Materials and methods: This was a prospective, open-label, multicenter, single-arm, phase IV postmarketing study conducted across multiple centers in India. Adults (18–65 years) with persistent asthma symptoms despite ICS ± LABA therapy received IND/GLY/MF DPI (160 µg mometasone furoate, 46 µg glycopyrronium bromide, 114 µg indacaterol acetate) once daily for 24 weeks. The primary endpoint was safety, based on treatment-emergent adverse events (TEAEs), serious TEAEs, and discontinuations. Secondary endpoints included changes from baseline in the asthma control questionnaire (ACQ-7) score, FEV_1, FVC, and FEV_1/FVC ratio at weeks 4, 12, and 24.

Results: A total of 200 patients were enrolled (safety set), of whom 196 were included in the modified intent-to-treat (mITT) analysis and 189 in the per-protocol (PP) population. TEAEs occurred in 9.5% of participants, with 6.5% considered drug-related; all events were mild or moderate in severity. No serious adverse events, severe TEAEs, or deaths were reported. Clinically meaningful and progressive improvements were observed in asthma control and lung function over 24 weeks. The ACQ-7 score decreased from 3.00 ± 0.59 at baseline to 2.36 ± 0.54 at week 4, 1.86 ± 0.54 at week 12, and 1.39 ± 0.61 at week 24, corresponding to mean change of −0.64 ± 0.50, −1.14 ± 0.74, and −1.62 ± 0.89, respectively (all $p < 0.0001$). Mean FEV_1 increased from 1.49 ± 0.51 L at baseline to 1.73 ± 0.60 L at week 4, 1.81 ± 0.53 L at week 12, and 1.95 ± 0.51 L at week 24, with corresponding mean changes of +0.24 L, +0.32 L, and +0.46 L (all $p < 0.0001$). Mean FVC improved from 2.13 ± 0.63 L at baseline to 2.30 ± 0.70 L, 2.33 ± 0.62 L, and 2.38 ± 0.59 L at weeks 4, 12, and 24, respectively (all $p < 0.0001$). The FEV_1/FVC ratio increased from 71.63 ± 12.76 at baseline to 76.71 ± 11.33, 80.86 ± 12.67, and 84.00 ± 8.93 at weeks 4, 12, and 24, with mean changes of +4.99, +8.91, and +12.10, respectively (all $p < 0.0001$).

No hospitalizations or rescue medication use were reported. Compliance with study medication was 100%, and both patients and physicians reported marked symptom improvement and high treatment satisfaction.

Conclusion: Once-daily IND/GLY/MF DPI demonstrated a favorable safety profile and significant, sustained clinical benefits in adults with asthma inadequately controlled on ICS–LABA therapy. The triple combination provided rapid onset and sustained improvement in asthma control and lung function, with excellent adherence and tolerability in real-world Indian clinical practice. These findings support IND/GLY/MF as an effective and practical single-inhaler triple therapy option for optimized asthma management.

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Introduction

Asthma is a chronic, heterogeneous airway disease characterized by variable symptoms and reversible airflow limitation.[1] Despite therapeutic advances, it remains a substantial global health burden, affecting over 260 million individuals and causing ~436,200 deaths annually.[2] In India, asthma continues to represent a major public health challenge, with an estimated 32 million cases, among the highest worldwide, driven by factors such as air pollution, urbanization, poor inhaler technique, and socioeconomic disparities.[2]

Optimal asthma control achieved through symptom reduction and prevention of exacerbations is the cornerstone of management.[3] Inhaled corticosteroids (ICSs) remain first-line therapy,[4] often combined with long-acting β-agonists (LABAs) for improved bronchodilation and symptom control.[5] For patients inadequately controlled on ICS/LABA, the addition of a long-acting muscarinic antagonist (LAMA) is recommended at advanced treatment steps.[3,6–8] Evidence from large randomized trials such as TRIMARAN, TRIGGER,[9] and IRIDIUM[10] shows that triple therapy (ICS/LABA/LAMA) enhances lung function, reduces exacerbations, and improves overall control compared with dual therapy. Moreover, early initiation of single-inhaler triple therapy (SITT) has been associated with faster symptom relief, better adherence, and simplified treatment regimens, key determinants of real-world outcomes.[11]

