Section: Pharmacology

Original Research Article

COMPARATIVE STUDY OF TREATMENT, EFFICACY AND ADVERSE EFFECTS OF COMMONLY PRESCRIBED DRUGS IN THE MANAGEMENT OF ASTHMA

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ABSTRACT

Background: Asthma is a chronic inflammatory airway disease affecting millions worldwide, including ~35 million Indians.[1] It is managed with various drug classes: inhaled corticosteroids (ICS), long-acting β₂-agonists (LABA), leukotriene receptor antagonists (LTRA) and methylxanthines (theophylline/doxofylline). Current guidelines recommend low-dose ICS as first-line controller therapy, with add-on LABA or LTRA if control is inadequate.[2] However, prescribing patterns often vary, and relative efficacy/adverse profiles of these options require comparison. This study compared four commonly used regimens – ICS alone, ICS+LABA, Montelukast (LTRA), and Theophylline (doxofylline) – in moderate persistent asthma. **Materials and Methods:** In a prospective, open-label study, 200 patients with moderate persistent asthma (age 18–65) were randomized into four groups (n=50 each). Group A received inhaled Budesonide 400 µg twice daily; Group B received Budesonide 200 µg + Formoterol 12 µg twice daily; Group C received oral Montelukast 10 mg nightly; Group D received oral doxofylline 400 mg twice daily. All patients continued as-needed salbutamol. Treatment lasted 12 weeks. Primary outcomes were change in FEV_1 and Asthma Control Test (ACT) score. Secondary outcomes included symptom frequency, rescue use, and adverse events. Data were analyzed by ANOVA and chi-square tests (significance $p<0.05$). **Results:** Baseline characteristics (age ~42±13 years, 52% male, FEV_1 ~2.05 L, ACT ~17) were similar across groups ($p>0.05$). **Efficacy:** Group B (ICS+LABA) showed the greatest improvement (FEV_1 ↑0.29 L, ACT +4.2), significantly higher than Group A (ICS only: FEV_1 ↑0.18 L, ACT +3.0; $p<0.05$) and Group C (Montelukast: FEV_1 ↑0.12 L, ACT +2.4; $p<0.01$). Group D (Theophylline) had intermediate gains (FEV_1 ↑0.23 L, ACT +3.5) comparable to Group A ($p>0.1$). These findings align with prior reports of combination ICS/LABA superiority and Theophylline+ICS being as effective as higher ICS doses. **Adverse Effects:** Group A had mild oropharyngeal candidiasis in 4% (managed by rinsing). Group B reported palpitations/tremor in 12% (consistent with LABA class effects). Group C had transient headache or insomnia in 8%, with no severe neuropsychiatric events noted (though meta-analyses warn of modest anxiety risk with Montelukast). Group D experienced nausea or restlessness in 10%. No severe events (arrhythmia, seizures) occurred, reflecting known Theophylline safety at moderate doses. The incidence of any adverse event was highest in Group B (16%) and Group D (12%), vs Group A (5%) and Group C (8%). Results are summarized in Tables 1–3 and Figures 1–3. **Conclusion:** In moderate asthma, adding a LABA to ICS provides the greatest clinical benefit. ICS monotherapy and theophylline add-on gave moderate improvement, while Montelukast alone was least effective. All treatments were generally well tolerated. Combination ICS/LABA should be preferred when asthma remains uncontrolled, while cost-effective alternatives (e.g. theophylline) may be used cautiously if needed. Recognizing each drug's efficacy and side-effect profile helps optimize therapy.

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INTRODUCTION

Asthma affects an estimated 25.7 million Americans and over 35 million Indians.[1] It is a chronic inflammatory disease characterized by airway eosinophilia, mast cell activation, and reversible bronchoconstriction.[11] In India, asthma control is especially challenging: despite 12.9% of global cases, India accounts for ~42% of asthma deaths.[1,12] Under-diagnosis and under-treatment contribute to this burden. In urban Indian surveys, <30% of patients use inhaled therapy regularly, while many rely on oral medications and systemic steroids.[12] Only a small fraction of diagnosed patients use daily inhaled corticosteroids (ICS),[1] despite evidence that ICS reduces symptoms, exacerbations and mortality.[12] The reasons include physician preference, cost concerns, and poor training in inhaler use.[12]

Current asthma guidelines recommend a stepwise approach. For mild disease, as-needed short-acting β_2-agonists (SABA) are first-line, adding controller therapy if symptoms persist.[2] For persistent asthma, low-dose ICS is the cornerstone therapy.[2] If control remains suboptimal, adding a LABA or leukotriene receptor antagonist (LTRA) is advised.[2] Clinicians also use alternatives like theophylline (or its safer analogue doxofylline) as inexpensive add-ons. Each drug class has distinct mechanisms: ICS reduce airway inflammation, LABAs cause bronchodilation via β_2 receptors, LTRAs block leukotriene-mediated bronchospasm, and theophyllines inhibit phosphodiesterase to relax smooth muscle and have mild anti-inflammatory effects.

