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Comparative Assessment of Adalimumab 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. Adalimumab (ADL) is a therapeutic monoclonal antibody that targets the proinflammatory cytokine tumor necrosis factor-alpha (TNF-α) and has been shown to effectively induce and maintain disease remission in patients with Inflammatory Bowel Disease (IBD). However, some patients fail to respond to this treatment, experiencing primary failure (no response to induction therapy), or losing efficacy over time (secondary failure). Therapeutic Drug Monitoring (TDM), in clinical practice, may lead to maintain therapeutic drug concentration thereby optimizing individual dosage regimen and improving treatment response, particularly in case of sedondary failure. Recently, a point of care testing (POCT) has been developed to rapidly measure trough levels in patients taking ADL. Comparative data with current gold standard are lacking.

Aim. To determine the degree of analytical correlation between a recently developed POCT (ProciseDx) ADL assay which analyze capillary whole blood and the comparative enzyme linked immunosorbent assays (ELISA) from serum samples.

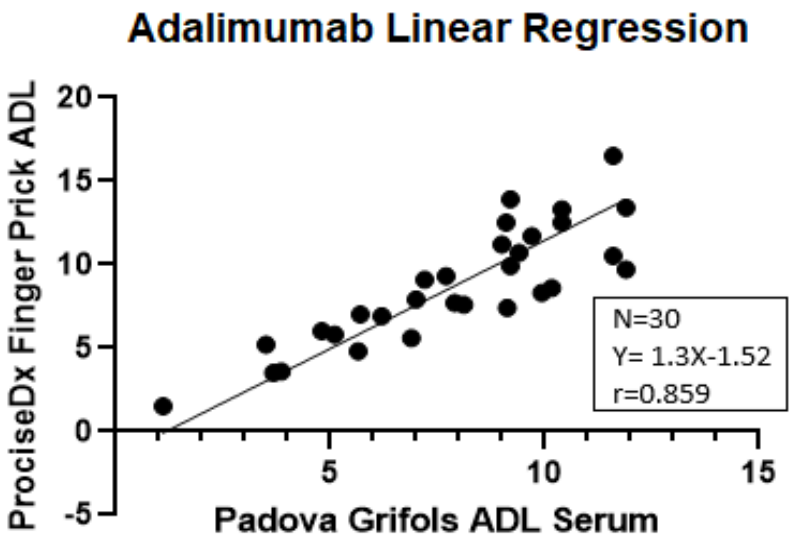

Figure 1. Correlation between ProciseDx and Grifols ADL levels

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 December 2020 to February 2021, consecutive patients (aged ≥ 18 years) taking ADL (Humira, Amgevita, Imraldi) were recruited at Gastroenterology Unit, Padua University Hospital, during outpatient visits. In each patient, ADL levels from capillary whole blood collected by finger stick were performed using the ProciseDx ADL assay with reportable range between 1.3 µg/mL - 51.5 µg/mL; at the same time, a serum sample from venous blood was collected to carry out Grifols' Promonitor ELISA test (range ≤ 0.024 – 12 µg/mL). A Deming regression test was used to identify the correlation between the two methods.

Results. Sixty patients were enrolled (67% males with mean age of 43±14), with 80% of them having CD, 17% UC and 3% an undetermined-Inflammatory Bowel Disease (IBD-U). The assessment with ProciseDx POCT was feasible and required a turnaround time of 3±0.2 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 patients (63% males with mean age of 41±14) had TL as assessed by ProciseDx ADL assay lower than 1.3 or greater than 12 µg/mL, in accordance with ELISA assessment. Among the remaining 30 patients (70% males with mean age of 43±15), the correlation between the two tests was high (R of 0.859 (95% CI 0.720 – 0.930) (Figure1).