[1]Professor, Department of Pulmonary Medicine, AIIMS Patna, Patna, Bihar; [2]Consultant Physician, Department of General Medicine, Jeevan Rekha Hospital, Belagavi, Karnataka; [3]Head and Assistant Professor, Department of Pulmonary Medicine, PKTB Hospital (MMCRI) Research Centre, Mysuru, Karnataka; [4]Consultant Physician, Care Multispecialty Hospital, Pune, Maharashtra; [5]Consultant Physician, Department of General Medicine, Aatman Hospital, Bopal, Gujarat; [6]Senior Consultant, Department of Respiratory and Sleep Medicine, Aakash Healthcare Super Specialty Hospital, New Delhi; [7]Consultant Pulmonologist, Sparsh Hospital and Critical Care, Bhubaneswar, Odisha; [8]Manager, Department of Medical Affairs; [9]Team Lead, Department of Medical Affairs; [10]Head, Department of Medical and Health Tech, Lupin Limited, Mumbai, Maharashtra, India; *Corresponding Author

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In India, poor adherence, device-handling errors, and limited follow-up often hinder effective management. SITT offers practical benefits through simplified, once-daily dosing and improved adherence. Indacaterol/glycopyrronium/mometasone furoate (IND/GLY/MF), marketed as DIFIZMA®, is a once-daily fixed-dose triple combination (FDC) delivered via a dry powder inhaler (DPI). It provides complementary bronchodilatory and anti-inflammatory effects. Although clinical trials have established its efficacy, real-world and postmarketing data in Indian asthma patients are limited.

To address this evidence gap, we conducted a prospective, multicenter, open-label, single-arm phase IV study evaluating the safety and effectiveness of DIFIZMA® (IND/GLY/MF DPI) over 24 weeks in Indian adults with asthma inadequately controlled on dual therapy. The study assessed clinical outcomes, including lung function, symptom control, safety profile, and patient-reported treatment satisfaction.

Materials and Methods

Study Design

This was a prospective, open-label, multicenter, single-arm, phase IV postmarketing study conducted across several centers in India to evaluate the safety and effectiveness of an FDC of indacaterol acetate, glycopyrronium bromide, and mometasone furoate (DIFIZMA®) delivered via DPI in adults with asthma.

Each capsule of the investigational product contained 160 µg of mometasone furoate IP (equivalent to 136 µg of mometasone furoate), 63 µg of glycopyrronium Ph. Eur. (equivalent to 46 µg of glycopyrronium bromide), and 173 µg of indacaterol IH (equivalent to 114 µg of indacaterol acetate) as an inhalation powder.

The treatment period spanned 24 weeks, designed to reflect real-world clinical practice and to generate pragmatic evidence on the safety, tolerability, and effectiveness of once-daily IND/GLY/MF triple therapy in Indian adults with asthma.

Ethics and Regulatory Compliance

The study was conducted in accordance with the principles of the Declaration of Helsinki, International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines, and all applicable Indian regulatory requirements. The study protocol and related documents were reviewed and approved by the Institutional Ethics Committee (IEC) at each participating site prior to initiation.

All participants provided written informed consent before enrollment. The study was prospectively registered with the Clinical Trials Registry of India (CTRI) under the registration number CTRI/2023/09/057963.

Study Participants

Eligible participants were adults aged 18–65 years with a documented diagnosis of asthma according to the GINA guidelines, who had persistent symptoms despite regular treatment with an ICS, with or without a short-acting β_2-agonist (SABA) or LABA, for at least four weeks before screening. Participants were required to have a prebronchodilator FEV_1 between 40% and 90% of the predicted normal value and demonstrate bronchodilator reversibility ≥12% and ≥200 mL.

Key exclusion criteria included refusal to participate, history of life-threatening asthma, more than four exacerbations or more than two asthma-related hospitalizations in the preceding year, smoking history exceeding 10 pack-years, pregnancy or lactation, known hypersensitivity to any study drug or excipient, and participation in another clinical trial within 30 days prior to screening.

Study Visits and Assessments

Participants attended an initial baseline visit (day 0), which included medical history, physical examination, spirometry, and assessment of asthma control using the Asthma Control Questionnaire (ACQ-7). Proper inhaler technique training was provided, and participants received diaries to record medication use and adverse events.

Subsequent in-clinic visits were scheduled at weeks 4, 12, and 24 with telephonic follow-ups at weeks 8, 16, and 20 for safety monitoring. Spirometry, ACQ-7, and safety assessments were repeated at each clinic visit. Adherence was evaluated using patient diaries, inhaler dose counters, and investigator review.

