Clinical: Therapy and Observation

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Serum risankizumab levels are associated with biochemical remission in Crohn's disease

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Background: Therapeutic drug monitoring (TDM) has become an established strategy in inflammatory bowel disease (IBD) to optimise biological therapy efficacy, particularly for anti-TNF agents. However, data on the relationship between risankizumab (RZB) serum concentrations and clinical outcomes remain scarce. This study aimed to assess the association between RZB trough levels and biochemical remission (BR) in Crohn's disease (CD) patients during maintenance therapy.

Methods: We conducted a prospective study including CD patients treated with RZB (intravenous induction at weeks 0, 4, and 8, followed by subcutaneous maintenance every 8 weeks) between 2024 and 2025 in a tertiary hospital. Trough RZB concentrations (RZBconc) were measured by ELISA (Shikari® Q-UST and S-ATU, Matriks Biotek) after 8 weeks of treatment, corresponding to the maintenance phase. BR was defined as faecal calprotectin ≤150 mg/kg. Data were analysed by quartiles, and a binary logistic regression model was used to identify predictors of BR at the time of pharmacokinetic assessment.

Results: Sixteen patients were included (male 63.5%; mean age 46 [28–76] years; body weight 73 [49–122] kg; baseline albumin 4.1 [3.4–4.7] g/dL; ileal disease L1 47.2%). Median RZB treatment duration was 24 (12–108) weeks, with prior exposure to ≥2 biologics in 93.7% of cases. Higher RZB concentrations tended to be associated with biochemical remission (Figure 1). A positive correlation was observed between RZB levels and BR rate, although logistic regression did not reach statistical significance ($p = 0.106$), likely due to limited sample size.

Conclusion: Higher serum RZB concentrations were associated with a greater likelihood of biochemical remission in CD. TDM of RZB may represent a valuable tool to personalise treatment and optimise clinical outcomes during the maintenance phase. Further studies with larger cohorts are warranted to validate these findings.

Conflict of interest:

Reygosa, María Cristina: No conflict of interest

Del Rosario García, Betel: No conflict of interest

Salas Pérez, Ana: No conflict of interest

Ramos Díaz, Ruth: No conflict of interest

Carrillo Palau, Marta: No conflict of interest

Alonso, Inmaculada: No conflicts

Gutiérrez Nicolás, Fernando: No conflict of interest

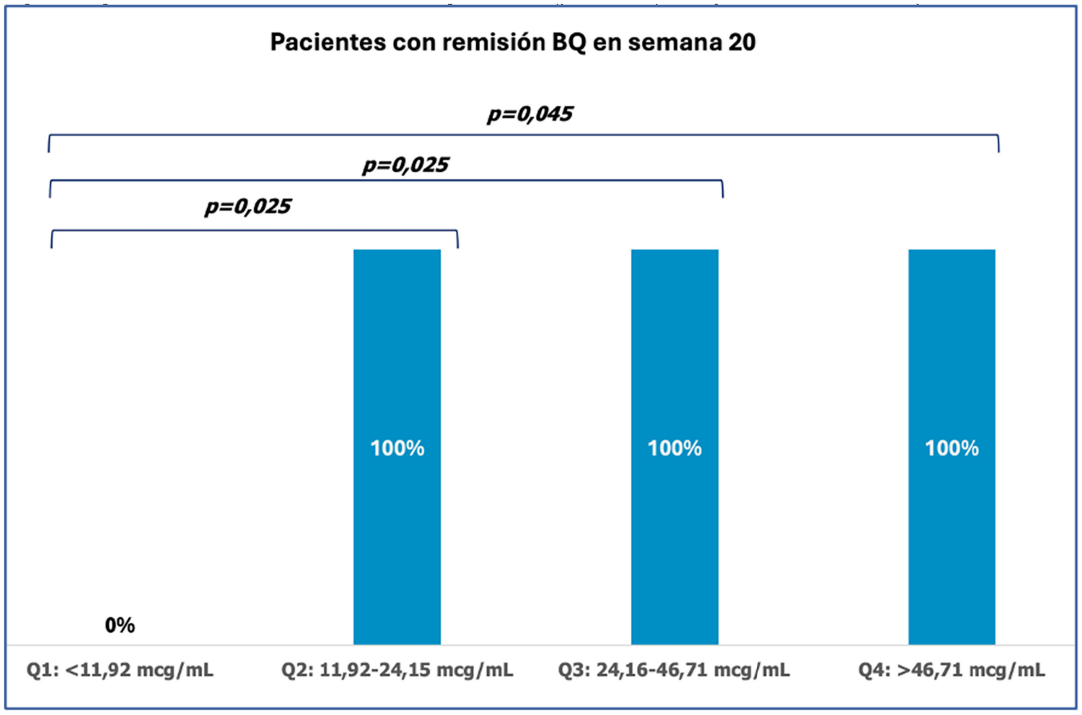
Medina Chico, José Sergio: No conflict of interest

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Figure(s)/Table(s): see next page

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