

Position statement of the Polish Society of Gastroenterology and the National Gastroenterology Consultant on vaccination against COVID-19 among patients with inflammatory bowel diseases

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The COVID-19 (coronavirus disease 2019) pandemic significantly impacted the functioning of the whole world, both with regard to health, society, and economics. It is the greatest civilizational challenge for humanity since World War II. So far, more than 80 million SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2) infections have been reported, and nearly 2 million people have died from this infectious disease (as of 4.01.2021) [1]. However, accurate statistics on the number of patients in whom infection did not lead to death but caused significant organ complications are unknown. The long-term effects of infection with the new coronavirus species also remain unelucidated.

Taking the above into consideration, actions must be taken to reduce the incidence of SARS-CoV-2 infection, especially among the groups at increased risk of severe COVID-19. One of the key solutions serving this purpose is the introduction of universal vaccination against COVID-19. Thanks to the advances in biotechnology and molecular biology, it was possible to develop and register such vaccines within a relatively short period of time. At present (as of 4.01.2021), three vaccines against COVID-19 [2–6] are available. A fragment of messenger ribonucleic acid (mRNA) is the key ingredient of both Comirnaty® (Pfizer® and BioNTech®) and Moderna® vaccines [2–5]. When injected, mRNA molecule uses the host translation apparatus (ribosome) to synthesize a fragment of the SARS-CoV-2 spike (S) pro-

tein, which plays the key role in the process of infecting cells with the new coronavirus species. This protein is then presented on the cell membranes of the host muscle cells, which generates an immune response. As the mRNA molecule is very unstable, it undergoes rapid intracellular degradation. In recent days, a vaccine with a somewhat different mechanism of action (by AstraZeneca®) was also approved for use. It is based on a modified, incapacitated adenovirus unable to replicate and induce disease, which contains a sequence in its genetic material that encodes the SARS-CoV-2 S protein. Following administration, adenovirus penetrates into human cells, which then produce S protein, present it on the cell membrane, triggering an immune response [6].

Large-scale clinical trials carried out to this date, as well as practical observations based on vaccinations performed since registration of the agents in question, have not produced any worrying data regarding a significant risk of adverse reactions [2–6]. The most commonly reported reactions include pain at the site of injection and weakness. These symptoms usually disappear within several hours from the administration of the vaccine. Other adverse reactions (e.g. fever, headache) are relatively rare and most often self-limiting. Early analyses of vaccine efficacy, on the other hand, indicate that they reduce the risk of symptomatic SARS-CoV-2 infection by as much as 95% [2–6].

To date, it has not been unequivocally demonstrated that inflammatory bowel disease (IBD) significantly increases the risk of SARS-CoV-2 infection, but there is evidence that certain medicines may be a risk factor for a severe course of COVID-19 [7, 8]. Until now, the recommended measures for the prevention of SARS-CoV-2 infection among patients with IBD included only non-specific methods (social distancing, use of protective masks, disinfection). In light of current knowledge, there are no studies clearly indicating differences with regard to the safety and efficacy of COVID-19 vaccination among IBD and non-IBD patients. Clinical trials on the efficacy of vaccination against COVID-19 conducted to date have not been focused on populations of patients on immunosuppression or with autoimmune disorders. However, given the available scientific data on the safety profile of other vaccines in IBD patients, it should be assumed that vaccines against COVID-19 approved to date will not differ with regard to the incidence of adverse reactions compared to those without IBD [9, 10]. The available vaccines against COVID-19 belong to the group of dead vaccines and therefore cannot cause infection even in immunosuppressed patients. There is also no evidence that IBD or the medication used in its therapy may adversely affect the effectiveness of COVID-19 vaccination. The results of studies for other vaccines in this context are not conclusive, but most do not indicate lower immunogenicity of vaccination of clinical significance [9, 10].

Taking the above data as well as the recommendations of other societies (i.a. oncology, hematology) into account, the Polish Society of Gastroenterology, as well as a national consultant in the field of gastroenterology, recommend that the use of active immunoprophylaxis against COVID-19 should be considered in every adult patient with IBD. This recommendation also applies to patients who have had COVID-19 in the past (patients without active SARS-CoV-2 infection) [11, 12].

Furthermore, based on the existing knowledge, it should be concluded that:

- inflammatory bowel disease in remission is not a contraindication to vaccination;
- the benefits of active immunoprophylaxis may be greatest in patients not taking immunosuppressive drugs. Therefore, in patients who are scheduled to be given immunomodulatory or biological therapy, vaccination should be carried out before commencing treatment, if possible;
- vaccination is also recommended during therapy with drugs acting on the immune system (immunomodulatory and biological drugs);
- it seems reasonable to plan the doses of the vaccine so that they do not overlap with the time of adminis-

tration of the biological agent. However, the optimal time interval between the administration of a biological drug and the application of the vaccine has not yet been clearly defined;

- in IBD patients in remission maintained by a chronic administration of immunomodulatory drugs, these agents should not be stopped, and it is not a contraindication to COVID-19 vaccination;
- the only absolute contraindication to COVID-19 vaccine is a systemic anaphylactic reaction after the previous dose of the vaccine or a systemic anaphylactic reaction to the substances in the vaccine. Special care should also be taken with regard to those people who have had an anaphylactic reaction to any substance in the past;
- inflammatory bowel disease exacerbation constitutes a temporary contraindication. In such situations, it is necessary first to induce disease remission before carrying out the qualification for vaccination.

With increasing knowledge on the efficacy and safety of COVID-19 vaccination, the above recommendations will need to be updated. However, given the available scientific data, there is every reason to believe that the implementation of widespread active immunoprophylaxis against SARS-CoV-2 infection is the only way to end the ongoing pandemic. Preventive vaccination is considered one of the most important achievements of the modern medicine, changing the history of mankind. It is the responsibility of every doctor to promote knowledge in this area, supported by reliable scientific data. On the other hand, active and widespread engagement in the preventive vaccination program is one of the cornerstones of social responsibility.

Conflict of interest

The authors declare no conflict of interest.

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