CLINICAL PHARMACOKINETICS OF ANTI-TNF THERAPY: OUR FIRST EXPERIENCE IN INFLAMMATORY BOWEL DISEASE

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What was done:

Pharmacokinetic monitoring (TDM) of anti-TNF therapies (infliximab/adalimumab) in inflammatory bowel disease (IBD) was implemented in our hospital by a multidisciplinary team of pharmacists, gastroenterologists and clinical analysts.

Why was done:

Numerous publications have demonstrated a correlation between serum concentrations (Cs) of anti-TNF drugs and the therapeutic response and a wide interindividual variability in pharmacokinetics among patients with IBD. TDM permits dosage individualization and optimization of anti-TNF therapy.

How it was done:

• A computer platform was developed within the hospital electronic records system to manage consultations of gastroenterologists with the Clinical Pharmacokinetics Unit (CPU) of the Pharmacy Department.

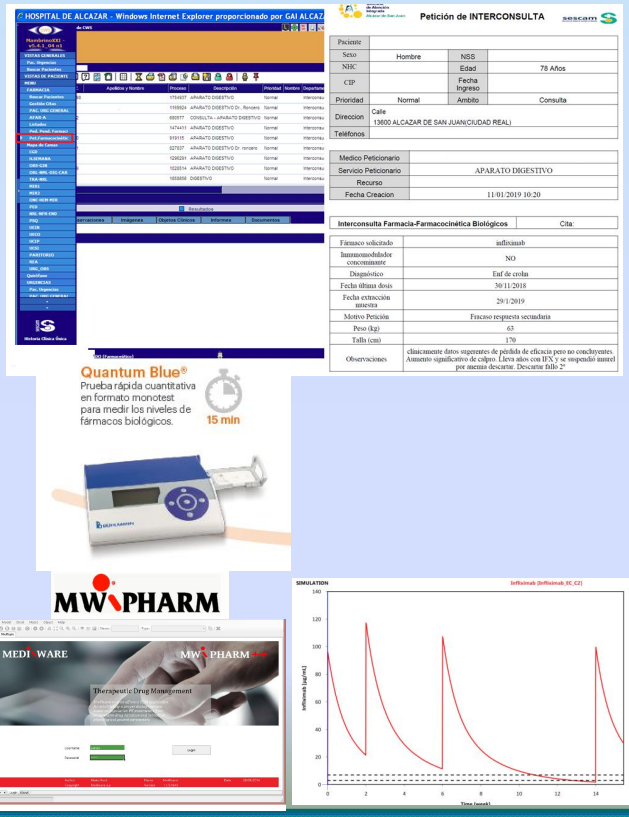
• Variables in this electronic interconsultation system: *"anti-TNF drug"*, *"concomitant immunomodulator (IMM)"*, "*diagnosis*", "*reason for consultation*", "*date of last dose"*, *"date of extraction*", *"weight/height"*, and *"observations*".

• Laboratory tests ordered from the Department of Clinical Analysis on the electronic request form included blood count, Cs of infliximab/adalimumab, albumin, C-reactive protein and faecal calprotectin.

•*Quantum Blue*® lateral flow immunoassay was used to quantify Cs of the anti-TNF drugs; when undetectable, the presence of anti-drug antibodies (ADAs) was investigated.

• The CPU developed pharmacotherapeutic recommendations based on therapeutic algorithms, pharmacokinetic/pharmacodynamic principles and population models implemented using *MW-Pharm*++® software, which incorporates the principle of Bayesian estimation.

• For a correct interpretation of the Cs observed, adherence to anti-TNF ± IMM regimens was evaluated using electronic dispensing records and the self-administered *Morisky-Green* questionnaire



What was achieved:

• Since its implementation (January 2019 – August 2020), the CPU has responded to 269 consultations on 121 patients treated with infliximab (46.3%) or adalimumab (53.7%): 70.2% were prescribed with IMM (89.4% with thiopurines); 93.4% adhered to the anti-TNF regimen and 82.4% to the IMM.

• Baseline anti-TNF Cs were subtherapeutic in 37.2% of patients, therapeutic in 35.5% and supratherapeutic in 27.3%.

• ADAs were positive in 28.6% of patients with undetectable anti-TNF Cs (n=28).

• A large proportion (84.8%) of consultations were related to proactive monitoring (to optimise treatment) and the remainder were reactive (after treatment failure).

•A very high percentage (89.9%) of the gastroenterology specialists accepted recommendations.

What is next:

Extend TDM to other biological therapies and immune-mediated diseases.

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