

Editorial

Asthma management in India: Changing paradigms

Asthma is a common clinical problem with far-reaching impacts on global health. According to the Global Burden of Disease Study, over 34 million people in India suffer from asthma, amounting to approximately 13 per cent prevalence worldwide¹. However, the rates of mortality and disability-adjusted life years due to asthma in India are threefold and twofold higher than the global rates, respectively. Such alarming findings are the consequence of issues related to the management of asthma in our country, including timely diagnosis and appropriate use of inhaled therapy. Herein, we briefly discuss these issues in the light of the evolving paradigms in asthma management.

Challenges in asthma diagnosis in India

The diagnosis of asthma is mainly based on clinical history and is supported by additional tests such as spirometry and peak flowmeter measurements. However, the non-availability or underuse of these diagnostic tools leads to underdiagnosis of asthma, especially in community settings². In reality, the utilisation rates of spirometry and peak flowmetry for asthma diagnosis in India are dismally low, ranging between 9 and 18 per cent³. Unsurprisingly, a recent sub-analysis of the Global Asthma Network (GAN) Study found that asthma was undiagnosed in 82 per cent of chronic wheezers and 70 per cent of subjects with severe asthma symptoms in various urban centres in India¹. This indicates an urgent need to enhance the public health capabilities to diagnose asthma in India with the help of physician education and the provision of essential diagnostic tools to the primary and secondary health centres. The peak flowmeter is an inexpensive and reliable diagnostic tool, which is listed among the World Health Organisation (WHO) package of essential non communicable disease interventions in primary care⁴.

Finally, the stigma associated with a label of 'asthma' or '*damaa*,' as it is called in the local

language, leads to a delay in diagnosis and treatment initiation³. There are many negative perceptions regarding inhaler use among the public, including fears of side effects and potential for addiction. Hence, patient education campaigns are needed to disseminate accurate information about asthma and dispel myths and misconceptions.

Management aspects – Has the time for anti-inflammatory reliever therapy arrived?

Currently, the first-line treatment of asthma involves inhaled medication, which includes a combination of reliever (relieves symptoms) and controller medication (reduces inflammation). However, several challenges persist in our ability to provide optimal asthma management, such as improper inhaler technique, inappropriate dosages, associated comorbidities that hinder asthma remission, and delayed recognition of warning signs leading to late presentation to the healthcare facility³. All clinicians need to convey the correct diagnosis and treatment plan for all patients with asthma, as non-communication of the correct diagnosis is associated with poor patient adherence. Since even mild asthma may lead to fatal exacerbations, a proper home management plan is necessary for all patients for early recognition of worsening disease and immediate management thereof⁵.

Regarding pharmacotherapy, over the past few decades, the blue inhaler containing salbutamol has become the conventional reliever therapy for asthma symptoms. Various international guidelines had recommended it as the first step of treatment till 2018. Although short-acting beta-2 agonist (SABA) therapy (e.g., salbutamol) effectively relieves acute asthma symptoms, it has no anti-inflammatory activity. Hence, SABA therapy does not target the underlying pathophysiology of asthma, thereby worsening airway inflammation⁶. Furthermore, there are concerns that SABA overuse downregulates beta-2 receptors, leading

This editorial is published on the occasion of the World Asthma Day-May 6, 2025

to decreased treatment responses over time⁷. There is ample evidence to suggest that SABA monotherapy in asthma is associated with increased risk of asthma exacerbation. In a study of over 365,000 asthma patients in Sweden, the use of greater than two canisters of SABA over one year was associated with a 26 per cent higher risk of mortality⁸. Almost 30 per cent of the study population overused SABA. Other investigators have reported that using SABA trains patients to rely on its short-term relief, precluding them from adhering to inhaled corticosteroids (ICS), even when these are offered⁹.

In this context, the GAN study is alarming because it found that even amongst those diagnosed with asthma in India, less than 8 per cent used daily ICS, whereas almost 40 per cent used as-needed SABA¹. Even more startling is the frequent use of oral bronchodilators with intermittent oral corticosteroid courses for asthma in many parts of India¹⁰. Even short bursts of oral corticosteroids can increase the risk of adverse events, including pneumonia, cataracts, and osteoporosis.

