CLINICAL USEFULNESS OF SERUM LEVEL OF ADALIMUMAB, IN PATIENTS WITH RHEUMATOID ARTHRITIS

J Rosas, F Linares-Tello, I de la Torre, L Valor, X Barber, C Santos-Ramírez, D Hernández, JM Senabre, L Carreño, G Santos-Soler, E Salas, M Sánchez-Barrioluengo, J Molina-García, and the group AIRE-MB.

Reumatology and Laboratory Department1, Hospital Marina Baixa, Villajoyosa (Alicante). Reumatology Department Hospital Universitario Gregorio Marañón2, Madrid. CIO- Universidad Miguel Hernández (Elche)3, Reumatology Unit, Hospital Marina Alta, Denia4 (Alicante). INGENIO (CSIC-UPV), Universitat Politècnica de València5, SPAIN

OBJECTIVE

1. To analyze the clinical relevance, in clinical practice, of serum levels of adalimumab (ADA) and the production of anti-ADA antibodies (anti-ADA-Ab).
2. To evaluate if there is a correlation between serum levels of ADA and disease activity index of RA: DAS28.
3. To determine the minimum appropriate serum levels of ADA to keep the patients in clinical remission or low disease activity.

RESULTS

Table 1. Relation of ADA level, Ab anti-ADA and DAS28-ESR, according to tertiles of ADA.

Table 2. ROC curves: cut-off, area under curve, sensitivity and specificity for the ADA level on remission (DAS28 ≤ 2.6) and/or low activity (DAS28 2.7-3.2) of rheumatoid arthritis.

DAS28 < 3.2

Cut-off

Area under curve

Sensitivity

Specificity

3.489

83.18%

83.33%

77.8%

DAS28 < 2.6

3.015

65.77%

50%

77.27%

CONCLUSIONS

1. The cut-off of ROC curve for serum level of ADA, to keep the patients in low activity of disease is 3.45 mg/L.
2. There is a negative correlation between the serum level of ADA and DAS28.
3. Serum level of ADA >7.3 mg/L does not increase the improvement of DAS28. In these patients, we can consider to decrease the ADA dose or its delay.
4. The prevalence of anti-ADA Abs in patients with RA treated with ADA and DMARD is 7%.

PATIENTS AND METHODS

- Prospective study in RA patients, treated more than 6 months with ADA
- Clinical characteristics of the patients and RA
- Activity index of RA: DAS28-ESR
  - Responders: DAS28-ESR < 2.6 (remission)
  - Low activity: DAS28 2.7-3.2: DAS28-ESR
- Serum levels of ADA and anti-ADA-Ab (ELISA kit. Promonitor®-ADA. Proteomika, Derio. Vizcaya, Spain)
  - Cut-off level for serum Abs for anti-ADA: >32 U/mL
  - Cut-off level for serum level of ADA <0.004 mg/L
- All the patients were receiving some DMARD (methotrexate, leflunomide or hydroxychloroquine).
- Serum samples were collected before injection of ADA (the same day), and stored frozen until analysis.
- The patients were distributed in three tertiles groups from serum levels of ADA: <2.8 mg/L; 2.9-7.3 mg/L; >7.3 mg/L.
- ROC curve was used to select the optimum cut-off level of ADA to keep the patients on remission or low activity level of disease.
- The correlation between DAS28 and serum level of ADA was evaluated.