

# Review of new biomarkers that predict the pharmacokinetics of biologic drugs in inflammatory bowel disease

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## Background and importance:

Adalimumab is an anti-TNF $\alpha$  monoclonal antibody used in inflammatory bowel disease (IBD). Its efficacy can benefit from therapeutic drug monitoring (TDM). Certain biomarkers can be useful in future pharmacokinetics adjustment model designs.

## Aim and objectives:

To study the correlation between plasmatic concentrations (Cp) of adalimumab and the plasmatic concentrations of prealbumin and albumin in patients with IBD.

## Métodos:

○ **Study design:** Observational and retrospective carried out from september 2020 to january 2022.

○ **Inclusion criteria:**

- Patients older than 18 years with diagnosis of IBD (Crohn disease (CD) or ulcerative colitis (UC)).
- Patients receiving treatment with adalimumab maintenance therapy.
- Having a trough Cp of adalimumab, albumin and prealbumin obtained the same day.

○ **Exclusion criteria:**

- The presence of anti-adalimumab antibodies.

○ **Variables collected:** Gender, age diagnosis, and Cp of adalimumab trough, albumin and prealbumin.

○ The analytical determinations of adalimumab were made by ELISA (Theradiag®). Range test 0.3-20 ug/ml.

○ The statistical analysis was made using R 4,1,1 Statistical software.

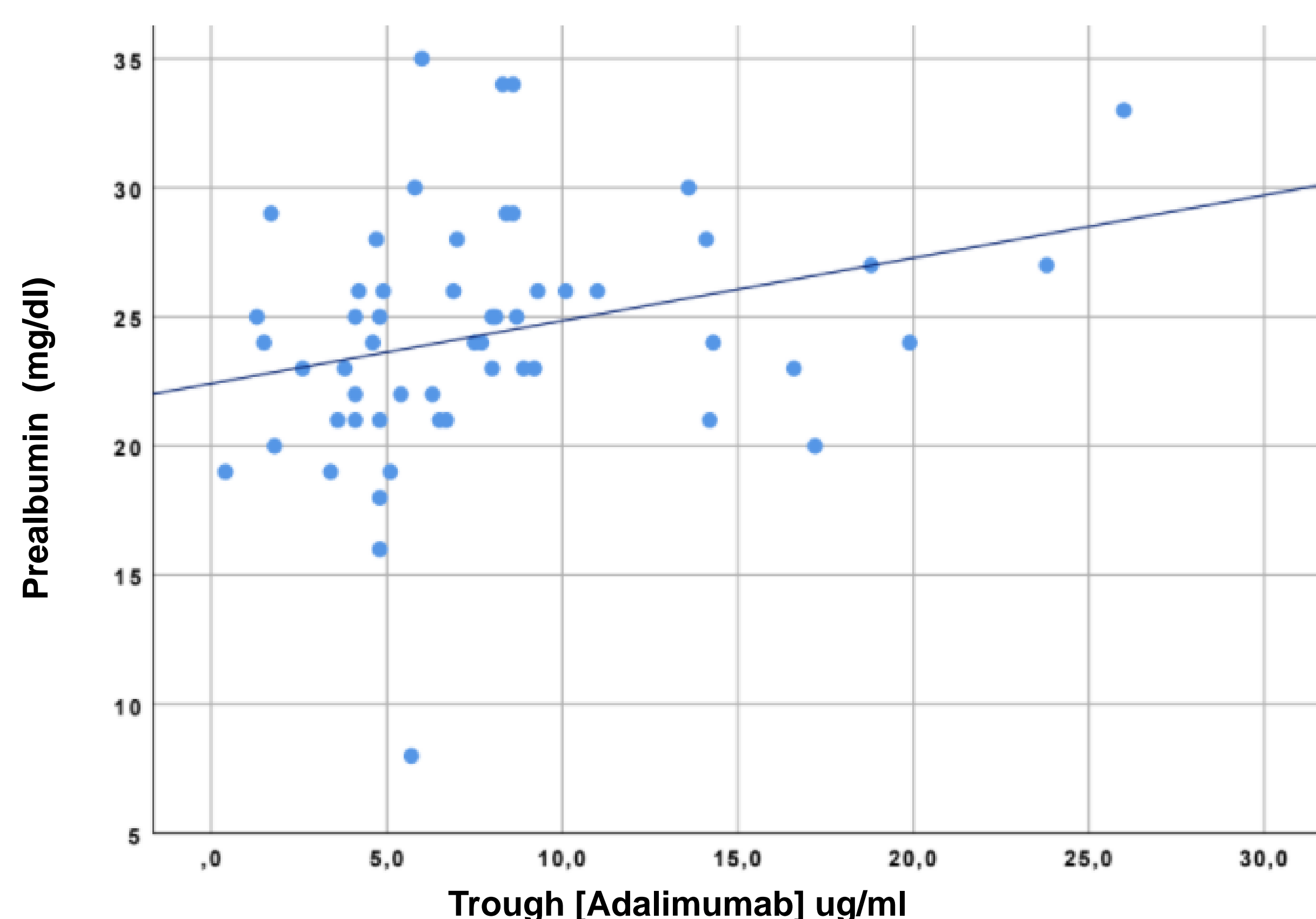
## Resultados:

