Performance of a rapid test for adalimumab monitoring versus conventional ELISA in a routine laboratory setting

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Introduction

- Adalimumab (ADM) revolutionized the treatment of patients with inflammatory bowel disease.
- Despite its therapeutic success, up to 40 % of patients do not respond to adalimumab induction treatment and 23 - 46 % of patients may lose response over time.[1]
- Therapeutic drug monitoring of adalimumab has shown to be useful to optimize treatment outcomes in patients with inflammatory bowel diseases.
- Early monitoring of adalimumab drug concentrations helps predict later anti-drug antibody development and the need for dose intensification.[2]
- There are scarce data regarding the performance of a rapid test for adalimumab monitoring in a routine laboratory setting.

Aims & methods

- To evaluate the performance of a rapid test for the quantitative measurement of ADM drug concentrations in a routine diagnostics laboratory, the Gastroenterology & Hepatology Diagnostic Laboratory (Erasmus MC, Rotterdam, the Netherlands) (Fig. 1).
- In total, 56 anonymized patient samples were collected in the routine and subsequently analyzed using the RIDA®QUICK ADM Monitoring (R-Biopharm, Darmstadt, Germany). Results were compared with a conventional ELISA technique, the apDia Adalimumab ELISA (apDia, Turnhout, Belgium), also distributed by R-Biopharm as RIDASCREEN® ADM Monitoring (Fig. 1).
- Six quality control samples, with a concentration within the assay analytical range, were used to verify the assay performance.
- Method comparison was performed using Bland-Altman plots, correlation analysis and linear regression analysis using the statistical programs R v3.5.2 and Graphpad Prism.

Figure 1: (A) The ADM concentrations were measured quantitatively using a portable and bench-top size reader, the RIDA®QUICK SCAN II and (B) the apDia Adalimumab ELISA.

Results

- The RIDA®QUICK ADM Monitoring was shown to correlate very well with the apDia Adalimumab ELISA (Pearson r = 0.91).
- Linear regression analysis showed no systemic nor proportional bias between the RIDA®QUICK ADM Monitoring and apDia Adalimumab ELISA (Table 1; y = 0.89 x – 0.48; y = RIDA®QUICK ADM Monitoring; x = apDia Adalimumab ELISA).

Table 1: Linear regression analysis and 95 % Confidence Intervals (CI) indicate the absence of any systemic or proportional bias.

Linear regression	Best-fit values	95 % CI
Slope	0.89	0.77 - 1.04
Y-intercept	- 0.48	- 1.86 - 0.90

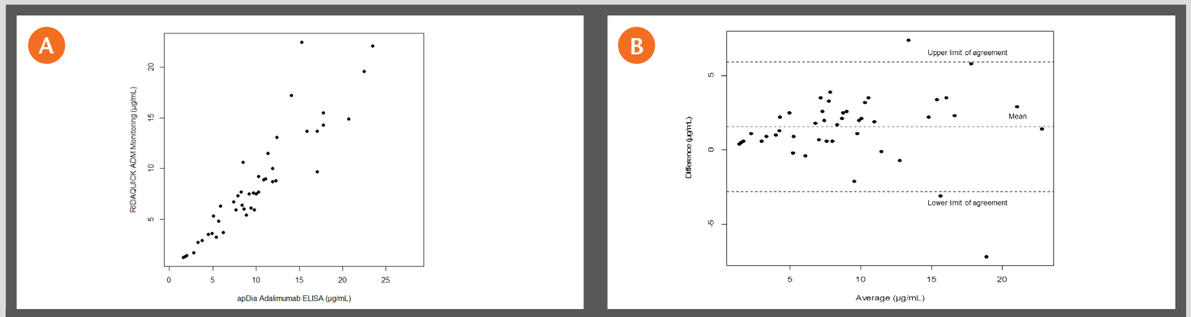

Figure 2: : (A) Scatter plot and (B) Bland-Altman plot showing a very good correlation and agreement of the RIDA®QUICK ADM Monitoring with the apDia Adalimumab ELISA for the quantification of ADM. The average bias was 1.6 ± 2.2 µg/mL (n = 56).

Conclusion

- The RIDA®QUICK ADM Monitoring revealed a very good agreement with the conventional apDia Adalimumab ELISA.
- In contrast to ELISA, the RIDA®QUICK ADM Monitoring allows to measure one sample at a time with a turn-around time of only 20 minutes.

Conflicts of interest:
TVS is an employee of R-Biopharm. The remaining authors declare no conflicts of interest in relation to this abstract. The RIDA®QUICK ADM Monitoring and apDia Adalimumab ELISA were provided free-of-charge to Gastro & Hepat Diagnostic Laboratory, R-Biopharm had no influences on the choice of patient samples.

References:
1. *Ben-Horin S, Kopylov U, Chowers Y.* Optimizing anti-TNF treatments in inflammatory bowel disease. Autoimmun Rev 2014;13:24-30.
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