

COMPARATIVE EVALUATION OF ENZYME-LINKED IMMUNOSORBENT ASSAY VERSUS A POINT-OF-CARE TECHNIQUE IN THE DETERMINATION OF ADALIMUMAB LEVELS

L04- IMMUNOSUPPRESSANTS

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BACKGROUND AND IMPORTANCE

Therapeutic drug monitoring in inflammatory bowel disease (IBD) is an useful tool for optimising biologic therapy. The analysis of adalimumab (ADL) concentrations in blood through enzyme-linked immunosorbent assay (ELISA) requires accumulation of samples to make it a cost-efficient technique, **delaying the results for several days**.

Point-of-care (POC) tests facilitate immediate decision making by providing ADL concentration results in **less than half an hour**. However, it is necessary to **demonstrate the equivalence of both methods and their interchangeability**.

AIM AND OBJECTIVES

The aim of this study is to **compare the reference technique for quantifying ADL levels** using ELISA with quantification using **POC test**

MATERIAL AND METHODS

From our own biobank with serum samples of **200 IBD patients treated with biologics**, those with adalimumab levels were selected

Statistical analysis



Correlation

Spearman's correlation coefficient (rs)

Concordance between the 3 different therapeutic groups

Weighted Cohen's kappa (κ)

Differences in classification for each group

McNemar test

60 patients were randomly selected
19 for ADL sub-therapeutic range (<5 $\mu\text{g/ml}$)
21 for ADL therapeutic range (5-12 $\mu\text{g/ml}$)
20 for ADL supra-therapeutic range (>12 $\mu\text{g/ml}$)

Quantitative sandwich ELISA assay was performed with **Promonitor[®] ADL kit**
POC test was performed with **Quantum Blue[®] assay**

RESULTS

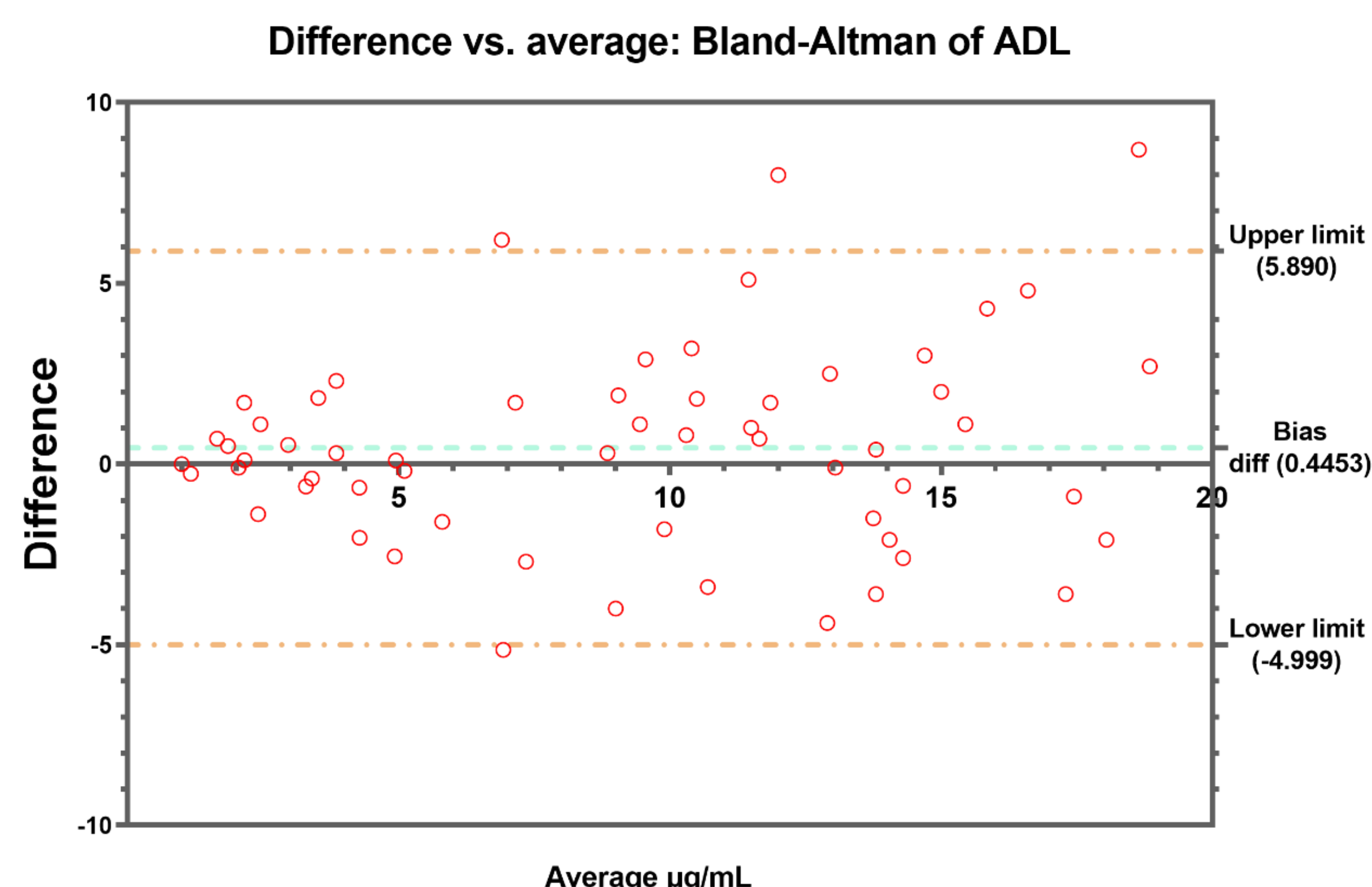
No statistically significant differences in ADL trough levels were observed between ELISA and POC

Assay	Median (IQR)
Promonitor [®]	10 $\mu\text{g/mL}$ (3.87-13.25)
Quantum Blue [®]	8.85 $\mu\text{g/ml}$ (3.67-13.62)

Good correlation of ADL trough levels (rs = 0.88)

Substantial **agreement in stratifying** in the different groups of **therapeutic ranges** (K= 0.751 \pm 0.063)

No significant differences among different ranges classification (p-value=1)



Bland-Altman's analysis revealed a bias difference of 0.4453

CONCLUSION AND RELEVANCE

The **Quantum Blue[®] POC test** represents an **alternative to ELISA** in determining **ADL concentrations**, allowing results to be obtained in **less time**, which facilitates therapeutic decision-making in patients with IBD

