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Comparative Assessment of Infliximab Trough Levels between Point-of-Care Testing and current Standard of Care (enzyme linked immunosorbent assay) in patients with Inflammatory Bowel Disease

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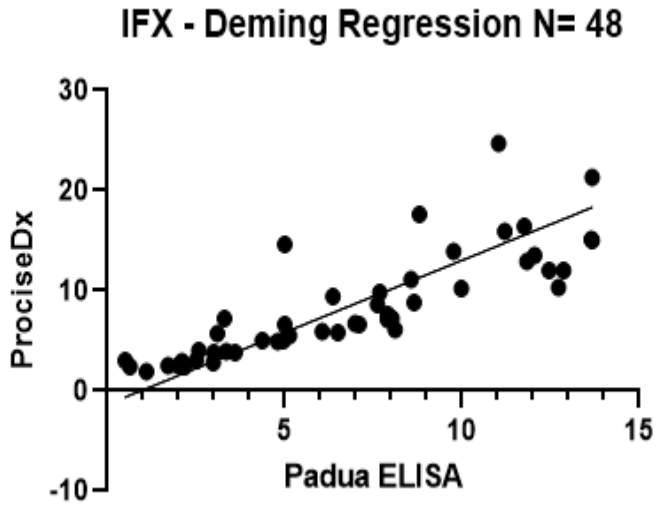
Background: Infliximab (IFX) monoclonal antibody used for the treatment of patients with moderate-to-severe active inflammatory bowel disease (IBD), both Crohn's disease (CU) and ulcerative colitis (UC). IFX induces and maintains clinical remission and mucosal healing in patients with IBD. Measurement of trough levels of IFX is important to assess if the drug is within therapeutic concentration. However, standard laboratory tests to assess IFX trough levels (enzyme linked immunosorbent assays, ELISA) present a long turnaround (about 3 hours), and the need of specialized equipment, offices and laboratory personnel. For this reason, point-of care testing (POCT) was recently developed in order to provide results within a few minutes from blood collection, leading to a rapid and informed decision-making approach.

Aim. to determine the degree of analytical correlation between a recently developed POCT (ProciseDx) IFX assay which analyze capillary whole blood and the comparative ELISA from serum samples



Y=1.44*X-1.36

r	0.831
95% confidence interval	0.717 to 0.902
R squared	0.691

Figure 1. Deming regression analysis

Conclusions.

- The ProciseDx POCT has similar accuracy than standard ELISA test, but it is more rapid in providing results and easy to be performed.
- These advantages may lead to a more rapid and effective optimization of the biological drug, thus avoiding treatment failure.

Material and methods. From October 2020 to January 2021, patients (aged ≥ 18 years) taking IFX were recruited at Gastroenterology Unit, Padua University Hospital, during outpatient visits or before drug administration. In each patient, IFX levels from capillary whole blood collected by finger stick were performed using the ProciseDx IFX assay with reportable range between 1.7 µg/mL - 77.2 µg/mL ; at the same time, a serum sample from venous blood was collected to carry out Grifols' Promonitor ELISA test (range 0.035 µg/mL – 14.4 µg/mL). A deeming regression test was used to identify the correlation between the two methods.

Results. Eighty-seven patients were enrolled (63% males with mean age of 44±16), with 52% of them having CD, 45% UC and 3% an undetermined-Inflammatory Bowel Disease (IBD-U). The assessment with ProciseDx POCT was feasible in each patient and only in three cases blood collection from finger prick was repeated. Moreover, from blood collection to results we needed about 3±0.5 minutes, while serum ELISA analysis required the collection of at least 40 samples (around three weeks at our centre) and 3 hours to be performed. Thirty-nine patients (59% males with mean age of 44±16) had TL as assessed by ProciseDx IFX assay lower than 1.7 or greater than 14.4 µg/mL, in accordance with ELISA assessment. Among the remaining 48 patients (67% males with mean age of 45±17), The correlation between the two tests was high (the total results showed a R squared of 0.691 (95% CI 0.717-0.902) (figure1).