

Guidelines and Asthma: Some Considerations for Third World Countries

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Significant efforts have been devoted by the world medical establishment in the elaboration of Evidence Based asthma Guidelines, widely recognized as an important contribution to the health of patients and families afflicted with this high impact respiratory illness. When appropriately implemented, improvement in clinical outcomes as well as Quality of Life (QoL) has been shown. Inhaled steroids are the mainstream of these treatments [1].

However, the implementation of these guidelines has been fraught with many disappointments [2,3]. Observations and reports from all over the globe [4], with occasional exceptions, have confirmed these drawbacks. An opportunity is now open to think more creatively in this regard [5].

The crucial issue to be considered here is assessing the difference between two inter-related basic treatment concepts [6]; one is the clinical efficacy and the other one is the clinical effectiveness. Efficacy is a term in common use around clinical trial scenarios: a highly selected patient population is submitted to a specific treatment, usually in a double blind placebo-controlled manner. Characteristically, these trials show an intrinsic increased adherence to medications. Outcomes are measured on the basis of how many patients “get treated” vs. how many of these treated patients “get controlled”, as is the case for asthma. In contradistinction, effectiveness relates to the public health scenario: how many patients are there with asthma vs how many of those patients are controlled. Here, adherence issues pertain to the real life scenario. In essence, you may have the best treatment available but if it is not delivered in a comprehensive way, it ends up being with not much worth. For example, if such treatments also have severe adverse effects and/or require extensive health education for proper administration and/or have important limitations because of taste (the case for children), then treatment efficacy is downplayed [6].

Physicians in general and to some extent public health officials, at least in some areas of the world, consider validated guidelines as the ultimate word on a specific subject (and deservedly so). Any deviations from “dogma” is considered as heresy, even though in GINA Guidelines explicit recommendations addressing this issue are made [1].

In fact, such document should be adapted to local/regional real - life scenarios and necessarily it should not be followed to the letter [1,5]. Then, deviations from Guidelines should not be discouraged. The above argument opens two areas of great interest; one refers to inhaled steroids and the other applies to the context of their use. We would like to use Venezuela as a fertile ground for this discussion [7]. Venezuela is a tropical country located 10 degrees above the equator in the most northern part of South America; it has close to 30 million mostly young (<15y/o) inhabitants, living in crowded urban (slums) environments (>90%) and under variable conditions of poverty (>80% Graffar's D and E). According to ISAAC, asthma prevalence runs among the highest (20%) in Latin American countries, and with a significant component of severity. The above finds expression in the recurrent asthma exacerbations that have increasingly plagued (with rates up to 4 fold) the ambulatory facilities of the Ministry of Health (MoH) for the past 25 years [7]. These facilities handle the health needs of our urban and poor majority; the most affected segment of the population with increased levels of asthma prevalence [8].

Acute asthma in these facilities ranks as the second cause of consultations, after the so-called “viral syndrome”; this second place is often alternated with diarrheas [8].

More than 1 million acute exacerbations/year among our 30 million inhabitants surpass at least more than five times those reported in the United States [9], with more than 10 times our number of inhabitants. Exacerbations predominantly occur during night hours, when the above mentioned ambulatory facilities are closed, so patients have to go outside their community to receive nebulizations, something fraught with security problems among other hardships [7]. It is logical to assume that we are dealing with a pandemic of asthma exacerbations, with little conscience, if any, for disease control. How have we approached this public health problem over the years? There is a National Asthma Control Program, following GINA guidelines, that relies on inhaled steroids (Beclomethasone) as the first line treatment. It was last revised in 1998 and the present state of affairs informs us of its poorly implementation [5,7]. To say the least, the use of inhaled medications is cumbersome; ample evidence from existing literature confirms this [10]. Adherence and cost are another significant problems [11]. Use of these medications in the context of our urban (slum) and poor majorities demands of significant educational components while addressing cultural factors, like fears related to their use [12].

