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Background and aim: During coronavirus disease 2019 (COVID-19) pandemic, immunomodulatory therapies as well as the access to high-risk places (i.e. hospitals, infusion centers) were associated to an increased risk of infection. Nevertheless, patients with inflammatory bowel diseases (IBD) treated with intravenous (i.v.) biologics had to move to hospital for drug infusion, in contrast to patients treated with subcutaneous (s.c.) therapies who could remain at home, monitored through telemedicine. We investigated whether patients hospitalized or treated at home showed similar COVID-19 risk, as well as the levels of anxiety in both groups

Materials and methods: We conducted a survey including consecutive IBD patients in clinical and biochemical remission treated with biologics referring to the lockdown period. Patients underwent the normally scheduled clinical visits, performed at home by means of telemedicine for patients treated with s.c. drugs and only in specific cases for patients treated with i.v. therapies. We administered to all patients the Hospital Anxiety and Depression Scale (HADS) questionnaire and other 12 questions, specifically related to COVID and its implications. Group differences in continuous and nominal variables were tested by Kruskal–Wallis test and Fisher exact test, respectively

Results: A total of 189 IBD patients were recruited, 112 (59.3%) treated with i.v. drugs and 77 (40.7%) with s.c. ones. No augmented risk of COVID infection were recorded in both groups (hospitalized vs. non-hospitalized, $p=ns$). The two groups of patients had similar scores in the 14 single items of the HADS questionnaire ($p>0.10$ for all). The total HADS score obtained by the sum of all items was also almost identical between groups (37.1 ± 2.8 vs 37.2 ± 2.8 ; $p=0.98$). In patients treated with i.v. drugs receiving a televisit ($n=17$), the rates of satisfaction about telemedicine (58.8%) and the lack of in-person care (33.3%) were significantly lower compared with those treated with s.c. drugs (94.8% and 92.2%, respectively; both $p<0.0005$).

Conclusions: Our results suggest that there is no need to convert patients from i.v. to s.c. therapy during COVID-19 outbreaks, since the risk of infection and its transmission is not increased. Moreover, anxiety levels are similar in both groups, emphasizing that hospitalization seems not affecting the psychological status of the patients and therefore not increasing the relapse rate.

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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 and aim: Adalimumab (ADL) is a therapeutic monoclonal antibody that targets the proinflammatory cytokine tumor necrosis factor- α and has been shown to induce and maintain remission in patients with Inflammatory Bowel Disease (IBD). However, some patients fail to respond to ADL, experiencing primary or secondary failure. Therapeutic Drug Monitoring (TDM), may lead to maintain therapeutic drug concentration thereby optimizing individual dosage regimen and improving treatment response. Recently, a point of care testing (POCT) has been developed to rapidly measure trough levels (TL) in patients taking ADL. Comparative data with current gold standard are lacking. The aim of the study was 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.

Materials and methods: From December 2020 to February 2021, consecutive patients (aged ≥ 18 years) taking ADL 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 $\mu\text{g/mL}$ - 51.5 $\mu\text{g/mL}$; at the same time, a serum sample from venous blood was collected to carry out Grifols' Promonitor ELISA test (range ≤ 0.024 –12 $\mu\text{g/mL}$). A Deming regression test was used to identify the correlation between the two methods.

Results: Sixty patients were enrolled (67% males; mean age of 3 ± 14), with 80% of them having Crohn's Disease, 17% Ulcerative Colitis 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 $\mu\text{g/mL}$, 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)).

Conclusions: The ProciseDx POCT has similar accuracy but was more rapid and easy to be performed in providing the results of TDM in outpatients taking ADL. This could lead to a more rapid and effective optimization of the biological drug, thus avoiding treatment failure.

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DETERMINANTS OF COVID-19 VACCINE HESITANCY IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE (IBD): RESULTS OF A NATIONAL SURVEY OF THE ITALIAN IBD PATIENTS' ASSOCIATION (AMICI ONLUS)

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