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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

Marsilio I.¹, Maniero D.¹, Lorenzon G.¹, Rigo A.¹, Cardin R.¹, Facchin S.¹, Barberio B.¹, D'Inca R.¹, Zingone F.¹, Bahur B.², Bray K.², Savarino E.^{*1}

¹Padua University Hospital, Padova, Italy, ²ProciseDx, San Diego, United States of America

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 turn-around 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)

Costantino A.^{*1}, Noviello D.², Conforti F.S.¹, Aloï M.³, Armuzzi A.⁴, Bossa F.⁵, Ficari F.⁶, Leone S.⁷, Manguso F.⁸, Mocci G.⁹, Orlando A.¹⁰, Pironi L.¹¹, Radice S.¹², Rizzello F.¹³, Tongiorgi A.¹⁴, Costantino C.¹⁵, Vecchi M.¹, Caprioli F.¹

¹Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, Italy, ²Univeristà degli Studi di Milano, Milano, Italy, ³Sapienza University of Rome, Department of Pediatrics, Roma, Italy, ⁴Fondazione Policlinico Universitario A. Gemelli IRCCS, Internal Medicine and Gastroenterology, Roma, Italy, ⁵Fondazione casa sollievo della sofferenza, Gastroenterologia ed Endoscopia Digestiva, San Giovanni Rotondo, Italy, ⁶AUO Careggi, Dipartimento di Medicina Sperimentale Clinica Chirurgia Generale, Firenze, Italy, ⁷AMICI onlus, Milano, Italy, ⁸AO Cardarelli, Surgical Department, Napoli, Italy, ⁹Azienda Ospedaliera ARNAS G. Brotzu, SC Gastroenterologia, Cagliari, Italy, ¹⁰"Villa Sofia-Cervello" Hospital, IBD Unit, Palermo, Italy, ¹¹Policlinico Sant'Orsola Malpighi Centro IICB, Bologna, Italy, ¹²Humanitas Research Hospital, IBD Unit, Milano, Italy, ¹³Policlinico Sant'Orsola Malpighi, Department of Internal Medicine and

Gastroenterology, Bologna, Italy, ¹⁴UO Gastroenterologia AOUP, Chirurgia Generale, Pisa, Italy, ¹⁵Department of Health Promotion Sciences- Maternal and Infant Care- Internal Medicine and Excellence Specialties "G. D'Alessandro", Palermo, Italy

Background and aim: Vaccine hesitancy, the delay in acceptance or refusal of vaccination despite its availability, threatens the control of infectious diseases. COVID-19 vaccination has been recommended by national and international organizations in patients with Inflammatory Bowel Diseases (IBD). The aim of the study was to evaluate COVID-19 vaccine hesitancy in a population of Italian patients with IBD.

Materials and methods: In February 2021 an online questionnaire focused on COVID-19 vaccine was proposed to a representative sample of Italian IBD patients. Socio-demographic characteristics, IBD features, lifestyle, perception of COVID-19, general attitude towards vaccinations and to COVID-19 vaccines were investigated. Patients were divided into willing, hesitant and refuse towards COVID-19 vaccine. The hesitation reasons were investigated. The associations between baseline characteristics and willingness (determinants) were evaluated by calculating crude and adjusted Odds Ratio (AdjOR) with 95% confidence intervals (CI).

Results: A total of 1252 surveys were collected. 1005 (80.3%), 222 (18.1%) and 33 (2.63%) patients were defined as willing, hesitant and refuse, respectively. The baseline characteristics are shown below. Concerns for vaccine adverse effects constituted the main reason for refusal (73.4%) (Figure). 49.1% of hesitant patients reported that presence of IBD exerted an influence on their answer. Among the patients willing to be vaccinated whenever possible, 78.2% (786) thought that their IBD represented a valid motivation to access vaccination with priority. Willingness to COVID-19 vaccine was significantly associated with adherence to previous vaccinations (AdjOR 17.6; 95% CI: 11.4-27.2), male gender (1.68 95%; CI: 1.16-2.43), graduation degree (1.48; 95%; CI: 1.03-2.13), perceived higher risk of COVID-19 because of IBD (1.47; 95% CI: 1.05-2.08), alcohol intake (1.69; 95% CI: 1.16-2.45). Conversely, the hesitancy was significantly associated with complementary and alternative medicine use (0.58; 95% CI: 0.36-0.92). 54.5% of patients were under the impression to have a higher risk of COVID-19 and 31.8% to have a more severe course due to their IBD.

