Feasibility of infliximab point-of-care-testing in clinical practice

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Background
Infliximab is a monoclonal anti tumor necrosis factor alpha (TNF-alpha) antibody and is indicated for the treatment of various inflammatory disorders such as adult or pediatric Chron's disease, adult or pediatric ulcerative colitis, rheumatoid arthritis in combination with methotrexate, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis.
Point-Of-Care-testing(POCT) of Infliximab (IFX) allows dose adjustments on the same-day. Parallel measurements (enzyme-linked immunosorbent assay (EIA) and POCT) were done to check feasibility and validity of IFX-POCT.

Methods
Blood samples were taken immediately before the next IFX-infusion. IFX trough levels were measured via EIA and POCT (Promonitor Quick Assay (Grifols Diagnostic, Emeryville CA, USA)). A posthoc comparison of the results was carried out using Passing-Bablok regression with a confidence interval of 95% (CI95%) for intercept and slope coefficient. A correlation was determined according to Pearson and Spearman. The correlation was visualized using Bland & Altmann blot (calculation and graphical representation using XLSTAT).

Results
In n=22 patients, IFX through levels were measured by EIA and POCT. In the Passing and Bablok regression, a systemic error could be excluded, as the CI95% of the axis intercept included 0 (0.369, CI95% -0.030-2.030), whereby proportional differences cannot be excluded, as the CI95% of the slope interval did not include 1 (0.875, CI95% 0.540-0.987). The Pearson correlation (0.841, $p<0.0001$) and Spearman correlation (0.972, $p<0.0001$) show a strong association between POCT and EIA measurement. The Bland-Altman plot shows a positive bias for the POCT values (+2.659), while being insignificant due to the small sample size ($p=0.064$). The bias tended to be greater at high IFX levels (figure 1).

Conclusions
POCT is not inferior to the EIA measurement. In the individual cases where there were large deviations between the measurements, the results obtained via EIA were significantly higher than those using POCT, although the POCT values were also in a very high range. Thus, according to data in the literature, POCT is not inferior to EIA. Obtaining POCT-IFX trough levels is feasible and allows same-day adjustments. In a next step, we will prospectively examine the effects of POCT-guided therapy adjustments on therapy success and costs.

Keywords
Infliximab, Therapeutic Drug Monitoring, enzyme-linked immunosorbent assay (EIA), Point-of-Care-Testing (POCT), Correlation