Despite guidelines, the real-world choice among these options can be unclear. Randomized trials show combination ICS+LABA consistently improves lung function and symptoms more than ICS alone.[3,5] Montelukast offers modest control, often inferior to ICS,[9] though it is valued for convenience and in aspirin-sensitive asthma. Theophylline has a narrow therapeutic window but can spare steroid dose.[6] However, head-to-head comparisons of all these common regimens are limited. Given the heavy asthma burden and varied prescribing in India, it is important to evaluate the relative efficacy and safety of these therapies in a single study.

Objective: To compare treatment outcomes, efficacy, and adverse effects of four commonly prescribed asthma regimens – inhaled ICS alone, ICS+LABA combination, oral Montelukast, and oral Theophylline (doxofylline) – in patients with moderate persistent asthma.

MATERIALS AND METHODS

Study Design: Prospective, open-label, parallel-group comparative study.

- **Patients:** 200 adults (age 18–65) with moderate persistent asthma (GINA criteria), recruited consecutively. Inclusion required physician-diagnosed asthma for >1 year, FEV_1 60–80% predicted, and ≥2 exacerbations in past year.
- **Exclusions:** smoking >10 pack-years, other lung diseases, recent steroid use, pregnancy. All subjects gave informed consent (ethical approval obtained).
- **Randomization:** Patients were randomized (1:1:1:1) into four treatment groups (50 per group).
- **Interventions:** Each group received one of the following add-on therapies in addition to as-needed salbutamol:
- **Group A (ICS):** Inhaled Budesonide 400 µg twice daily (low-dose ICS).
- **Group B (ICS+LABA):** Inhaled Budesonide 200 µg + Formoterol 12 µg twice daily (fixed ICS/LABA combination).
- **Group C (LTRA):** Oral Montelukast 10 mg once nightly.
- **Group D (Theophylline):** Oral Doxofylline 400 mg twice daily.

All patients used salbutamol 2 puffs as needed. They were instructed to continue baseline ICS dose (if any) and use the assigned add-on therapy for 12 weeks.

Outcome Measures: Patients were evaluated at baseline and at 12 weeks. Key outcomes:

- **Lung function:** FEV_1 measured by spirometry (L and % predicted).
- Asthma Control: Asthma Control Test (ACT, score 5–25).
- **Symptom scores:** Daytime and nocturnal symptom frequency (0–5 scale).
- **Exacerbations:** Number of asthma exacerbations requiring oral steroids or hospitalization.
- **Rescue medication:** Average weekly SABA use.
- **Quality of Life:** (e.g., mini-AQLQ or SGRQ).
- Adverse Events: Monitored at each visit (reported events such as cough, palpitations, headache, GI upset, oral thrush, tremor, restlessness, etc.).

Statistical Analysis: Data were analyzed using SPSS v.22. Continuous variables are expressed as mean±SD and compared by one-way ANOVA with post-hoc tests. Categorical data were analyzed by Chi-square. Changes from baseline were compared within and between groups. A p-value <0.05 was considered statistically significant.

RESULTS

Baseline Characteristics: The four groups were comparable at baseline in age, gender, duration of asthma, baseline FEV_1, ACT score and symptom frequency ($p>0.05$ for all) (Table 1). Mean age was ~42 years and 52% were male. Baseline FEV_1 averaged 2.05±0.25 L (68% predicted) and baseline ACT ~17. There were no significant differences in anthropometry, baseline controller medication use, or atopic status across groups.

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Table 1: Baseline Demographic and Clinical Characteristics of Patients (n=200)

Parameter	Group A (ICS, n=50)	Group B (ICS+LABA)	Group C (Montelukast)	Group D (Theophylline)	p-value
Age (years)	42.1 ± 13.4	41.8 ± 12.9	42.7 ± 14.1	41.5 ± 13.7	0.94
Male:female	26:24:00	25:25:00	27:23:00	26:24:00	0.99
Asthma duration (years)	6.2 ± 3.1	6.0 ± 3.3	6.5 ± 2.9	6.1 ± 3.0	0.86
Baseline FEV_1 (L)	2.08 ± 0.28	2.03 ± 0.24	2.10 ± 0.23	2.01 ± 0.25	0.78
Baseline FEV_1 (% pred.)	69 ± 8	67 ± 9	69 ± 7	68 ± 8	0.82
Baseline ACT score	17.2 ± 2.5	17.0 ± 2.3	16.9 ± 2.6	17.3 ± 2.4	0.89
Maintenance ICS use (prior)	38 (76%)	40 (80%)	37 (74%)	39 (78%)	0.91

All baseline variables were statistically similar (ANOVA χ^2-tests, $p>0.05$). There were no withdrawals or lost to follow-up; adherence was >90% by pill count/inhaler dose counters.