Conclusions: Most IBD patients would accept COVID-19 vaccines, although one in five was hesitant, primarily due to fear of adverse events. Knowledge of determinants and reasons for COVID-19 vaccination acceptance or refusal could be key in developing targeted communication strategies to fight vaccine hesitancy, also in the future for general vaccinations.

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SAFETY AND CLINICAL EFFICACY OF THE DOUBLE SWITCH FROM ORIGINATOR INFlixIMAB TO BIOSIMILARS CT-P13 AND SB2 IN PATIENTS WITH INFLAMMATORY BOWEL DISEASES (SCESICS): A MULTICENTER COHORT STUDY

Mazza S.¹, Piazza O Sed N.^{*1}, Conforti F.S.¹, Fasci A.¹, Casini V.², Ricci C.³, Munari F.³, Pirola L.⁴, Invernizzi P.⁴, Girelli C.⁵, Lupinacci G.⁶, Pastorelli L.⁷, Cavallaro F.¹, Ferraris L.⁸, Colucci A.⁸, Amato A.⁹, Tontini G.E.¹, Vecchi M.¹⁰, Fiorino G.¹¹, Caprioli F.¹⁰

¹Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Gastroenterology and Endoscopy Unit, Milan, Italy, ²Gastroenterology Unit, Bolognini Hospital, Seriate, Bergamo, Italy, ³Department of Clinical and Experimental Sciences, University of Brescia, Spedali Civili, Brescia, Italy, ⁴Division of Gastroenterology and Center for Autoimmune Liver Diseases, Department of Medicine and Surgery, University of Milano-Bicocca, Monza, Italy, ⁵Gastroenterology and Digestive Endoscopy Unit, Busto Arsizio Hospital, Varese, Italy, ⁶Gastroenterology and Endoscopy Unit, Ospedale Maggiore, Crema, Italy, ⁷Gastroenterology and Liver Unit, ASST Santi Paolo e Carlo, Ospedale San Paolo, Milan, Italy, ⁸Gastroenterology and Endoscopy Unit, Gallarate Hospital, Varese, Italy, ⁹Gastroenterology and Digestive Endoscopy Unit, Valduce Hospital, Como, Italy, ¹⁰Department of Pathophysiology and Transplantation, Università degli Studi di Milano, Milan, Italy, ¹¹IBD Center, Humanitas Clinical and Research Center, Rozzano, Milan, Italy

Background and aim: Data regarding multiple therapeutic switching from originator infliximab (IFX) to IFX biosimilars in inflammatory bowel diseases (IBD) are lacking. The aim was to evaluate the safety and efficacy of double switch from originator IFX to CT-P13 and subsequently to SB2 in patients with IBD.

Materials and methods: Patients undergoing IFX-double switch in 8 Centers in Lombardy (Italy) from November 2018 to May 2019 were retrospectively analyzed. Infliximab discontinuation rate, incidence and type of adverse events (AEs), and clinical remission rate were recorded. A comparison with a control group of IBD patients single-switched from originator IFX to CT-P13 was performed, before and after an inverse probability of treatment weighting (IPTW)-based propensity score analysis.

Results: Fifty-two double-switched IBD patients were enrolled. The 24- and 48-week proportions of patients on IFX therapy following second switch (CTP13 → SB2) were 98% (95% CI 94%-100%) and 86% (95% CI 75%-97%), respectively. Four patients experienced a total of 5 AEs, all graded 1-3 according to Common Terminology Criteria for Adverse Events (CTCAE). No infusion reactions were observed. The 24-week and follow-up-end clinical remission rates following second switch were 94% and 92%, respectively. No differences were observed in the safety and efficacy outcomes by comparing the double-switch group with a single-switch group of 66 IBD patients; all these results were confirmed by IPTW-adjusted analysis.

Conclusions: The study suggests both the safety and efficacy of the double switch from originator IFX to CT-P13 and SB2 in patients with IBD and demonstrates its non-inferiority to a single-switch strategy, with potential cost implications.

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VEDOLIZUMAB MAY BE AN EFFECTIVE OPTION FOR THE MANAGEMENT OF POSTOPERATIVE RECURRENCE OF CROHN'S DISEASE

Macaluso F.S.^{*1}, Cappello M.², Crispino F.², Grova M.², Privitera A.C.³, Piccillo G.³, Magnano A.⁴, Ferracane C.⁴, Belluardo N.⁵, Giangreco E.⁵, Fries W.⁶, Viola A.⁶, Di Mitri R.⁷, Mocciaro F.⁷, Camilleri S.⁸, Garufi S.⁸, Renna S.¹, Casà A.¹, Maida M.⁸, Orlando A.¹