Free serum IgE in patients with severe allergic asthma treated with omalizumab

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INTRODUCTION

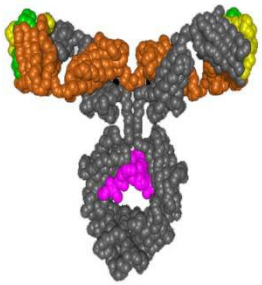

Fig. 1: Omalizumab

- Omalizumab:
  - Monoclonal anti-IgE-antibody
  - Interrupts allergic cascade
  - Approved as add-on treatment for patients with inadequately controlled severe persistent IgE-dependent allergic asthma
- Clinical benefit with Omalizumab is observed when free serum IgE is reduced to ≤ 50 ng/ml
- Ability of omalizumab to reduce free serum IgE is dependent on patients' body weight, serum total IgE level, and omalizumab dose
- Decision if omalizumab is effective is solely based on physicians' judgement (GETE*)

- Commercially available IgE assays recognize both free IgE and IgE molecules as part of omalizumab-IgE-complexes
  → Monitoring free serum IgE not feasible once omalizumab treatment is initiated

METHODS

- 31 patients with severe allergic asthma (55% female, pre-tx FEV_1 68±13%)
  - Therapy with omalizumab for a minimum of 4 months
  - Response to omalizumab as judged by GETE*

Newly developed Recovery-ELISA
(patented BioTeZ, Berlin-Buch, Germany)
(ATS 19.05.2010, A5674)

- Free trough serum IgE level

*Global Evaluation of Treatment Effectiveness

RESULTS

- Mean baseline total serum IgE 300 ± 189 IU/ml (range 42-843 IU/ml)
- Median omalizumab dose 600 mg/month (range 150-750 mg/month)
- Median duration of treatment with omalizumab 4 months (range 4 months – 6.5 years)
- No correlation between free serum IgE and pre-tx FEV_1 (r=0.023), omalizumab dose (r=0.206), or duration of therapy (r=-0.157)

Free serum IgE in patients responding to omalizumab therapy

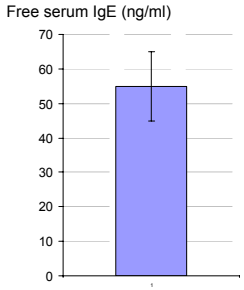

Fig. 2: Mean ± SEM free serum IgE (55 ± 10 ng/ml, range 7-272 ng/ml)

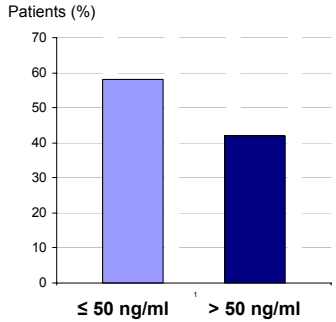

Fig. 3: % of patients with free serum IgE ≤ 50 ng/ml (n=18) vs. > 50 ng/ml (n=13)

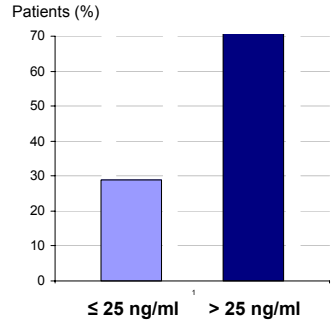

Fig. 4: % of patients with free serum IgE ≤ 25 ng/ml (n=9) vs. > 25 ng/ml (n=22)

Variability

- Quantification of free serum IgE twice within 1-3 months (n=17)
- Intraindividual change: Mean ± SEM 15.5 ± 12.6 ng/ml (range 20-208 ng/ml)

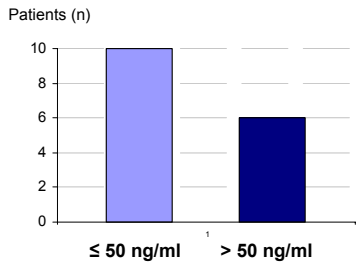

Fig. 5: No. of patients consistently ≤ 50 ng/ml or > 50 ng/ml

CONCLUSION

- It is feasible to routinely monitor serum concentrations of free serum IgE in patients treated with omalizumab
- Free serum IgE showed a stable pattern over time
- Majority of responders demonstrated low IgE levels, however only 58% of patients ≤ 50 ng/ml (therapeutic target)
- Level of free serum IgE is not related to treatment response

- As yet, the clinical relevance of routine measurements of free serum IgE is limited
- Responses to omalizumab have to be judged based solely on clinical scoring systems