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

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Introduction

Therapeutic drug monitoring (TDM) has become standard clinical practice over the last few years. There are overwhelming clinical evidence that optimization of anti-TNF drugs improve clinical outcome partly because this decreases the risk for anti-drug-antibodies (ADA) and improves the efficacy of the drug itself. There is also another aspect for advocating TDM, that is improving the heath economic aspect of these very expensive drugs. However, this has been hampered by 2 aspects; 1) the high cost of such assessment and; 2) the absence to near patient testing since these test have been ELISA -based and the test-result are usually delayed for several days. This means that when pts comes for infusion, the trough level is not available for dose adjustment until next infusion. We know that approx. 44% of the pts are correctly dosed, 21% under dosed and 26% had IFX levels >7. This accounts for nearly half of all pts do need dose optimization.

Aims of the study

The study had two aspects; first is to correlate a CE -marked rapid test for IFX trough level, the Quantum Blue Infliximab test (QB-IFX) (Bühlmann Laboratories, Basel, Switzerland) to an ELISA very similar to the Loeven assay. Secondly, to correlate the performance of such a test performed by; A) a nurse and B) a trained laboratory person.

Material and methods

The study comprised 64 pts with IBD receiving IFX treatment (Remicade or Remzina). At the day of infusion, ordinary routine bloodtest (CRP, Hb, LFT etc) and plasma for IFX-trough ELISA was collected in addition to 3 ml serum for QB-IFX rapid test.

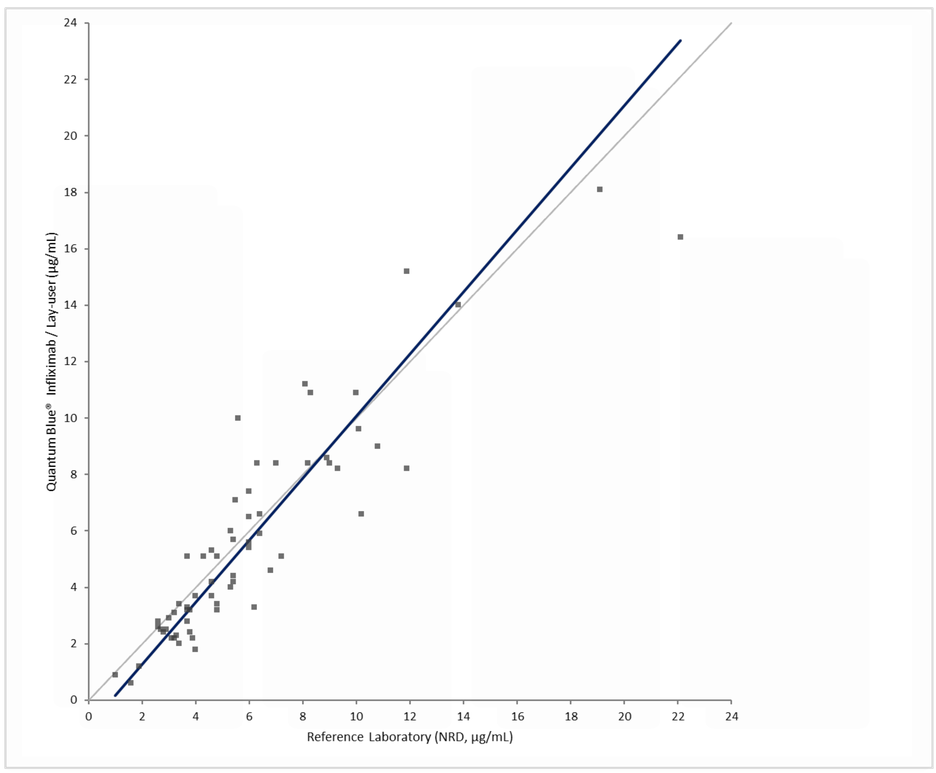
Part A : A nurse (IS) received one hour of "laboratory" training before running the QB-IFX under supervision of AR. The serum was thawed, vortexed and diluted 10uL in 190 uL assay buffer and again vortexed for 5 sec. 70uL was applied to the rapid test cassette and a 15 min. timer started. A new cassette was loaded every two min. After 15 min, the first cassette was read using the Q B- IFX dedicated electronic reader. Subsequently, a cassette was read every two min thereafter.

Part B: The same procedure was followed, but this time by a highly experienced lab technician (GHM).

Results

There was a very good correlation between the QB-IFX rapid test and the laboratory ELISA test, $r = 0.91$, $p < 0.001$. Slope was 1.1. Bland-Altman plot showed bias -7.9%.

Furthermore, the correlation between the results obtained by the QB-IFX rapid test done by a nurse and a lab person was acceptable with $r = 0.92$, $p < 0.001$.



Conclusions

To our knowledge, this is the first study that documents a close correlation between a 15 min. rapid test for IFX trough level with that of an ELISA test. Furthermore, we have shown that such a test can accurately be performed by a nurse. This means that TDM now can be moved from a distant laboratory to the near patient facility like the infusion centre and ensure correct dosing in IBD and other patients on IFX treatment.

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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