

## Reasons for poor asthma control

### 5: Individual variation in response to treatment

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**We need to identify the factors and patient characteristics that could predict individual responses to asthma therapies. A better understanding of individual variations in response to treatment will help clinicians to optimise asthma therapy and enable each patient to have full quality of life with minimal or no impediment from their asthma.**

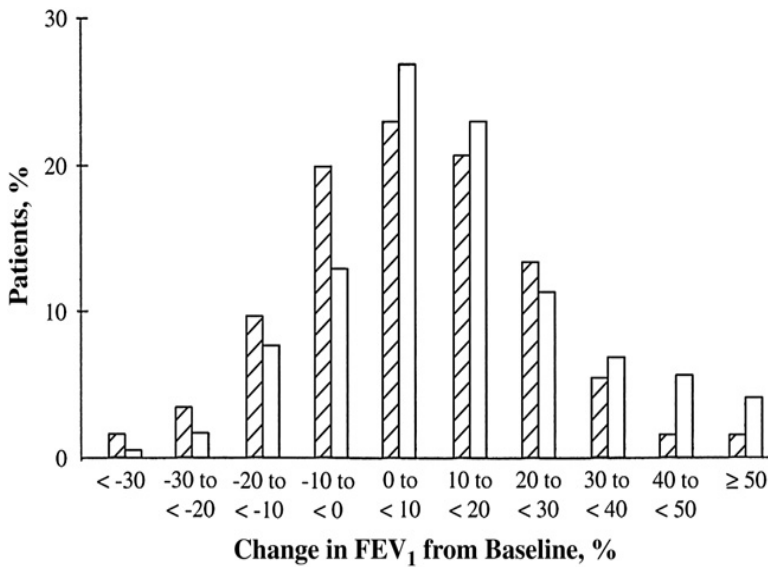
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Traditional, formal randomised controlled trials (RCTs) are established as the bed-rock of recommendations made by clinical guidelines. However, several factors limit our ability to generalise the results of many RCTs to the patients we see in primary care practice:

1. Fewer than 10% of people with asthma in a general practice population satisfy all the entry criteria and none of the exclusion criteria for the typical formal RCT in asthma.<sup>1,2</sup>
2. The inclusion and exclusion criteria can influence RCT results.<sup>3</sup> For example:
  - Inclusion of only patients with documented reversibility of >20% after  $\beta$ -agonist—thus known responders to a bronchodilator—will likely favour the effects of adding bronchodilator therapy (eg, long-acting  $\beta$ -agonist) over other therapies.
  - Inclusion of known steroid-responsive patients with asthma symptoms not controlled on low-dose anti-inflammatory therapy could favour effects of additional anti-inflammatory therapy (eg, inhaled steroid or leukotriene receptor antagonist) over other therapies.<sup>3</sup>
3. Patient adherence to therapy, in particular to complex therapeutic regimens, may be better in the setting of a clinical trial than in the real world because of training and greater contact with health care professionals provided in a formal RCT.
4. Asthma is a heterogeneous disorder, and the definition of “response” to therapy may influence the interpretation of study results. For example:
  - The correlation between lung function measurements and clinical control of asthma is now recognised to be poor.
5. Clinical trial data are typically reported as group mean data. This may help us to know how best to treat a population but may not help us in the real-life clinical scenario: one patient in the clinician’s office. (See examples overleaf)

Data from two studies that illustrate this limitation.<sup>4,5</sup>

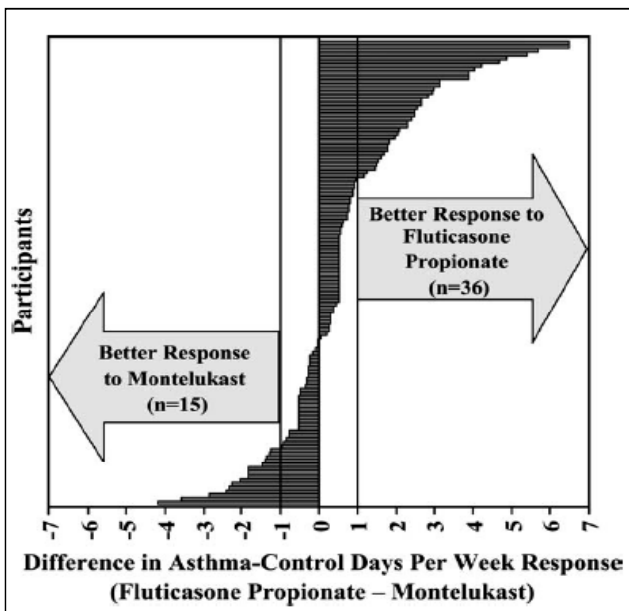
Figure 1. Individual variability: Are all patients the same?



Distribution of FEV<sub>1</sub> responses among adults with chronic asthma after 12 weeks of therapy with inhaled beclometasone (white bars) or oral montelukast (striped bars). The mean improvement from baseline in FEV<sub>1</sub> was 13.1% with beclometasone and 7.4% with montelukast; however, the distribution of individual FEV<sub>1</sub> responses to treatment shows wide variation.

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Figure 2. Individual patient versus average patient



Intra-individual response profile to therapy among children and adolescents with persistent asthma. Individual patient responses with regard to changes from baseline in asthma control days suggest that, while some patients responded to both inhaled steroid and montelukast, others showed a better response to one or the other.

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