Study Endpoints

The primary endpoint was the evaluation of the safety and tolerability of IND/GLY/MF DPI over 24 weeks, assessed by (i) the incidence, type and severity of adverse events (AEs) and treatment-related TEAEs and serious TEAEs (STEAEs); (ii) the number and severity of asthma exacerbations (mild, moderate, or severe) over 24 weeks; and (iii) overall drug tolerability throughout the treatment period.

Secondary endpoints assessed treatment effectiveness, including changes from baseline in ACQ-7 score, FEV_1, FVC, and FEV_1/FVC ratio at weeks 4, 12, and 24; use of rescue medication; patient and physician satisfaction; and treatment compliance.

Statistical Analyses

Descriptive statistics (mean ± SD for continuous variables; frequency and percentage for categorical variables) were used to summarize demographic and baseline characteristics. The safety set included all participants who received at least one dose of study medication. The modified intent-to-treat (mITT) population comprised participants who consumed at least one dose of the investigational product and had at least one postbaseline assessment. The per-protocol (PP) set included those who completed the study without major protocol deviations.

Safety analyses were performed on the safety set, summarizing AEs by system organ class, preferred term, and maximum severity.

Effectiveness analyses were performed on both the mITT and PP populations. Changes from baseline in ACQ-7 score, FEV_1, FVC, and FEV_1/FVC ratio were assessed using paired *t*-tests, with results presented as mean change ± SD. A two-sided p-value < 0.05 was considered statistically significant.

Results

Patient Disposition

A total of 200 patients were screened and enrolled, all of whom received at least one dose of IND/GLY/MF DPI, constituting the safety population. The mITT population comprised 196 patients, while the per-protocol (PP) population included 189 participants. Four patients were excluded from the mITT set due to missing postbaseline effectiveness assessments, and seven from the PP set owing to major protocol deviations (noncompliance, missed follow-ups, or inadequate spirometry). No participants were lost to follow-up. Figure 1 depicts patient disposition across the study populations.

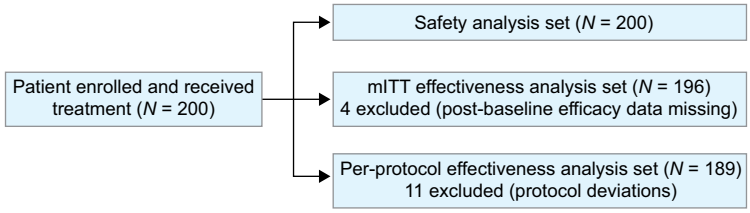


Fig. 1: Patient disposition showing numbers screened, enrolled, and included in safety, mITT, and PP populations

Table 1: Baseline demographic and clinical characteristics

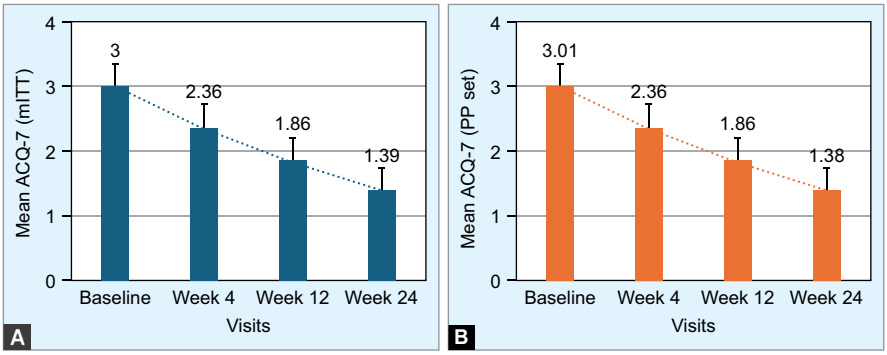
Parameter	*Safety (n = 200)*	*mITT (n = 196)*	*PP (n = 189)*
Female, *n* (%)	75 (37.5)	74 (37.8)	70 (37.0)
Male, *n* (%)	125 (62.5)	122 (62.2)	119 (63.0)
Age (years), mean	43.9	44.0	44.3
Height (cm), mean	162.6	162.8	162.8
Weight (kg), mean	62.4	62.4	62.1
BMI (kg/m^2), mean	23.6	23.5	23.4
Hypertension, *n* (%)	12 (6.0)	12 (6.1)	11 (5.8)
Diabetes mellitus, *n* (%)	7 (3.5)	7 (3.6)	6 (3.2)

