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THE LEGACY OF COVID-19 PANDEMICS: REMOTE MONITORING OF PATIENTS WITH INFLAMMATORY BOWEL DISEASE AS AN EFFECTIVE MANAGEMENT STRATEGY

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Background and aim: COVID-19 pandemics has led many IBD clinics to adopt a remote monitoring approach in order to ensure an adequate follow-up of patients with inflammatory bowel disease (IBD) while complying with the rules of social distancing while access to hospital had to be restricted.

Materials and methods: The Aim of the study was to perform a remote monitoring survey in our tertiary referral center in order to assess patient adherence, perceptions and satisfaction, as well as their views for future monitoring. We also assessed changes in disease activity and quality of life. Consecutive patients scheduled for follow-up visits switched to remote monitoring via email from March 2020 to February 2021. They were asked to fill out a questionnaire focusing on 3 elements of the intervention: self-assessment, action plans and educational messages. For the self-assessment questions, we used the SIBDQ (to assess quality of life) and IBDI (to rate symptoms as patient-reported outcomes). Serum iron HBI and Mayo UC score were calculated by treating physicians.

Results: 424 subjects, 100% Caucasians, completed the survey. 233 (55.1%) were male, 220 (52.0%) had Crohn's Disease (CD). Median baseline Mayo Score and Harvey Bradshaw Index were 3 and 4, respectively. 9 (2.1%) patients were referred to emergency department because of disease flares. 2 (1%) UC patients needed to add topical therapy, 9 (4%) CD patients started therapy with systemic steroids and 3 (1.3%) with biologics. 410 (96.9%) patients were satisfied about telemedicine, and 320 (76.5%) patients reported that would maintain this approach also after COVID-19 outbreak. On univariate logistic regression analysis, a high ferritin value was the only variable related to patients' satisfaction ($p=0.001$). Lower calprotectin ($p=0.012$) and need for treatment change ($p<0.001$) were found to be related to QoL, while CD ($p=0.052$), age ($p=0.027$), disease duration ($p=0.046$) and higher calprotectin ($p=0.021$) were associated to the need for treatment change. None of the variables were significant on multivariate analysis.

Conclusions: Our results confirm, that a telemedicine approach can replace face-to-face consultations, at least for patients in remission or with mild clinical activity. Referral to emergency services or steroid use for disease flare were not significantly affected. Telemedicine could be the Covid19 legacy in the management of IBD in order to reduce the cost of patients' care and rationalize the use of health resources.

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EFFICACY OF USTEKINUMAB IN THE TREATMENT OF PATIENTS WITH CROHN'S DISEASE WITH FAILURE TO PREVIOUS CONVENTIONAL OR BIOLOGIC THERAPY: AN OBSERVATIONAL REAL-LIFE STUDY

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Background and aim: Ustekinumab (UST), a human anti-IL12/23p40 monoclonal antibody is approved to treat moderate to severe Crohn's disease (CD). The effectiveness of UST in inducing deep remission, including mucosal and transmural healing, in patients with CD is not completely clear; We assessed efficacy of UST in patients with CD who failed to respond to other biologic agents, having as endpoints clinical response, clinical remission and deep remission. Incidence of TRAEs was our secondary endpoint.

Materials and methods: We enrolled 92 subjects (47 males; 45 females; mean age: 42 (17-78) with confirmed diagnosis of moderate to severe Crohn's disease. Before inclusion, all patients had failed to conventional and/or at least one biological therapy. The administration of UST was as follows: IV at week 0 (3 vials of 130 mg each if body weight of 55-85 kg; 2 vials of 130 mg each if body weight <55 kg); subsequent SC (90 mg) q8w thereafter. At enrollment, all subjects underwent colonoscopy and were divided into groups according to endoscopic evaluation: 5 (5.4%) patients had erosions; 24 (26.1%) inflammation; 63 (68.5%) ulcers. Based on the CDAI value, 52 (56.5%) patients had a CDAI of 180-220, 35 (38%) of 220-450, and 5 (5.4%) >450. Subsequent endoscopic examination and bowel MRI or ultrasonography at baseline and at week 52 were performed to evaluate mucosal and transmural healing. Clinical response was defined as a reduction of CDAI by at least 100 points; clinical remission when CDAI was lower than 150. CDAI was evaluated at baseline and on 5 different occasions throughout a 12 months follow-up. Incidence of TRAEs was recorded during the study period.

Results: Seventeen patients interrupted therapy while 75 patients continued follow-up until the fifth visit. Clinical response at week 52 was achieved in 38 (50.5%) patients and clinical remission in 29 (39%). Twenty-six (35%) patients showed mucosal healing, 34 (45%) - partial endoscopic response; 15 patients (20%) did not show any change during endoscopic evaluation at follow-up. All patients showing mucosal healing also showed transmural healing. No major TRAEs were observed during treatment.

Conclusions: In this multi-center, real life study, we show that UST was well tolerated and effective in inducing clinical response and clinical remission in patients with moderate to severe CD who had previously failed to respond to conventional or biologic therapy. UST showed limited efficacy in inducing deep remission (i.e. mucosal+transmural healing).

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ADHERENCE TO MESALAZINE AND IDENTIFICATION OF PATIENTS WITH ULCERATIVE COLITIS IN HEALTHCARE ADMINISTRATIVE DATABASES OF TUSCANY (ITALY)

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Background and aim: Drug supply can be used to identify patients with a specific disease in healthcare administrative databases (HAD), particularly when they have a univocal indication. For drugs with multiple indications, other elements must be considered, such as dosing or scheduled regimen. This is the case of mesalazine