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IBDnet position paper on the current use of SARS-CoV-2 targeted vaccines

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1. Current data on risk of SARS-CoV-2 in IBD patients

PD Dr Luc Biedermann

The largest global reporting system of COVID-19 cases in patients with IBD, the so-called SECURE-IBD registry (as of January 2021 more than 4000 cases are included) allows to draw the following important conclusions according to the data so far: The risk of a severe course of COVID-19 including need for ICU, respiratory support, or death was not found to be increased in IBD patients using most standard treatment options for IBD including biologics (1). The risk was, however, found to be significantly increased in patients on systemic steroids at the time of COVID-19 infection. The effect of systemic steroids was comparable to other well-established risk factors such as comorbidities and advanced age. An increased risk for severe COVID-19 on thiopurines and anti-TNF-combo therapy may be possible (2). While the SECURE-IBD registry is large and global cases are reported, it does not provide a population-based picture on risk of COVID-19 infection in IBD patients overall compared to the general population. Important data from Denmark (3) clearly indicate that the risk of COVID-19 was not increased compared to the general population (at least in the first wave of infection in early 2020 when the study was conducted). While this study does not allow to draw any conclusion on the potential underlying reasons for this rather lower risk of COVID-19 infection (e.g. more conservative and restrictive behaviour with a lower exposure to potential infection in IBD patients), these data are certainly reassuring and overall indicate that the risk of COVID-19 infection in IBD does not appear to be increased in general and specifically in patients under treatment with immunosuppressive agents and biologics, thus confirming the results from SECURE-IBD.

2. Currently approved vaccines in Switzerland

Prof Stephan Vavricka

By early mid-February, it is expected that three COVID vaccines will be approved in Switzerland. The following table summarizes the main expected response rates and side effects so far published in phase I/II and phase III studies.

			BNT 162 Pfizer BioNTech Comirnaty ® (n=43'998)	mRNA-1273 Moderna (n=30'000)	ChAdOx1 Astra Zeneca (n=43'751)
Vaccine efficacy	SARS-CoV-2-infection		95%	94.1%	70%
	Severe infections		90% (10 cases of which 9 in the placebo group)	100% (30 cases, all in placebo group)	Estimated 100%
Side effects	Phase I and II	Adults	After second dose: fever 17%, shivers 58%, fatigue 75%	After second dose: fever 0%, shivers 7%, fatigue 27%	Pain 50%; sensation of fever 36%, fever 16%, muscle ache 48%, headache 61%, nausea 34%
		Elderly patients	Fever 8%, shivers 17%, fatigue 42%	Fever 11%, shivers 36%, fatigue 72%	56-69 years: fever 0%, shivers 10%, fatigue 30% Over 70 years fever 0%, shivers 0%, fatigue 15%
	Phase III		Fatigue 3.8% headache 2%, older patients fewer side effects	Pain at injection site 2.7%, fatigue 9.7%, muscle ache 8.9% arthralgias 5.2%, headache 4.5%, pain 4.1%, redness at injection site 2%	No severe side effects

Source: Kanton Zürich, Gesundheitsdirektion (https://www.zh.ch/content/dam/zhweb/bilder-dokumente/themen/gesundheit/corona/impfung/factsheet_fachinformation_coronaimpfung.pdf)

3. Indications/contraindications for vaccine administration in IBD patients

PD Dr Michel Maillard

According to the January 7th Swiss Public Health Office, patients suffering from acquired or congenital immunodeficiency are eligible for SARS-CoV-2-targeted vaccine administration. In line with this statement, IBD patients are considered as part of the immune-mediated inflammatory disorders. Despite the above-related reassuring data (see 1.), IBD patients are at risk of wasting disease, thromboembolic complications or extra-intestinal manifestations. In addition, they are more prone than the general population to be exposed to steroids or immunosuppressive drugs that would increase their risk of adverse outcome. For those reasons, we consider that all IBD patients should get vaccinated regardless of their disease state or their ongoing treatment. Contraindications are those that apply to all groups, i.e., ongoing pregnancy, past history of anaphylactic shock due to a vaccine, fever > 38°C in the past 48h as well as all criteria requiring a SARS-CoV-2 test and an ongoing quarantine.

4. Influence of the various IBD therapy on vaccination safety and efficacy

Prof Pierre Michetti

Most therapies used in IBD have an immunosuppressive effect, which is limited for most drugs. The new mRNA vaccines against SARS-CoV-2 (Pfizer/BioNTech and Moderna) have not been tested in immunosuppressed patients (the phase III Moderna trial, there were 92 HIV patients in the treatment group), but there is a theoretical possibility that the efficacy of these vaccines is decreased in immunosuppressed patients. This may be the case in IBD patients treated with infliximab, especially if they also receive an immunomodulator. This is, however, not the case for vedolizumab. Ustekinumab may slightly enhance vaccination efficacy based on response to classical vaccines. Tofacitinib impaired response to some usual vaccines, but not to others. Regarding safety, none of the currently available vaccines, including the AstraZeneca/Oxford vaccine are live vaccines, thus safety in immunosuppressed patients is not considered to be different from safety in regular persons, but will of course continue to be examined.

Summary

Taken into consideration the current data on risk and disease course of SARS-CoV-2 infection in IBD patients, given indication and contraindication for vaccine administration in IBD patients within the context of ongoing IBD therapies, we recommend that all IBD patients should get vaccinated for SARS-CoV-2.

Reference

1.

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