Table 2: Overall summary of adverse events (safety analysis set, *n* = 200)

Event category	*n (%)*
Any adverse events (AEs)	19 (9.5)
Any TEAEs	19 (9.5)
Drug-related TEAEs	13 (6.5)
Severe TEAEs	0 (0.0)
Serious TEAEs (SAEs)	0 (0.0)
TEAEs leading to death	0 (0.0)

Table 3: Mean FEV_1/FVC ratio from baseline–mITT and PP populations

Visit	*mITT (mean ± SD)*	*Mean change*	*p-value*	*PP (mean ± SD)*	*Mean change*	*p-value*
Baseline	71.63 ± 12.76	–	NA	71.80 ± 12.68	–	NA
Week 4	76.71 ± 11.33	+4.99 ± 9.89	< 0.0001	76.88 ± 11.35	+5.00 ± 9.45	<0.0001
Week 12	80.86 ± 12.67	+8.91 ± 13.10	< 0.0001	80.92 ± 12.77	+8.86 ± 13.10	<0.0001
Week 24	84.00 ± 8.93	+12.10 ± 12.28	< 0.0001	84.24 ± 8.59	+12.22 ± 11.95	<0.0001



Figs 2A and B: Mean ACQ-7 score: (A) mITT analysis set (*n* = 196); (B) PP analysis set (*n* = 189)

Baseline Demographics and Clinical Characteristics

Baseline demographics and clinical characteristics were comparable across analysis populations (Table 1). The mean age of participants was 43.9 years, with 37.5% females. The mean height, weight, and BMI were 162.6 cm, 62.4 kg, and 23.6 kg/m^2, respectively. Hypertension (6.0%) and diabetes mellitus (3.5%) were the most common comorbidities.

Prior and Concomitant Medications

The most frequently used medications were telmisartan (4.5%), multivitamin–multimineral supplement (3.5%), and metformin (3.0%). Concomitant medications were rare, with paracetamol reported in 1.0% of participants; all other therapies were <1%.

Safety Evaluation

In the safety population (*n* = 200), 19 participants (9.5%) experienced TEAEs, of which 13 (6.5%) were considered drug-related. No severe TEAEs, serious adverse events (SAEs), or deaths were reported. Table 2 summarizes the overall adverse events reported.

Treatment-emergent adverse events (TEAEs) were distributed across multiple system organ classes. The most frequent events were cough (3.0%), dyspepsia (1.5%), and pyrexia (1.5%). Other events, including nausea, headache, ligament pain, asthenia, and upper respiratory tract infection, occurred in ≤1% of participants.

Of the 19 TEAEs, 16 were mild, and 3 were moderate in severity. Most were assessed as "unlikely" or "possibly" related to the investigational product. Cough was the most common drug-related TEAE, with half classified as "certainly" and the remainder as "possibly" related to treatment. No TEAEs led to treatment discontinuation, and clinical laboratory parameters and vital signs remained stable throughout the study.

Efficacy Results

Asthma Control (ACQ-7 Score)

In the mITT population (*n* = 196), mean ACQ-7 score decreased significantly from 3.00 ± 0.59 at baseline to 2.36 ± 0.54 at week 4, 1.86 ± 0.54 at week 12, and 1.39 ± 0.61 at week 24 (corresponding mean changes –0.64 ± 0.50, –1.14 ± 0.74, –1.62 ± 0.89; all $p < 0.0001$) (Fig. 2A).

The PP population (*n* = 189) showed similar improvements, decreasing from 3.01 ± 0.60 at baseline to 2.36 ± 0.54, 1.86 ± 0.53, and 1.38 ± 0.60 at weeks 4, 12, and 24, respectively (all $p < 0.0001$) (Fig. 2B).

Lung Function

FEV_1: In the mITT population, mean FEV_1 increased significantly from 1.49 ± 0.51 L at baseline to 1.73 ± 0.60 L, 1.81 ± 0.53 L, and 1.95 ± 0.51 L at weeks 4, 12, and 24 (corresponding mean changes +0.24 L, +0.32 L, +0.46 L; all $p < 0.0001$) (Fig. 3A). Similar improvements were observed in the PP population (+ 0.23 L, +0.31 L, +0.46 L; all $p < 0.0001$) (Fig. 3B).

