

Criteria to evaluate efficacy of biologics in asthma: a Global Asthma Association survey

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Abstract

Background: Several biologics are now available as add-on treatment for severe asthma but, currently there are no universally accepted criteria to measure the response to these therapies. This survey aims to establish consensus criteria to use in practice for the initial evaluation of response to biologics after four months of treatment. **Method:** Using Delphi methodology, a questionnaire including ten items was developed and validated by a 13-member panel of international experts in asthma. The electronic survey circulated within the INterasma Scientific Network platform, Global Asthma Association membership, contact list of the co-authors, national associations for specialists, and social media. For each item, five answers were proposed graduated from “no importance” to “very high importance” and by a score (A=2 points; B=4 points; C=6 points; D=8 points; E=10 points). The final criteria were selected if the median score for the item was ≥ 7 and $>60\%$ of responses accorded “high importance” and “very high importance”. All selected criteria were validated by the thirteen experts. **Results:** Four criteria were identified to evaluate the efficacy of biologics in asthma: to reduce daily systemic corticosteroids dose by $\geq 50\%$ (ideally complete withdrawal); to decrease the number of asthma exacerbations requiring systemic corticosteroids by $\geq 50\%$, (ideally no asthma exacerbation); to have no/minimal side-effects and to obtain asthma control according validated questionnaires. The consensual decision was that ≥ 3 criteria are needed to conclude a good response to biologics. **Conclusions:** Specific criteria

were defined by an international panel of experts and could be used as tool in clinical practice.

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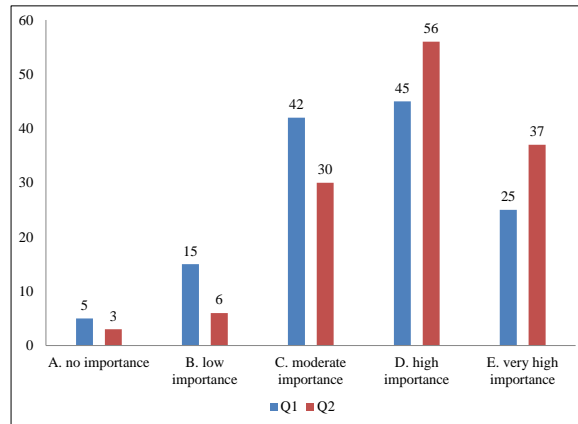


