THERAPEUTIC DRUG MONITORING OF ETANERCEPT BIOSIMILAR IN PSORIATIC PATIENTS
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Purpose
- A limited number of studies have related serum biological levels to clinical response in psoriasis.
- Studies on clinical relevance of therapeutic drug monitoring for etanercept biosimilar (ETAb) are scarce.
- The aim of this study is to analyze ETAb concentrations in patients with moderate-to-severe plaque psoriasis.

Methods
Observational retrospective study (Ethics committee approved this study)

- Inclusion criteria: 100 % psoriatic patients treated with ETAb (Erelzi®) and monitored in Pharmacy Service between 01/2018 - 09/2019 in a tertiary hospital.
- Data sources: sex, age, weight, date of psoriasis diagnosis, previous treatment with biologics drugs, duration of ETAb treatment, dosage/weight (mg/Kg), concomitant treatment (immunosuppressive drugs, oral corticosteroid, retinoids), Psoriasis Area and Severity Index scale-PASI- before start of ETAb treatment (PASIb) and at blood extraction time (PASle), ETAb concentration, adverse events.

Patients were classified into two groups: Good-responders (>PASI75) and non-responders (<PASI75)

- Statistical Method: Descriptive analysis (SPSS software v.19) → quantitative variables (median/range) and qualitative (percentage).

ETAb serum levels were assessed immediately prior to administration of drug (Ctough).
Concentrations were quantified by capture ELISA immunoassay (Triturus® analyzer).

Key Findings

10 Patients (7 men)
48.5(26-68) years old
25.5 (8-45) years at diagnosis and weight 73 (64-112) Kg

PASIB = 9.0 (3.0-17.3) → PASLE =1.2 (0.0-14.8)

Blood extraction time?
3.9 (0.9-14) month of treatment

PASI variation → - 92.3 (-82.7-100)

100% NAIVE
- ETANERCEPT dosage/Weight 0.7 (0.5-8) mg/Kg
- Concomitant treatment: Metotrexate + 1-cyclosporine

42.9%
Non-responders
Etab level: 2.6 (0.6-4.8) mcg/mL

57.1%
Good-responders
Etab level: 2.7 (1.8-4.4) mcg/mL

- No significant difference in demographic data
- No significant difference in ETAb level (p>0.05)
- No incidence of adverse events in both groups

Conclusion
- Drug concentration was detected in all patients.
- No relationship was found between ETAb concentration and clinical response (efficacy and toxicity).
- Further researches are needed to determine the clinical significance between ETAb concentration and clinical response, hence the usefulness of therapeutic drug monitoring in psoriatic patients.