FVC: Mean FVC increased from 2.13 ± 0.63 L at baseline to 2.30 ± 0.70 L, 2.33 ± 0.62 L, and 2.38 ± 0.59 L at weeks 4, 12, and 24 in the mITT population, with comparable changes in the PP set (+0.16 L, +0.19 L, +0.26 L; all $p < 0.0001$) (Figs 3A and B).

FEV_1/FVC Ratio

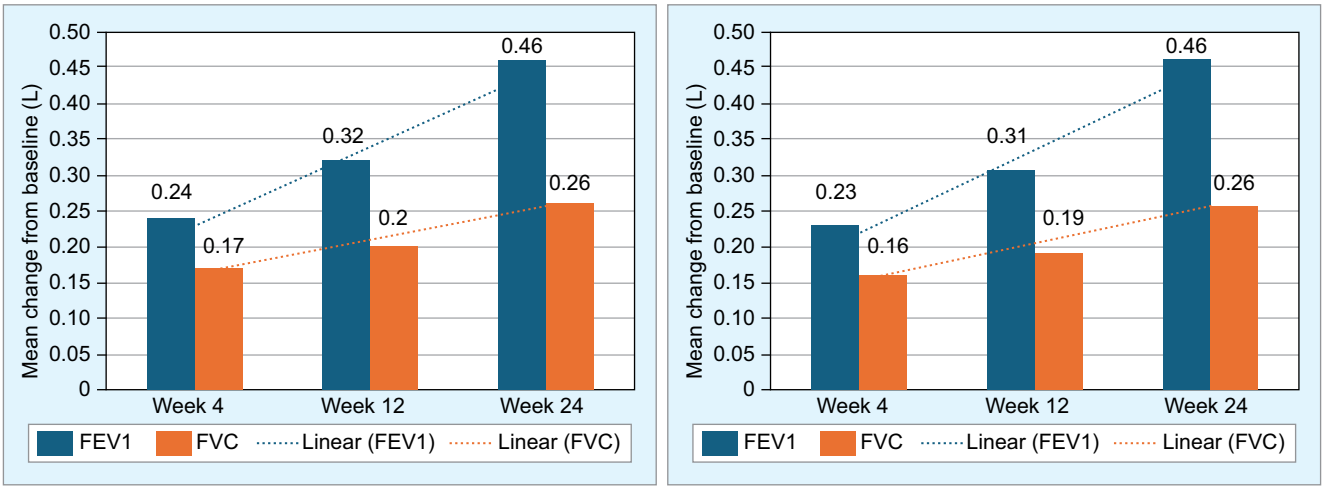
In the mITT population, the mean FEV_1/FVC improved significantly from 71.63 ± 12.76 at baseline to 76.71 ± 11.33, 80.86 ± 12.67, and 84.00 ± 8.93 at weeks 4, 12, and 24 (corresponding mean changes +4.99, +8.91, +12.10; all $p < 0.0001$). Results in the PP population were consistent (Table 3 and Fig. 4).

Hospitalization and Compliance

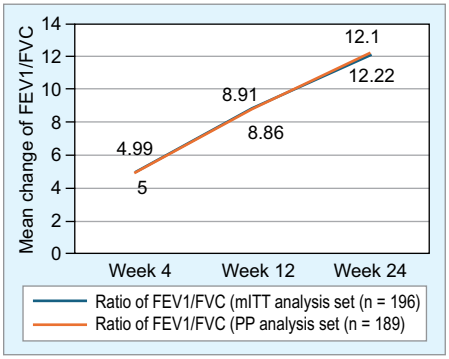
No participants required hospitalization or rescue medication during the study. Treatment compliance with the investigational product was 100% across all participants.

Patient-reported Outcomes and Physician Assessments

Both patient and physician evaluations demonstrated consistent improvement across



Figs 3A and B: Improvement in lung function parameters: (A) FEV1; (B) FVC



Figs 4: Mean change in FEV1/FVC from baseline—mITT analysis set (*n* = 196); PP analysis set (*n* = 189)

all assessed symptoms over the 24-week treatment period. By the end of the study, over 90% of participants were free of fever and sore throat. Symptoms such as cough, dyspnea, fatigue, and myalgia showed marked resolution, with moderate cases nearly eliminated.

