

Brazilian IBD Study Group position statement on SARS-CoV2 vaccination

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ABSTRACT – Mass vaccination offers the best strategy to fight against COVID-19 pandemic, and SARS-CoV2 vaccines are being approved in several countries for emergency use. In Brazil, vaccine approval is expected in the next few days, however potential concerns exist regarding vaccine recommendations for specific populations, such as patients with inflammatory bowel disease (IBD). To address these questions, the Brazilian IBD Study Group (GEDIIB) provides this practical advice with key recommendations about the COVID-19 vaccines in IBD population.

COVID-19 pandemic is a public health emergency of international concern and Brazil is currently one of the hardest hit regions, having one of the greatest COVID-19 death rates in the world⁽¹⁾. Given that the introduction of SARS-Cov-2 vaccines represents the first chance to eliminate the virus on a long-term basis, many countries are already implementing mass vaccination programs. In Brazil, although no immunization program is planned so far, approval of vaccines is expected in the next few days. However, the availability of vaccines has raised some concerns in the media and public opinion regarding whether or not to vaccinate particular groups of patients, such as patients with inflammatory bowel diseases (IBD). Facing this scenario, this Brazilian IBD Study Group (GEDIIB) document aims to strongly recommend IBD patients to be given a COVID-19 vaccine once it is widely available. Moreover, this manuscript also may help both patients with IBD and physicians clarify specific safety issues that may arise, regarding COVID vaccination.

I. Should IBD patients be prioritized in vaccination allocation groups?

IBD patients often require treatment with immunosuppressant medications, which can increase their risk of infections. However, recent data suggest that they do not have an increased risk of infection of SARS-CoV-2 or the development of COVID-19 complications⁽²⁾. Therefore, it is unlikely that a patient with IBD will qualify for a priority allocation vaccination group based only on the diagnosis of IBD itself. Prioritization should be carried out on the basis of age and related comorbidities.

II. Which vaccines are currently available?

So far, no SARS-CoV-2 vaccine has been approved in Brazil. The first approved immunizations by the European and American regulatory agencies were the mRNA vaccines. In Brazil, it is very likely that our regulatory agency will issue emergency use authorization for Oxford/AstraZeneca and Sinovac SARS-CoV-2 vaccines. TABLE 1 provides an overview of SARS-CoV-2 vaccines.

III. Does immunosuppression affect the effectiveness of COVID-19 vaccine?

For other common vaccines, it has been demonstrated that immunosuppressant medications may result in some reduction in antibody formation and lower vaccine response. For instance, it has been shown that immune response to pneumococcal polysaccharide vaccination (PSV-23) is impaired in Crohn's disease (CD) patients on combination of TNF-blockers and immunomodulators⁽³⁾ and that the serologic conversion rate to influenza vaccine is lower in immunosuppressed IBD patients^(4,5). On the other hand, treatment with ustekinumab or vedolizumab does not appear to reduce responses to flu vaccine^(6,7).

We do not know whether the available vaccines will be as effective in IBD patients, given that most vaccine trials excluded IBD patients. Taking into account the higher level of effectiveness of the available vaccines against symptomatic COVID-19, and severe COVID-19 (70–95%), much better than the flu vaccine (50–60%), it is anticipated that SARS-CoV-2 vaccine already protects at higher rate, even if treatment with immunosuppressant agents can make it slightly less effective.

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TABLE 1. Overview of approved SARS-CoV-2 vaccines.

Developer	Pfizer/ BioNTech	Moderna	Oxford/ AstraZeneca	Sinovac Biotech / Instituto Butantan
Name	BNT162b2	mRNA-1273	AZD1222	Coronavac
Doses	2 doses	2 doses	2 doses	2 doses
Time interval	3-12 weeks	4-12 weeks	4-12 weeks	2-3 weeks
Mechanism	mRNA encoding SARS-CoV2 spike protein	mRNA encoding SARS-CoV2 spike protein	Non-replicating adenovirus vector containing SARS-CoV2 spike protein gene	Inactivated SARS-CoV-2
Storage	-80°C -60°C	-20°C	+2°C a +8°C	+2°C a +8°C
Efficacy	95%	94.1%	70% [†]	50.38% (overall) 78% (mild cases) 100% (moderate to severe) [‡]
Safety	No serious concerns. Twenty one cases of anaphylactoid reactions since approval*	No serious concerns	No serious concerns	No serious concerns

*Available at <<https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm>>. Accessed on Jan. 11, 2020.

[†] Pooled data from two trials: 62% effective for volunteers given two full doses and 90% effective for a smaller subgroup who received a half dose followed by a full dose. [‡] Unpublished data disclosed by researchers.

IV. Is there any safety concern regarding SARS-Cov-2 vaccination in IBD patients?

There is no evidence to suggest an increased risk of the vaccine against SARS-CoV-2 in patients with IBD. Even though it is possible that other vaccines will soon become available, it is important to emphasize that, for those listed in TABLE 1, immunosuppression is not a contraindication. In addition, SARS-CoV2 vaccines have been tested in tens of thousands patients with safety profiles very similar to other vaccines commonly used in IBD patients, such as the flu vaccine. Also, IBD patients have been vaccinated with both influenza and pneumonia vaccines for many years with no indication of worsening IBD symptoms or flares following vaccination⁽⁴⁾. Thus, analogous to other vaccines used for many years, immunization appears very unlikely to affect IBD activity.

V. Should IBD patients postpone their biologic or hold their immunosuppression in order to get vaccinated?

We recommend that COVID-19 vaccine should be administered at any time regardless of last biologic infusion/subcutaneous dose received, as it is not a live vaccine. The one recommendation in this regard is that patients should avoid receiving their vaccine at the same day of an infusion/subcutaneous dose just in case the patient develop a reaction or adverse event it would be difficult to identify which one (vaccine or biologic) has caused it.

Therefore, in light of current evidence, we strongly support the recommendation to vaccinate all patients with IBD against SARS-CoV-2, regardless of their current treatment. For specific situations not discussed in this document, we recommend that the decision

regarding whether to vaccinate or not should be taken individually, during shared decision making with patients.

CONCLUSION

This review represents an expert group opinion. It is in accordance with available evidence and positioning of main international IBD experts groups. Other approved vaccines and new data may be available in few weeks. Therefore, this position statement may change accordingly and will be reviewed frequently.

Authors' contribution

All authors were equally involved in study design, manuscript writing and review. All authors contributed to revision of the manuscript for important intellectual content, granted final approval of the version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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RESUMO – A vacinação em massa oferece a melhor estratégia para enfrentamento da pandemia de COVID-19, e as vacinas contra SARS-CoV2 estão sendo aprovadas em vários países para uso emergencial. No Brasil, a aprovação da vacina é esperada em breve, no entanto, existem potenciais preocupações em relação às recomendações de vacinas para populações específicas, como pacientes com doença inflamatória intestinal (DII). Para responder essas questões, o Grupo Brasileiro de Estudos IBD (GEDIIB) fornece conselhos práticos com recomendações importantes sobre as vacinas para COVID-19 na população com DII.

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