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

Angelica Tiotiu¹, Andras Bikov², Francisco-Javier Gonzalez-Barcala³, Silviya Novakova⁴, Plamena Novakova⁵, Herberto Chong-Neto⁶, Pierachille Santus⁷, Ignacio J Ansotegui⁸, Juan Carlos Ivancevich⁹, Krzysztof Kowal¹⁰, Stefan Mihaicuta¹¹, Denislava Nedeva⁵, Giorgio Walter Canonica¹², Jonathan Bernstein¹³, Louis-Philippe Boulet¹⁴, and Fulvio Braido¹⁵

¹Centre hospitalier regional universitaire de Nancy
²Wythenshawe Hospital
³Complejo Hospitalario Universitario de Santiago de Compostela
⁴UMBAL Sveti Georgi
⁵Medicinski universitet-Sofia
⁶Universidade Federal do Parana Hospital de Clinicas
⁷Università degli Studi di Milano Dipartimento di Scienze Biomediche e Cliniche Luigi Sacco
⁸Hospital Quirónsalud Bizkaia
⁹Clinica Santa Isabel
¹⁰Medical University of Bialystok
¹¹Center for Research and Innovation in Precision Medicine and Pharmacy
¹²Humanitas University
¹³University of Cincinnati Department of Internal Medicine
¹⁴Institut universitaire de cardiologie et de pneumologie de Quebec
¹⁵University of Genoa

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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 ≥50% (ideally complete withdrawal); to decrease the number of asthma exacerbations requiring systemic corticosteroids by ≥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 1C

Figure 1D
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.
To improve the ACQ score by 0.5 points or the ACT score by 3 points
To obtain an ACQ score <1.5 or an ACT score ≥20 points
To decrease the number of asthma exacerbations requiring OCS by 50%
To have no asthma exacerbation requiring OCS
To improve the FEV1 by 10%
To improve the FEV1 by 12% and 200 mL
To reduce daily OCS dose by 50%
To achieve complete withdrawal of daily OCS
To have no side-effects
To have minimal side-effects

Figure 4