Demographics		
<b>Disease/Patients (n, %)</b>	Crohn disease 50 (89.3%)	Ulcerative colitis 6 (10.7%)
<b>Women (%)</b>	48.2%	
<b>Age (years)*</b>	40.0 (22.5-46.0)	
<b>Weight (Kg)*</b>	62.0 (53.0-77.0)	
<b>Albumin* (mg/dl)</b>	4246 (3960-4472)	
<b>Prealbumin* (mg/dl)</b>	24.0 (21.0-27.0)	
<b>Adalimumab* (ug/ml)</b>	6.9 (4.6-9.3)	

\*Median, (p25-p75)

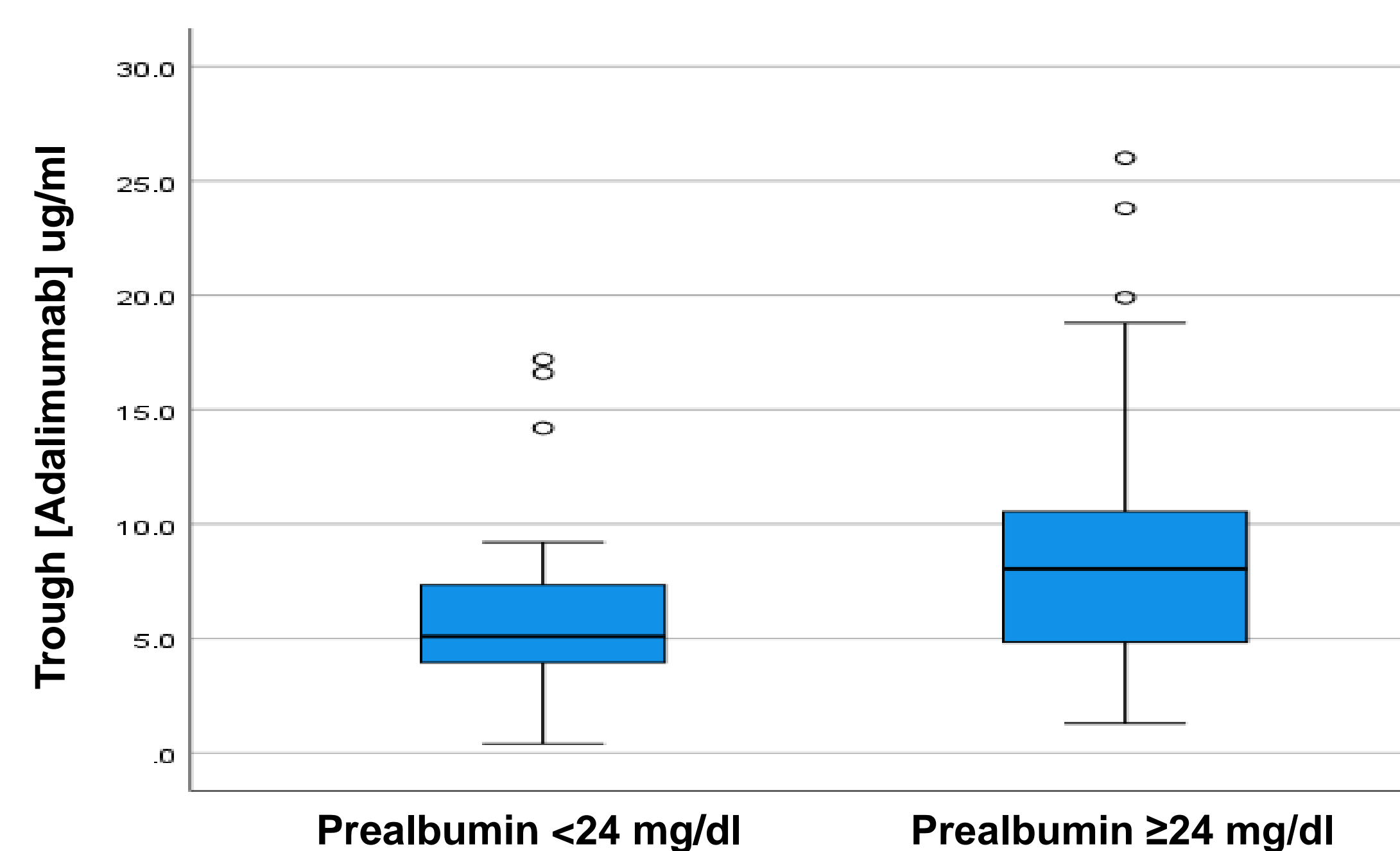
Correlation between the adalimumab trough Cp and the Cp of prealbumin:

R2: 0.287; p: <0.05



In those patients with prealbumin levels  $\geq 24$  mg/dl, the mean adalimumab trough Cp in maintenance therapy were significantly higher than those obtained that had prealbumin levels < 24 mg/dl.

Prealbumin	Median (Adalimumab trough)	p25-p75	p
< 24 mg/dl	4.80 ug/ml	(3.70-7.35)	0.009
$\geq 24$ mg/dl	8.20 ug/ml	(5.58-11.65)	



## Conclusions:

• In the studied population sample of patients with IBD, a positive correlation between Cp of adalimumab and prealbumin was observed.

• Prealbumin is a protein with a smaller half-life than albumin, it could be used as a predictive biomarker of adalimumab clearance modification.

• To our knowledge it is the first study to find this association.

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