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Letter to the Editor

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Safety of COVID-19 Vaccination in Inflammatory Bowel Disease Patients on Biologic Therapy

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We read with great interest the manuscript by Wellens *et al*. reviewing the evidence on SARS-CoV-2 vaccination in patients with inflammatory bowel disease [IBD].[1] The authors highlight that IBD patients should receive vaccination against SARS-CoV-2. In fact, the International Organization for the Study of IBD has already recommended vaccinating all patients with IBD as soon as they are able to receive the vaccine, regardless of immune-modifying therapies or disease activity.[2]

Nevertheless, some articles have shown that a large percentage of IBD patients are unwilling to receive the COVID-19 vaccine due to fear of potential adverse events [AEs].[3,4] Moreover, individuals with IBD were excluded from safety and efficacy phase III vaccine trials, as well as those being treated with immunosuppressive therapies.

Thus, we performed a monocentric real-life survey to assess AEs of COVID-19 vaccination among IBD patients. All adult individuals with IBD undergoing biological treatment and followed at Centro Hospitalar Universitário de São João were included. Each patient answered a telephone questionnaire conducted by a gastroenterologist.

A total of 301 patients agreed to participate in the study, the majority being females [53.2%], with a median age of 42 years [interquartile range 32–54 years]. IBD diagnosis included Crohn's disease [76.7%] and ulcerative colitis [23.3%]. The proportions of patients receiving tumour necrosis factor inhibitors, ustekinumab and vedolizumab were 75.4%, 13.0% and 11.6%, respectively.

This cohort included 239 vaccinated patients [59.0% Pfizer-BioNTech, 20.5% Moderna, 14.2% Janssen and 6.3% AstraZeneca], 173 [57.5%] of whom had complete vaccination. Of the remaining individuals, only 12 did not intend to be vaccinated. The main reasons were: fear of potential AEs [50.0%], lack of confidence in the vaccine development process [25.0%] and little information about vaccination in IBD patients [16.6%].

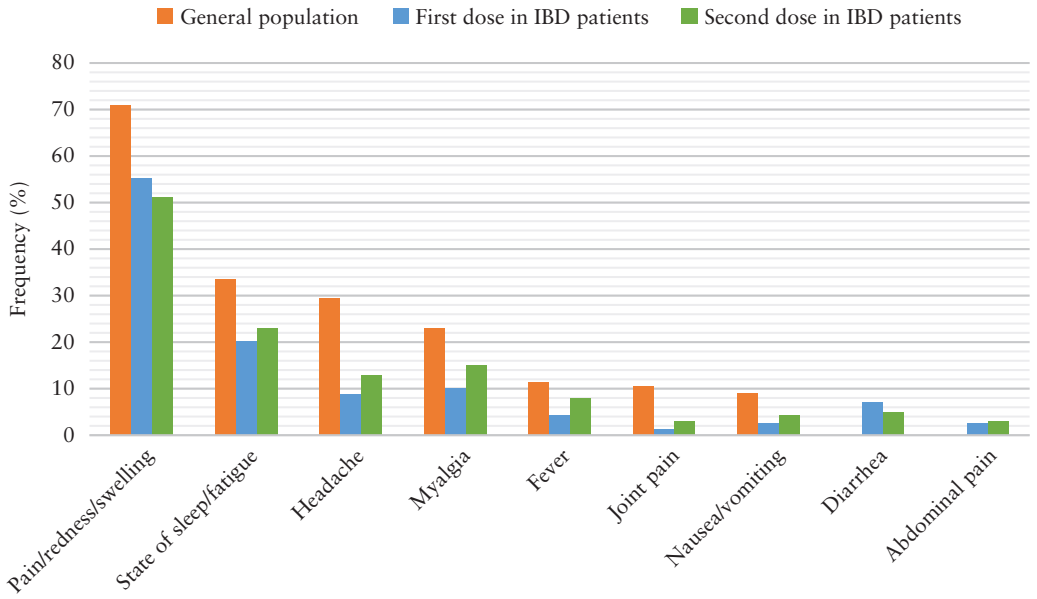

Figure 1. Adverse reactions occurring within 7 days after vaccination in IBD patients compared with the general population.[5].

Among vaccinated patients, the overall AE frequency was 56.8% after dose 1 [D1] and 74.1% after dose 2 [D2]. The two most common symptoms were localized injection-site reactions and fatigue. The vast majority of AEs were mild and lasted only a few days. Only four [1.7%] patients had IBD exacerbation after the vaccine. No serious AEs were reported and no patient was hospitalized. The percentage of AEs was higher among patients younger than 50 years [77.6% vs 62.5% after D1, $p = 0.011$; 83.0% vs 58.8% after D2, $p = 0.002$]. No significant differences were seen based on sex, vaccine type, biologic drug or disease type. Compared to the general population, a lower percentage of IBD patients suffered from local or systemic reactions during the first week after vaccination [Figure 1].[5]

In conclusion, we found a high acceptance rate and a good safety profile of SARS-CoV-2 vaccination in IBD patients treated with biologics. Indeed, AEs were common but overall mild and transitory. These data support the prioritization and rapid vaccination of these individuals.

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Conflict of Interest

The authors have no disclosures to report.

Author Contributions

I.G. performed the literature review and drafted the manuscript. I.G., S.L. and G.M. critically revised and finalized the manuscript. All authors approved the final version of the manuscript. The data underlying this article are available in the article and in its online supplementary material. Guarantor of the article: I.G.

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