Discussion

This 24-week, real-world phase IV study demonstrated that once-daily IND/GLY/MF DPI (DIFIZMA®) is both safe and effective in Indian adults with asthma inadequately controlled on dual therapy. Treatment led to significant and sustained improvements in asthma control, as measured by ACQ-7 scores, alongside notable gains in lung function parameters (FEV_1, FVC, and FEV_1/FVC ratio). Improvements in patient- and physician-reported outcomes corroborated enhanced symptom control, better treatment satisfaction, and consistently high adherence throughout the study.

The enrolled population represented typical patients seen in Indian clinical practice, with frequent comorbidities such as hypertension (6.0%) and diabetes mellitus (3.5%). Despite these conditions, IND/GLY/MF DPI demonstrated a favorable tolerability profile and produced clinically meaningful benefits, underscoring its effectiveness across diverse patient profiles. These findings are consistent with pivotal randomized trials, such as the IRIDIUM study, which reported that SITT with IND/GLY/MF achieved superior improvements in lung function and asthma control compared with dual therapy using mometasone/indacaterol (MF/IND) alone.[10] Similarly, the ARGON trial found that IND/GLY/MF SITT provided better lung function outcomes, improved adherence, and greater convenience than multiple-inhaler regimens.[12]

The present study extends these data to real-world Indian settings, where asthma control remains suboptimal due to factors such as high pollution exposure, lower baseline lung function, limited follow-up, and poor adherence. The consistent improvements observed in ACQ-7 scores and spirometry parameters reaffirm the clinical utility of IND/GLY/MF DPI in achieving better control in these challenging contexts. The once-daily dosing schedule and user-friendly device design likely contributed to the 100% treatment adherence, emphasizing the practical advantages of SITT in routine care.

Globally, several fixed-dose ICS/LABA/LAMA combinations, such as umeclidinium/vilanterol/fluticasone furoate (UVF), are approved for patients inadequately controlled on dual therapy. Clinical trials with these combinations have demonstrated reductions in exacerbation rates, enhanced quality of life, and superior lung function compared with dual therapy.[13–15] The current findings complement global evidence by providing postmarketing, real-world validation of IND/GLY/MF effectiveness and safety among Indian patients, including those with comorbidities. The absence of SAEs and the predominance of mild TEAEs further reinforce its favorable safety profile.

Key strengths of this study include its multicenter design, real-world context and inclusion of patients with comorbid conditions, all of which enhance the generalizability of results to clinical practice. The findings highlight that DIFIZMA® can deliver meaningful clinical benefits under routine conditions, aligning with international recommendations for SITT as an escalation strategy in patients remaining symptomatic on dual therapy. Clinically, this supports the use of IND/GLY/MF DPI as a simplified, once-daily regimen that may improve adherence and facilitate better disease management, particularly in patients with concurrent chronic illnesses.

However, the open-label, single-arm study design represents a limitation, as it precludes direct comparisons of effectiveness with dual or alternative triple therapies. Future controlled, long-term comparative studies are warranted to further evaluate the sustained effectiveness, safety, and pharmacoeconomic implications of IND/GLY/MF in both Indian and global populations.

Conclusion

Once-daily fixed-dose triple therapy with IND/GLY/MF delivered via DPI demonstrated a favorable safety and tolerability profile in adults with asthma inadequately controlled on standard ICS/LABA therapy. No SAEs or treatment-related deaths occurred, and the majority of TEAEs were mild and non-serious. Vital signs and laboratory parameters remained stable, and patient-reported tolerability was high, confirming that the primary safety objective was achieved.

Effectiveness analysis showed significant and sustained improvements in lung function (FEV_1, FVC, and FEV_1/FVC ratio), asthma control

(ACQ-7), and both patient- and physician-reported outcomes over 24 weeks. Clinical benefits were evident as early as week 4 and maintained through week 24, indicating that the triple combination of IND/GLY/MF provides rapid and durable control of asthma symptoms and airflow limitation.

Overall, these findings support SITT of IGM as a safe, effective, and convenient treatment option for patients with persistent asthma despite optimized dual therapy. In real-world practice, once-daily IND/GLY/MF offers sustained clinical benefits, excellent tolerability, and simplified disease management, addressing key unmet needs in asthma care.

Orcid

Saurabh Karmakar https://orcid.org/0000-0002-8138-4864

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