

Critically Appraised Topic

Title: Basophil degranulation test has not been used for prediction or evaluation of drug hypersensitivity reactions to biologicals

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Clinical question (PICO): Can the basophil degranulation test be used for prediction and evaluation of hypersensitivity reactions to biologicals in patients treated with those drugs?

Clinical scenario: 43 year old men developed chest pain and severe hypotension immediately following second infusion of infliximab for psoriasis treatment. Results of skin testing cannot be reliable.

Search strategy:

Cochrane with the terms "(Hypersensitivity, Immediate OR Drug Hypersensitivity) and (monoclonal antibodies OR fusion proteins OR soluble receptors) and Basophils in Title, Abstract or Keywords 5 articles, none relevant

TRIP database search with the terms (Hypersensitivity, Immediate OR Drug Hypersensitivity) AND (monoclonal antibodies OR fusion proteins OR soluble receptors) AND Basophils returned 67 articles, none relevant

Medline using the Pubmed interface: (((("Antibodies, Monoclonal/therapeutic use"[Mesh])) OR ("Recombinant Fusion Proteins/therapeutic use"[Mesh])) OR ("Receptors, Cytokine/therapeutic use"[Mesh]))) AND ("Basophil Degranulation Test"[Mesh]) 2 articles, none relevant

Medline using the Pubmed interface: ((infusion reaction)) AND (((("Antibodies, Monoclonal/therapeutic use"[Mesh])) OR ("Recombinant Fusion Proteins/therapeutic use"[Mesh])) OR ("Receptors, Cytokine/therapeutic use"[Mesh])) AND (hypersensitivity OR allergy) 59 articles, none relevant

Medline using the Pubmed interface: (Monoclonal Antibodies OR Recombinant Fusion Proteins OR Cytokine Receptors) AND ("Basophil Degranulation Test"[Mesh] OR "Basophil activation Test ") 21 articles, none relevant

Comments: Antibodies response to biologicals is not rare, particularly in patients treated with humanized molecules. The early infusion reaction may be IgE mediated. However, the presence of those antibodies is rarely evaluated. The mostly employed tests for diagnosis of type I

hypersensitivity to biologicals are skin tests, followed by *in vitro* detection of IgE. Basophil degranulation test may be useful tool to complement aforementioned tests due to its flexibility and lack of commercial tests for testing IgE specific to most of the biologicals. Therefore studies addressing its value in this clinical and laboratory setting are urgently needed.

Conclusion: There are no studies of Basophil degranulation tests in patients treated with biologicals and, consequently, nor of its value in predicting or evaluating adverse reactions to these agents.