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Patient-near Adalimumab trough-level testing by a novel quantitative rapid test: The Quantum Blue Adalimumab assay

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Introduction

Therapeutic drug monitoring (TDM) has become standard clinical practice and overwhelming clinical evidence indicates that dose-optimization improve clinical outcome by decreasing the risk for anti-drug-antibodies and improves the efficacy of the drug itself. Watanabe et al. (*Clin Gastroenterol Hepatol*, in press) recently demonstrated that increasing trough-levels were closely associated with endoscopic response and mucosal healing. However, this has been hampered by the high cost of and the absence of a near patient testing.

Aims of the study

To correlate a CE-marked Point-of-Care (POC) rapid test for Adalimumab (ADA) trough-level with an established laboratory test used by Norwegian physicians. This POC facilitates the Quantum Blue reader developed by the BüHLMANN Laboratories, AG, Basel, Switzerland. We also wanted to investigate whether a nurse without ordinary lab training could successfully perform this assay.

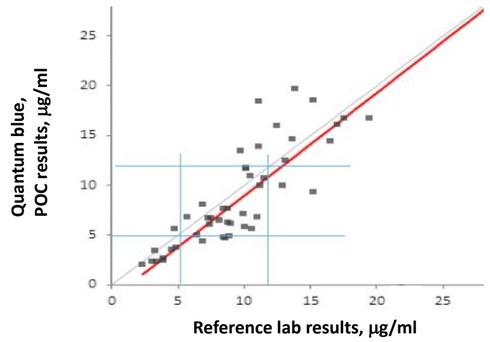
Material and methods

The study comprised 49 patients with inflammatory bowel disease (IBD) receiving ADA treatment. At the day of infusion, blood for ADA trough-level was collected in addition to 3 ml serum for QB-ADA rapid test.

All the practical work was performed by the nurse (IL) . After vortexing for 3 seconds, the serum was diluted 10 μL in 190 μL assay buffer and vortexed for 5 seconds. 80 μL was applied to the rapid test cassette and read after 15 minutes using the QB reader.

Results

There was a good correlation between the QB-ADA rapid test and the laboratory-based test (Spearman rank r = 0.88, p < 0.001; figure). The average within and between assay CV was 23.0 and 16.9, respectively. Importantly, the ADA-POC correctly identified all 8 trough-values below 5 μg/ml, and all 19 above therapeutic range of 12 μg/ml. Twenty-two values were between 5 and 12, and the POC correctly identified 21 of these.



Conclusions

In this investigation, we document a close correlation between a 15-minute rapid test for ADA trough-level with that of an standard laboratory test.

We have also shown the robustness of this test since a nurse can accurately perform it. This means that TDM now can be performed in a near patient facility like an IBD nurse in an out patient clinic without any significant delay.

Unger-Vetlesen's Institute was officially opened in 2011. Named after the Norwegian physician dr.med. Johan Carl Unger Vetlesen (1851-1914), the institute is devoted to clinical medical research at Lovisenberg Diakonale Hospital in Oslo, Norway.

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