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P529 Evolution of COVID19 serology in a real-life population of IMID patients. Results of the BELCOMID study: BELgian Cohort study of COVID-19 in Immune Mediated Inflammatory Diseases (IMID)

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Background: Immunomodulators (IMM) and Targeted Immune-Modulating Therapies (TIMT) such as anti-TNF, anti-interleukins and Janus Kinase inhibitors, for treatment of Immune Mediated Inflammatory Diseases (IMID) could theoretically interfere with the cytokine storm and humoral immune response against COVID19 infection and vaccination. We investigate seroprevalence and evolution of SARS-CoV2 antibodies in relation to previous vaccination and/or exposure to COVID19 and ongoing IMID-treatment in a Belgian, real-life population of IMID patients.

Methods: A cross-disciplinary, prospective, observational cohort study was set up at two university hospitals. All patients with IMIDs of the gut (Crohn’s disease, ulcerative colitis), joints (rheumatoid, psoriatic or spondyloarthritis) and skin (psoriasis, hidradenitis suppurativa, atopic dermatitis) visiting the respective clinics were asked to participate. Patients had to fill out an electronic survey (REDCap®, based on WHO-ISARIC) and blood samples were drawn for serology testing (anti-Spike(S) and antiviral Nucleocapsid(N) protein antibody IgG, Abbott). Results at baseline, prior to the national vaccination program and at 6 months follow-up are presented. R version 4.0.2 was used for statistical analyses.

Results: At baseline 2163 IMID patients consented to take part. In 3.2% SARS-CoV2 anti-N seroconversion was confirmed. Of the anti-N seroconverted patients 72.9% reported a positive PCR test prior to inclusion.
At 6-months follow-up, data of 1853 IMID patients was collected. Of these, 81.7% were fully and 14.4% partially vaccinated. Serocconversion for anti-N antibodies was confirmed in 2.5% of all participants and seroconversion for anti-S antibodies in 90.8%. In 5.1% (61/1483) of fully vaccinated IMID patients no seroconversion in anti-N nor anti-S antibodies was found.

Chi Square analyses show, at 6-months follow-up, no significant association between anti-S seroconversion rate and treatment with systemic steroids (RiskRatio 1.22, 95%CI 0.38–3.9, P=0.99), TIMT (RiskRatio 0.57, 95% CI 0.3–1.1, P=0.12), IMM (RiskRatio 1.65, 95% CI 0.85–3.19, P=0.19) or combination treatment IMM/TIMT (RiskRatio 1.60, 95% CI 0.75–3.4, P=0.32).

Appearance of COVID19 symptoms followed the epidemiological curve in Belgium (Fig1).

Conclusion: In this real-life IMID cohort, the number of COVID19 cases confirmed by PCR prior to vaccination was low. Seroconversion rate for anti-N antibodies was lower at 6-months follow-up, suggesting decrease in antibody titre over time. Full COVID19 vaccination led to a high anti-S antibody seroconversion rate. Nonetheless, 5.1% of fully vaccinated patients showed no antibody seroconversion. So far, no significant association between anti-S antibody seroconversion and IMID treatment was noted.

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Vedolizumab as the first line of biologic therapy for ulcerative colitis and Crohn’s disease - a systematic review with meta-analysis

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Background: Several studies have indicated a reduced efficacy of vedolizumab among patients with ulcerative colitis (UC) and Crohn’s disease (CD) previously exposed to biological therapies. The purpose of this study was to determine the efficacy and safety of vedolizumab among bio-naive patients with UC or CD as compared with bio-exposed patients.

Methods: The systematic review and meta-analysis were conducted according to Cochrane’s recommendations. PubMed, EMBASE, and The Cochrane Library databases were searched from database inception till December 2020 for studies that reported any efficacy or safety outcome among bio-naive patients with UC or CD receiving vedolizumab. Meta-analyses were performed using a random-effects model based on the inverse-variance method. The methodological quality of was assessed in line with National Institute for Health and Care Excellence (NICE) guidelines.

Results: The systematic search identified 79 eligible studies, including a total of 2,830 and 2,381 bio-naive patients with UC and CD, respectively, compared with 7,392 and 10,511 bio-exposed patients, respectively. The mean NOS score was 6.0 and 6.1 in UC and CD, respectively. Meta-analysis showed that bio-naive patients with UC more frequently achieved clinical remission at week 14 (risk ratio (RR)=1.27 [95% confidence interval (CI) 1.00, 1.62]) and week 52 (RR=1.25 [95% CI 1.11, 1.42]) compared to bio-exposed patients. Similar results were found in terms of steroid-free clinical remission at week 52 (RR= 1.36 [95% CI 1.06, 1.76]). Likewise, bio-naive patients with CD were more likely to achieve clinical remission at week 52 (RR= 1.23 [95% CI 1.05, 1.43]), while clinical remission at week 14 and steroid-free clinical remission could not be assessed in a meta-analysis. A similar pattern was observed regarding the achievement of endoscopic remission at week 52 in UC (RR= 1.48 [95% CI 1.28, 1.72]) but not in CD (RR=1.48 [95% CI 0.82, 2.65]) (Tables 1–2).

Finally, bio-naive UC patients did not experience any difference in rates of adverse events as compared with bio-exposed patients (UC: RR= 0.96 [95% CI 0.70, 1.31]) but experienced significantly less serious adverse events (RR= 0.47 [95% CI 0.26, 0.82]). In line with this, patients with CD experienced fewer adverse events (RR= 0.73 [95% 0.64, 0.83]) and serious adverse events (RR= 0.54 [95% CI 0.34, 0.85]).

Table 1: Probability of outcomes among bio-naive patients with ulcerative colitis as compared with bio-exposed patients

| Outcome                          |Observational studies |Interventional studies |
|----------------------------------|----------------------|-----------------------|
| Clinical response                | Week 52              | Week 52               |
| Start of steroid-free clinical remission | 1.25 (95% CI 1.11-1.40) | 1.25 (95% CI 1.11-1.42) |
| Endoscopic remission             | Week 26              | Week 26               |
| Start of steroid-free clinical remission | 1.39 (95% CI 1.10-1.72) | 1.39 (95% CI 1.10-1.72) |
| Adverse events                   | Week 52              | Week 52               |
| Serious adverse events           | 0.89 (95% CI 0.68-1.18) | 0.89 (95% CI 0.68-1.18) |

Table 2: Probability of outcomes among bio-naive patients with Crohn’s disease as compared with bio-exposed patients

| Outcome                          |Observational studies |Interventional studies |
|----------------------------------|----------------------|-----------------------|
| Clinical response                | Week 52              | Week 52               |
| Start of steroid-free clinical remission | 1.27 (95% CI 1.00-1.62) | 1.27 (95% CI 1.00-1.62) |
| Endoscopic remission             | Week 52              | Week 52               |
| Start of steroid-free clinical remission | 1.36 (95% CI 1.06-1.76) | 1.36 (95% CI 1.06-1.76) |
| Adverse events                   | Week 52              | Week 52               |
| Serious adverse events           | 0.90 (95% CI 0.68-1.05) | 0.90 (95% CI 0.68-1.05) |

Conclusion: This meta-analysis suggests that the reduction of efficacy of vedolizumab following exposure to other biologicals is statistically and clinically significant. Our findings add to the body of evidence regarding tailoring of biological therapies for patients with UC and CD.