Figure 1A

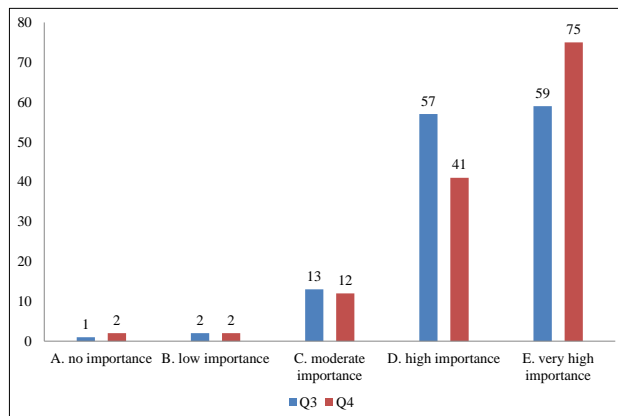


Figure 1B

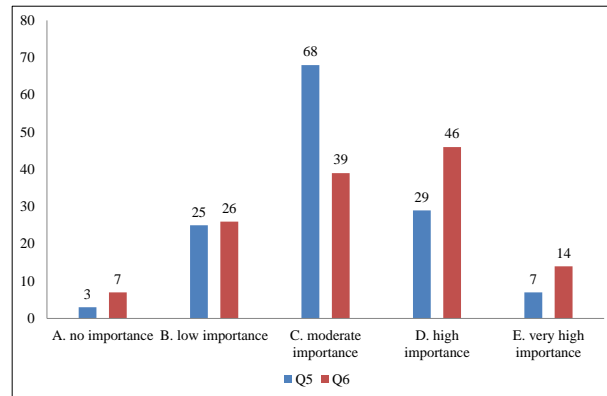


Figure 1C

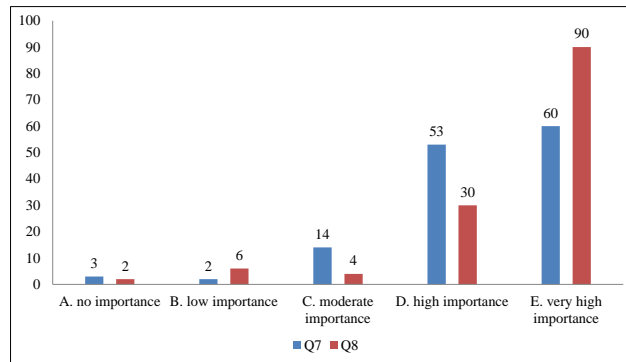


Figure 1D

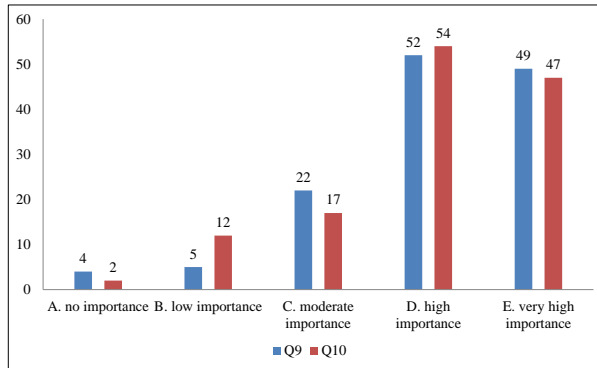


Figure 1E

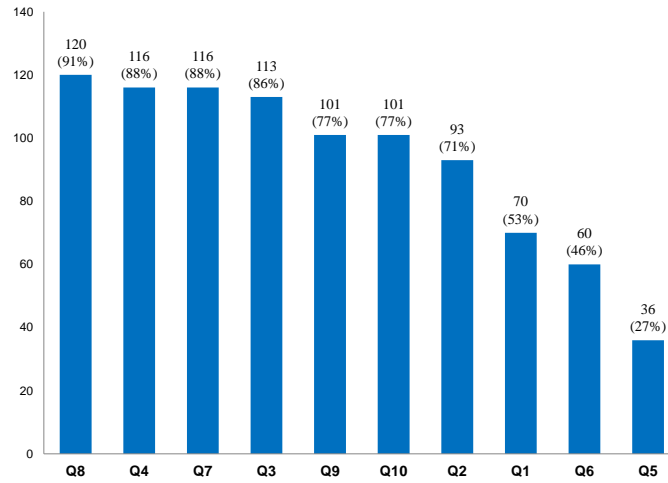


Figure 2A

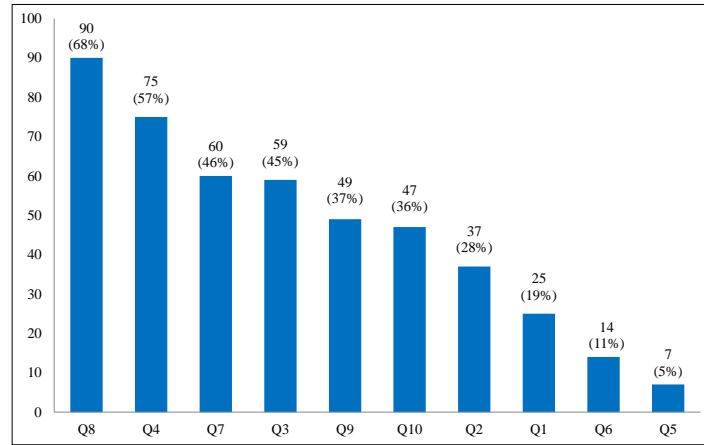


Figure 2B

Criteria for evaluation of biological therapies efficacy in asthma

1. To reduce daily OCS dose by at least 50%, ideally to achieve complete withdrawal
2. To decrease the number of asthma exacerbations requiring OCS by at least 50%, ideally no asthma exacerbation after starting of biologics
3. To have no or minimal side-effects
4. To obtain asthma control: an ACQ score <1.5 or an ACT score ≥ 20 points

The achievement of ≥ 3 criteria is necessary to conclude a good response to biological therapy.

Figure 3

Figure 4

