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COMMENTARY



Is It Time to Leave Behind the Concept of Asthma Control and Severity Steps?

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ABSTRACT

After 25 years of GINA, we need an overarching strategy. The resounding changes in GINA 2019 should be accompanied by another major change in general strategy of asthma management. The concept of control asthma and step strategy was established in 1997 by GINA; but still there is a great gap between GINA objectives and outcomes. O'Byrne and colleagues proposed a continuum of care approach; where patient-adjusted therapy would comprise both a controller and reliever (usually ICS/fast-acting LABA) in a single inhaler. We use a similar approach in our asthma centre.

Abbreviations: GINA: global initiative for asthma; ICS: inhaled corticosteroids; LABA: long acting beta2 agonists; PRN: pro re nata (as needed); SABAs: Short acting beta2 agonists; ESC: European Society of Cardiology; ESH: European Society of Hypertension; GP: general practitioners; GOAL: The Gaining Optimal Asthma Control study; FABA: fast acting beta agonists.; FDA: food and drug administration.

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Commentary

This year saw one of the most important changes in asthma management in the last 30 years. GINA incorporated an off-label recommendation at steps 1 and 2: ICS/formoterol as needed is now recommended at step 1, rather than nothing (1,2). But the change was not unqualified, because SABAs remain a second-line option for rescue medication. GINA cites an anonymous review from 1997 supporting the use of SABAs as a bronchodilator in asthma as Evidence A. In fact, Evidence A systematic reviews and meta-analyses demonstrate an association between asthma mortality and SABA overuse; the deleterious effect of SABAs on asthma has a clear evidence base (3). GINA 2019 leaves SABAs at the bottom of box 3–5 A, as the second-line option for rescue medication across all the steps (1). But what happens when individuals with asthma do not claim their maintenance therapy at the appropriate interval? Most of the time, they take SABAs as monotherapy, and in this way may initiate SABA overuse with the concomitant increased risk (3).

The resounding changes in GINA 2019 should have been accompanied by another major change in the general strategy of asthma management. The

concept of controlled asthma and the step strategy was established in 1997 by GINA (4); but still there is a substantial gap between GINA objectives and outcomes and a rigid step-wise approach focused on control may be hindering rather than helping asthma management. O'Byrne and colleagues (5) proposed a continuum of care approach; where patient-adjusted therapy would comprise both a controller and reliever (usually ICS/fast-acting LABA) in a single inhaler. We use a similar approach in our asthma center (6). After 25 years, we need an overarching strategy.

The definitions of control were derived from the treatment goals of the Global Initiative for Asthma/National Institutes of Health guidelines (7): "totally controlled" or "well controlled" or uncontrolled (if neither definition was fulfilled). Both control definitions were composite measures that included the following asthma outcomes: peak expiratory flow; rescue medication use; symptoms; nighttime awakenings; exacerbations; emergency visits; and adverse events. However, none of those variables appear in the GINA Box 3–5 A. In fact, since 1997, GINA has not defined what each step in the figure means. For example, does uncontrolled asthma mean the same thing at step 3 as it does at step 4?

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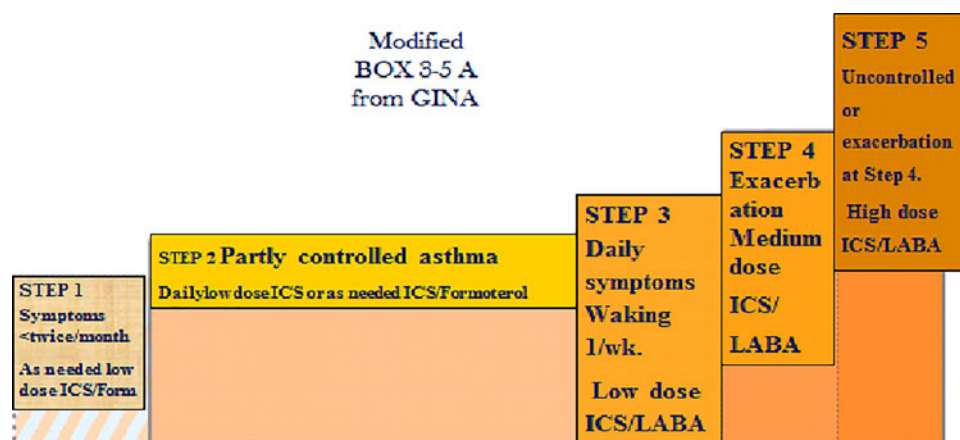


Figure 1. Modified Box 3–5 A from GINA 2019.

Furthermore, other guidelines explicitly endorse a graded approach to the commencement of therapy. A good example of such an approach is the ESC/ESH (8) guidance, which recommends the initiation of blood pressure-lowering treatment (lifestyle changes and medication) at different Grades, according to arterial blood pressure. Similarly, recommendations in diabetes take an algorithmic approach according to different levels of hemoglobin A1c (9). Currently, common sense results in most GPs initiating asthma treatment at step 1, independent of severity, the result would be that most of individuals with asthma received SABA PRN monotherapy. If the GINA steps are to be maintained, Box 3–5 might be modified to preclude initiation at step 1 whatever the asthma severity at presentation.

How do GPs decide at which step to begin treatment from Box 3–5? A further way in which the steps figure could be improved is shown in Figure 1: by adding a major clinical criterion for each therapeutic step. The recommendation that total control should be the aim of management for all patients with persistent asthma is based on the fact that, as demonstrated in GOAL (10), it is achievable in a considerable proportion of patients (41%; all strata) and that it is associated not only with the greatest improvement in usual asthma end points but also results in a majority of patients achieving health status that approaches complete freedom from the impact of asthma (asthmatic but without asthma). But what about the 59% of individuals that do not achieve total control? As it was pointed out by O’Byrne and colleagues (11), ongoing “asthma activity” could be reduced with anti-inflammatory reliever therapy with ICS/FABA like formoterol, whenever asthma symptoms are experienced. Elsewhere, I highlight the importance of the treat to target approach in asthma

as another option to continuum of care (6). Both strategies focus on treatable traits, instead of using maintenance or reliever medications concepts. Is replacing the concept of control with that of asthma activity a viable alternative?

Furthermore, “disease modifying anti-asthmatic agents” could replace the denomination of maintenance therapy and this concept should disappear together with the concept of reliever rescue therapy with SABAs. Regrettably, however, it is likely that the FDA approval for over-the-counter inhaled epinephrine will only further entrench the model of traditional reliever therapy for the coming years in the United States of America.

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