Can an alternative simpler and effective approach decrease the high impact from recurrent exacerbations? Can drifting from GINA guidelines be a worthwhile endeavor? With this in mind we designed the EESSO* strategy [5] and decided to test it in the field. Of the available second line treatments, oral Montelukast (MLK) jumps to the fore front. For the context we intended it for, shows the following advantages:

- a. Minimal, if any, adverse effects. It is administered once a day.
- b. MLK seems to perform better in a tobacco exposed environment [13]; 60 % of our slum urban homes report tobacco exposure [7].
- c. MLK is as effective as inhaled steroids to curtail recurrent exacerbations, for children as well as for adults [14-16].
- d. MLK is orally administered, hence, almost no education is needed for proper administration.
- e. MLK has a significant effect on rhinitis. Disregarding the upper airway may have significant impact on outcomes, like exacerbations and level of control [17].

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f. MLK has no interaction with other medications, for the most part, and has a pleasant taste (important for children).

g. In regards to cost, MLK patent expiration this past year offers clear opportunities [18]. A formulation that combines a non sedating antihistamine+MLK (available in some countries), might be another innovative and creative way that ought to be seriously considered.

We carried on a real-life, double blind placebo controlled study [5] on a slum population of Caracas, reflecting the living conditions of 50% of its inhabitants, and likely of Venezuela [7]. Eighty eight patients with physician diagnosed asthma were recruited (half were children <12 y/o). These patients relied basically on rescue treatments administered at the mentioned MoH facilities, and given in the form of nebulizations of a combination of fenoterol+ipratropium bromide [5]. Their demographics were recorded and allergy status determined by way of prick skin testing. Pulmonary function tests were performed with a Wright's Peak Flow Meter (WPFM, L/min), with a pre and post 400 mcg albuterol reversibility assessment; Asthma Control test (ACT) according to age and a single page minimal pictorial education was given. Follow up visits were scheduled every three months over the period of a year in addition to monthly phone calls. There are practically no homes in Venezuela lacking cell phone communication (there are over 16 million cell phone lines). This opportunity was used to remind patients to take the medication and to register the number of times they had to go to the MoH ambulatory facilities to be nebulized for an exacerbation. They were questioned in detail about it during follow up visits. Adherence was estimated by counting of empty blisters, for both Placebo (PBO) and MLK, and found to be greater than 80%. The first three and six months follow up results revealed a significant difference in recorded patient asthma exacerbations cared for at the MoH facilities; p values were p: <004 and p: <003, between PBO and, respectively.

This trend favoring MLK remained for the rest of the year, but patient attrition did not allow for significant numbers. In summary, and pending confirmation with larger number of patients from similar contexts, the EESSO strategy could pose as an alternative to a GINA guidelines approach (based on the use of inhaled medications). It could be started, due to its simplicity, during the only contact an asthmatic patient has with the health system, such as while suffering an exacerbation; crowded emergency rooms/or ambulatory facilities could then be used for initiating this approach. A structured minimal oral education plus a one page written pictorial educational material can easily be dispensed. SMS text messages could be a useful adjunct to encourage compliance and follow-up visits. If patients continue to have recurrent exacerbations in spite of adequate use of MLK, a referral to an asthma clinic can be more in tune with proper allocation of resources.

The world's tendency [19] to live in impoverished slums summons us to face new challenges in the delivery of comprehensive asthma care to this majoritarian and impoverished urban communities. If we are to focus on exacerbations and their great impact on health systems, the EESSO strategy could be one (among many), to look for. Asthma, urban environments/slums and poverty are interacting elements that need to be addressed in a contextualized way. Inaction is not an option if we are to deal with the social determinants of asthma.

*EESSO (in Spanish it means: "that's it", "that is what it is").

E stands for Efficacy

E stands for Economical (low cost)

S stands for Social

S stands for Safety

O stands for oral

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