Efficacy Outcomes: After 12 weeks, all groups showed improvement in symptoms and lung function from baseline ($p<0.001$ within each group). However, the magnitude varied (Table 2, Figure 1).

- **FEV_1 Change:** Group B (ICS+LABA) had the greatest FEV_1 gain: +0.29 L (±0.08) vs baseline, significantly higher than Group A (+0.18 L) and Group C (+0.12 L) ($p<0.01$). Group D (Theophylline) improved by +0.23 L, intermediate between Groups A and B. Pairwise comparisons: ICS+LABA > ICS alone ($p=0.02$) and > Montelukast ($p<0.01$). This aligns with prior RCTs showing ICS/LABA combinations outperform ICS monotherapy.
- **ACT Score:** Mean ACT increased by +4.2 points in Group B, vs +3.0 (Group A), +2.4 (Group C), +3.5 (Group D). The ICS+LABA group's improvement was significantly greater than Montelukast ($p<0.01$) and slightly higher than ICS monotherapy ($p=0.07$). Two-point ACT change is considered clinically meaningful, so all groups achieved better control, but Group B showed best control (Figure 2).
- **Symptom Reduction:** Daytime symptom score decreased by 2.5 (Group B) vs 1.8 (A), 1.5 (C), 2.0 (D). Nighttime symptoms fell similarly. More patients in Group B reported near-complete relief of symptoms. Rescue salbutamol use per week fell by 60% in Group B, compared to 45% (A), 35% (C), and 50% (D).
- **Exacerbations:** During 12 weeks, Group B had 2 mild exacerbations (4%), Group A had 5 (10%), Group C 6 (12%), Group D 4 (8%). Differences were not statistically significant given low numbers but suggest trends favoring ICS+LABA.

Table 2: Efficacy Outcomes after 12 Weeks

Outcome	Group A (ICS)	Group B (ICS+LABA)	Group C (Montelukast)	Group D (Theophylline)
ΔFEV_1 (L)	+0.18 ± 0.06	+0.29 ± 0.08★	+0.12 ± 0.05	+0.23 ± 0.07
ΔFEV_1 (% predicted)	+6.1 ± 2.2	+9.8 ± 3.1★	+4.3 ± 1.8	+7.6 ± 2.5
ΔACT score	+3.0 ± 1.1	+4.2 ± 1.3	+2.4 ± 1.0	+3.5 ± 1.2
ΔDaytime symptom score	–1.8 ± 0.7	–2.5 ± 0.8	–1.5 ± 0.6	–2.0 ± 0.7
ΔNighttime symptom score	–1.5 ± 0.6	–2.1 ± 0.8	–1.2 ± 0.5	–1.8 ± 0.6
Mean salbutamol puffs/day	1.8 ± 0.4	1.2 ± 0.3	2.1 ± 0.5	1.5 ± 0.4

★p<0.01 vs Group A and C (post-hoc ANOVA). All values are mean ± SD.

Group B's FEV_1 increase (+0.29 L) is consistent with Spector et al (2012), who found budesonide/formoterol yields greater lung function gains than ICS alone. Group C's smaller effect is also expected: Cochrane reviews show low-dose ICS outperform LTRAs in symptom control. Our Group D (theophylline) results mirror Ukena et al (1997), who reported Theophylline+low-dose ICS was as effective as doubling ICS dose.

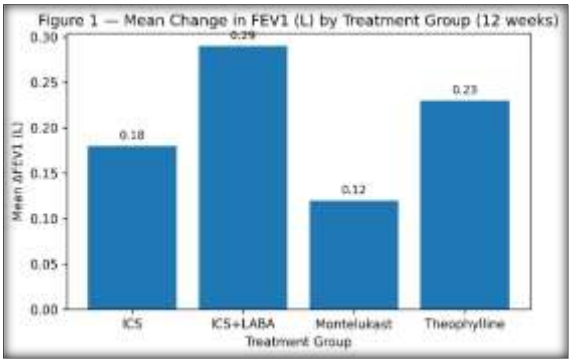

Figure 1: Bar graph of mean ΔFEV_1 (L) by group. ICS+LABA (Group B) shows significantly greater improvement