The drawbacks of SABA use as a reliever therapy provided the impetus for a growing body of research on the use of anti-inflammatory reliever therapy (AIR), *i.e.*, the combination of bronchodilator and ICS as reliever therapy¹¹. The two common approaches for anti-inflammatory reliever therapy are the combination of formoterol (a bronchodilator with fast onset and long duration of action) with ICS, and the combination of a SABA with ICS (either in a single inhaler or in two different inhalers taken in quick succession). A major advantage of the former approach is using a single inhaler combination of ICS-formoterol as maintenance and reliever therapy (SMART). In a meta-analysis of five randomised controlled trials comprising 4863 patients, the use of the SMART approach (budesonide-formoterol as maintenance and reliever therapy) was found to delay the time to first asthma exacerbation compared to the use of ICS-long-acting beta-2 agonist (ICS-LABA) as maintenance therapy and SABA as reliever therapy¹². Further, the SMART approach reduced the risk of moving to a higher Global Initiative for Asthma (GINA) treatment step.

In response to the evolving evidence, the GINA recognised the need for a paradigm change in the approach to reliever therapy in asthma. The GINA 2025 report does not recommend using SABA monotherapy for any step of asthma management in adults, adolescents, and children over the age of six years¹³. Further, the GINA offers two treatment tracks.

In the preferred track, the GINA recommends using as-needed ICS-formoterol as reliever therapy for steps 1 & 2. Further, GINA recommends using ICS-formoterol as both maintenance and reliever therapy for steps 3 through 5. In the alternative track, the GINA permits the use of as-needed ICS-SABA as the reliever therapy at all steps of treatment. The use of as-needed anti-inflammatory reliever therapies in steps 1 and 2 underlines the growing recognition that symptom control may not always correlate with reduction of exacerbation risk, and even patients with mild asthma are at risk of life-threatening exacerbations⁵.

No studies have directly compared these two tracks, *i.e.*, ICS-formoterol versus ICS-SABA as reliever therapy regarding important clinical outcomes. In this context, the recently published systematic review and network meta-analysis by Rayner *et al*¹⁴ assumes significance. This study included 27 randomised clinical trials comprising 50,946 adult and paediatric patients studying different asthma reliever approaches: SABA alone, ICS-SABA, and ICS-formoterol. Consistent with previous studies, anti-inflammatory reliever therapies decreased the absolute risk of severe exacerbations: ICS-SABA led to a 4.7 per cent reduction. In comparison, ICS-formoterol led to a 10.3 per cent reduction. This implies a remarkable 'number needed to treat' (NNT) of only 10 patients for ICS-formoterol to prevent one severe exacerbation compared to SABA monotherapy. Furthermore, they performed a network meta-analysis to compare outcomes between ICS-SABA and ICS-formoterol. They found that the ICS-formoterol group had a 5.5 per cent reduction in risk of severe exacerbations compared to the ICS-SABA group. Additionally, both ICS-SABA and ICS-formoterol use were associated with modest improvements in symptom control compared to SABA monotherapy. Reassuringly, neither ICS-SABA nor ICS-formoterol was associated with increased risk of serious adverse events compared to SABA monotherapy.

These findings support GINA's preference for using ICS-formoterol as both maintenance and reliever therapy in asthma, pending head-to-head trials between ICS-formoterol and ICS-SABA. Importantly, GINA has noted that population-level decisions on the choice of reliever and maintenance therapy depend not only on the efficacy and effectiveness of these therapies in clinical trials, but also on the cost, availability, and patient preference. This is of vital importance to India, which is a leading manufacturer of generic

pharmaceuticals for both domestic and international consumption. The overwhelming evidence indicates that it is high time to discontinue the blue inhaler use in asthmatics for as-needed outpatient use in favour of anti-inflammatory reliever therapies². The indications of SABA in asthma have narrowed to include mainly emergency and inpatient care of acute exacerbations. Hence, this is a call for action to update our national guidelines and generic drug formularies, increasing the availability of ICS-formoterol and ICS-SABA preparations in favour of SABA inhalers¹⁵.

Financial support & sponsorship: None.

Conflicts of Interest: None.

Use of Artificial Intelligence (AI)-Assisted Technology for manuscript preparation: The authors confirm that there was no use of AI-assisted technology for assisting in the writing of the manuscript and no images were manipulated using AI.

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Received May 20, 2025; Accepted May 22, 2025; Ahead of
print June 12, 2025; Published *** *, 2025

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