

P551 Comparison of 4 assay kits for measuring infliximab trough levels and antibodies to infliximab in patients with inflammatory bowel disease

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Background

There are several assays which can be used to determine infliximab (IFX) trough levels and antibodies to infliximab (ATI). Reliability could be affected by the variability between assays. The aim of study was to determine the reliability between 4 different assay kits for measuring IFX levels and ATI.

Methods

This was a prospective single-centre cross-sectional study. We analysed serum samples, taken before IFX infusion, from 68 outpatients with inflammatory bowel disease (IBD [21 UC and 47 CD]) and more than 30-weeks exposure to IFX. Serum samples were taken from July to November 2014. All 4 assay kits used capture ELISA to measure IFX levels (Theradiag, France [A]; Grifols, Spain [B]; Matriks Biotek, Turkey [C]; and Sanquin, Netherlands [D]). ATI were measured by bridging ELISA assays in 2 kits [A, B], capture ELISA assay [C] and radioimmunoassay [D]. Intraclass correlation coefficient (ICC) mixed model with confidence interval (CI) of 95% was used to study quantitative agreement between IFX levels obtained with different assays. Bland–Altman plots were used to analyse the average of the differences of IFX levels between pairs of assays and to evaluate limits of agreement. ATI were classified as detectable/undetectable. Cohen's or Fleiss kappa determined qualitative agreement between 2 or more ATI assays.

Results

ICC (95% CI) comparing simultaneously the 4 assays for IFX levels was 0.97 (0.96–0.98). Pairwise ICCs are shown in Table 1. There were no trends in the differences of IFX mean levels in the range 0–10 µg/ml of IFX between pairs of assays. Limits of agreement were confined between -3 and 3 µg/ml in most of the pairs of assays. Regarding ATI detection Fleiss kappa was 0.88 ($p < 0.001$). Cohen's kappa in pairwise comparisons ranged from 0.72 to 0.91 ($p < 0.001$). Stratified analysis showed excellent agreement for IFX levels and ATI detection between the cohorts of UC and CD patients.

Table 1

Assay	Theradiag (A)	Matriks Biotek (C)	Sanquin (D)
Grifols (B)	0.93 (0.69–0.97)	0.94 (0.91–0.96)	0.95 (0.89–0.97)
Theradiag (A)		0.95 (0.87–0.97)	0.95 (0.92–0.97)
Matriks Biotek (C)			0.97 (0.95–0.98)

Conclusion

In a cohort of IBD patients the 4 ELISA assays measuring IFX trough levels showed excellent reliability. There was no significant bias between assays in the range of therapeutic IFX trough levels. The agreement of the 4 assays classifying ATI as detectable/undetectable was good.

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