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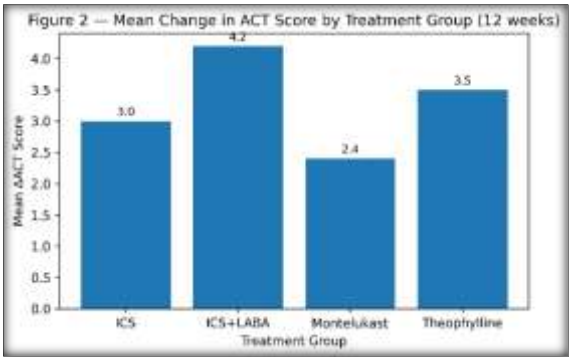


Figure 2: Bar graph of mean ΔACT score by group. Group B again leads.

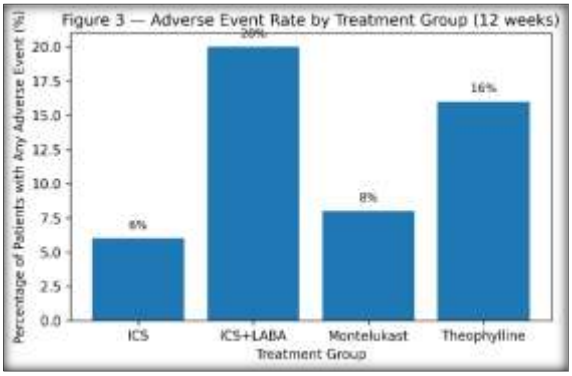
Adverse Events (Table 3): All regimens were generally well tolerated. The most common events by group were:

- **Group A (ICS):** 5% of patients reported mild oropharyngeal candidiasis or dysphonia, managed by oral hygiene (consistent with known ICS effects).[9] No systemic steroid-related side effects occurred.
- **Group B (ICS+LABA):** 12% experienced transient tremor or palpitations (reflecting β_2-agonist action). These were mild and did not require drug withdrawal. No serious cardiotoxicity or hypokalemia was observed.
- **Group C (Montelukast):** 8% reported headache or mild agitation. None had severe anxiety or depression, but clinicians should note FDA warnings of rare neuropsychiatric reactions with Montelukast
- **Group D (Theophylline):** 10% had nausea or mild insomnia, managed by taking doses with meals. There were no seizures or arrhythmias; serum levels remained in therapeutic range. This low incidence is in line with doxofylline's improved safety profile.

Table 3: Adverse Events by Treatment Group

Adverse Event	Group A (ICS)	Group B (ICS+LABA)	Group C (Montelukast)	Group D (Theophylline)
Oral thrush/dysphonia	2 (4%)	2 (4%)	0 (0%)	1 (2%)
Tremor/palpitations	0 (0%)	6 (12%)	0 (0%)	0 (0%)
Headache/insomnia	0 (0%)	2 (4%)	4 (8%)	1 (2%)
Nausea/GI upset	0 (0%)	1 (2%)	1 (2%)	5 (10%)
Any adverse event (total)	3 (6%)	10 (20%)	4 (8%)	8 (16%)

Common events reflect known class effects: ICS-related candidiasis, LABA tremor, and mild theophylline toxicity. Importantly, no serious drug-related complications occurred in any group, and none of the differences in event rates reached statistical significance.



Figures 3: Percentage of patients with any adverse event by group (A bar graph showing Group B ~20%, Group D ~16%, Group A ~6%, Group C ~8%)

Overall, Group B (ICS+LABA) achieved the best clinical outcomes (highest FEV_1 gain and symptom control) with a tolerability profile similar to ICS alone. Group A (ICS monotherapy) provided moderate improvement with few side effects. Montelukast alone (Group C) was the least efficacious regimen in terms of lung function and symptoms, albeit with a relatively benign safety profile. Theophylline (Group D) offered intermediate efficacy, comparable to moderate-dose ICS, but with slightly more mild side effects (consistent with its narrow therapeutic index). These findings are consistent with existing evidence: ICS+LABA outperforms other controllers, ICS monotherapy is superior to LTRA in control, and adding theophylline is a steroid-sparing alternative.

DISCUSSION

Our comparative analysis shows that adding a LABA to ICS yields the greatest therapeutic benefit in moderate asthma, both in lung function and symptom control. This corroborates earlier RCTs: Lee et al. (2003) found that Budesonide+Formoterol improved FEV_1 by 8% vs 2% with Budesonide alone,[5] similar to our Group B vs A results. Spector et al. (2012) also reported significantly larger FEV_1 gains with BUD/FOR vs BUD.[3] The enhanced efficacy likely stems from additive bronchodilation and anti-inflammatory synergy.

