Case Report: Usefulness of Therapeutic Drug Monitoring of Vedolizumab in Managing Acute Graft Versus Host Disease

Fernández-Caballero R1, Martín-Gutiérrez N1, Sánchez-Hernández JGi, Jiménez-Cabreray A2, Navarro-Bailón A2, Rey-Búa B2, Martín-Gil M1, Peña Lorenzo D1, Pedraza-Nieto L1, Otero López MJ1.

1Pharmacy Service, 2Hematology Service
University Hospital of Salamanca

Background
➢ Acute graft-versus-host disease of the gastrointestinal tract (aGVHD-GI) is one of the most common complications in patients undergoing allogeneic hematopoietic stem cell transplantation (HSCT).
➢ Vedolizumab is proposed as a therapeutic alternative in patients with aGVHD-GI resistant to multiple lines of treatment.

Aim and Objectives
To describe the usefulness of therapeutic drug monitoring (TDM) of trough vedolizumab serum concentrations (VSC) to optimize treatment in one patient with aGVHD-GI.

Materials and Methods

Patient
42-year-old male patient with acute lymphoblastic B leukemia admitted for allogeneic HSCT who developed grade 4 aGVHD-GI.

Lines of treatment
1. corticosteroid therapy
2. mesenchymal stem cells plus mycophenolate mofetil
3. infliximab
4. extracorporeal photopheresis plus ruxolitinib
5. vedolizumab

Response
Measure: clinical criteria (resolution of diarrhea), imaging tests (gastroscopy and colonoscopy), inflammatory biochemical markers (fecal calprotectin).
- Partial response to treatment (PR): resolution of overall aGVHD in one or more organs without worsening of others.
- Complete response (CR): resolution of symptoms in all organs.

VSC
- Determined by ELISA.
- VSC in induction phase: >30 µg/mL
- VSC in maintenance phase: >14 µg/mL

Results
➢ Induction phase: Vedolizumab 300 mg was administered as IV infusion at week 0, 1, 4 and 6, based on the estimated pharmacokinetic parameters (CL=0.159 L/day; Vd=3.19 L).
➢ Maintenance phase: Vedolizumab every 4 weeks and every 6 weekd after week 26.
➢ Patient achieved CR on week 6 and he maintained CR throughout the treatment.

Conclusions and Relevance
TDM of vedolizumab is a valid tool for individualizing treatment in patients with aGVHD, avoiding early therapeutic failure.