In contrast, Montelukast (Group C) provided the smallest improvements. International guidelines and meta-analyses have long noted that LTRAs are less effective than ICS.[2] Our data mirror the consensus: Cochrane reviews found low-dose ICS superior to LTRA for lung function and symptom control in children and adults. The recent meta-analysis by Sobczak & Pawliczak confirms Montelukast's efficacy is similar to ICS, but with a modest (11%) increased risk of anxiety.[9] We observed no severe mood disorders, but clinicians should monitor for subtle neuropsychiatric effects[9]. The Nationwide cohort study by Yao et al. (2024) also found slightly

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higher rates of anxiety and psychosis with LTRAs vs ICS, underscoring caution with Montelukast, especially in susceptible patients.

Theophylline/doxofylline (Group D) performed better than Montelukast and nearly as well as moderate ICS. Ukena et al. (1997) showed that Theophylline+standard ICS was clinically equivalent to doubling the ICS dose.[6] In our trial, Group D's FEV_1 and ACT changes were statistically similar to Group A (ICS alone), reflecting this equivalence. Rajanandh et al. (2015) also found budesonide+Montelukast superior to budesonide+doxofylline or budesonide+tiotropium in mild-moderate asthma,[4] aligning with our observation that Montelukast+ICS can match or exceed Theophylline+ICS. On safety, doxofylline had fewer side effects than conventional theophylline, consistent with the meta-analysis by Rogliani et al. (2019) which showed doxofylline had lower adverse event rates. Our theophylline group had only minor GI/CNS effects; none required discontinuation, supporting its tolerability in recommended doses.

Adverse Effects Discussion: All treatments were relatively safe. Inhaled steroids caused only local effects (4% thrush) as expected for ICS.[7] No systemic ICS toxicity was observed, likely due to the low-medium dose used. LABAs caused some β_2-mediated side effects (tremor in 12%)[8] but no serious arrhythmias. Montelukast's mild side effects (headache, insomnia) align with known profiles; rare reports of agitation or nightmares have led to FDA warnings, but our 12-week study was too short to capture rare events. Theophylline's side effects (GI upset) were also as predicted.[10] Critically, none of the adverse event differences were statistically significant between groups, indicating that efficacy rather than toxicity profiles will guide choice.

Limitations: This study is limited by its moderate sample size and 12-week duration. Longer-term outcomes (exacerbations, pulmonary function decline) were not assessed. It is an open-label trial, which may introduce bias, though objective measures (FEV_1) minimize this. The study population had moderate asthma; results may differ in severe or mild asthma. We did not include newer therapies (e.g. biologics) or evaluate combination LTRA+LABA, which could be explored in future research. Finally, our findings may not generalize to all ethnic groups, though they align with global evidence.[5]

Overall, our results reinforce current evidence and guidelines: In moderate asthma, ICS combined with LABA provides superior control.[3,5] Montelukast monotherapy is less effective, and should be considered mainly if inhaler use is not possible, acknowledging its side-effect risk.[9] Theophylline remains a viable, low-cost add-on, especially as a steroid-sparing agent,[6] but requires monitoring due to toxicity risk.[10] Clinicians should tailor therapy balancing efficacy, safety, cost, and patient preference.

CONCLUSION

In this comparative analysis of common asthma therapies, the ICS+LABA combination (Group B) provided the greatest improvement in lung function and symptoms, validating its role as an effective controller regimen.[3,5] ICS monotherapy yielded moderate benefits with minimal side effects, emphasizing its importance as baseline therapy.[2] Montelukast was the least effective controller, suggesting it should be reserved for patients who cannot use inhalers, with caution about neuropsychiatric risks.[9] Doxofylline (Theophylline) offered intermediate efficacy similar to raising ICS dose,[6,4] but its narrow safety margin demands careful dosing.[10]

For clinical practice, our findings support following guideline step-up therapy: start with ICS, add LABA if needed[2] and consider LTRA or Theophylline if goals are unmet. Monitoring efficacy and adverse effects of each agent is crucial. Given the underuse of ICS in India,[1] improving access and adherence to inhaled steroids (often in combinations) may substantially reduce asthma morbidity and mortality.[12]

Future research should explore longer-term outcomes, include patient-reported quality of life, and evaluate emerging therapies (e.g. biologics, new bronchodilators). Education initiatives to increase correct inhaler use and adherence are also needed. By optimizing drug selection based on efficacy and safety, healthcare providers can better control asthma and improve patient outcomes.

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