

Study finds COVID-19 vaccines safe for IBD patients

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IBDs, including Crohn's disease and ulcerative colitis, are chronic conditions that occur when the intestinal immune system becomes overreactive, causing chronic diarrhea and other digestive symptoms. In a published survey at the beginning of COVID-19 vaccine distribution, 70% of IBD patients reported concern about side effects from the vaccines.

"What we've learned is that if you have IBD, the <u>side effects</u> you're likely to experience after a <u>vaccine</u> are no different than they would be



for anyone else," said Gil Melmed, MD, corresponding author of the study and director of Inflammatory Bowel Disease Clinical Research at Cedars-Sinai. "If you're being treated with advanced therapies such as biologics, these side effects might even be milder. So, don't let that be a reason that you're not getting vaccinated.

Evaluating post-vaccine side effects

Patients with IBD and other immune-related conditions on biologic therapies were excluded from COVID-19 vaccine trials, so Melmed and fellow researchers evaluated post-vaccination side effects in 246 adult IBD patients in a nationwide COVID-19 vaccine registry used by investigators at Cedars-Sinai.

These patients, like those in the general population, most often reported pain and swelling at the injection site, followed by fatigue, headache and dizziness, fever and chills, and gastrointestinal symptoms. Most side effects were mild and lasted only a few days.

Very few IBD patients reported severe side effects—most commonly fatigue, fever and headache. And just two of the 246 patients studied reported severe gastrointestinal symptoms.

Many IBD patients expressed concern that vaccination would cause a "flare" or worsening of their condition. Research into whether post-vaccination GI symptoms were from flares or simply reactions to the vaccine is ongoing. However, Melmed emphasized that the vast majority of reported gastrointestinal symptoms were short-lived and resolved on their own.

Around 80% of patients in the study were being treated with advanced therapies that inhibit the body's immune response in a targeted way, including various biologic and Janus kinase inhibitor therapies. Melmed



said this inhibition of the immune system might partially explain the slightly lower number of side effects these patients reported.

"A lot of these adverse events might actually be due to the immune system reacting to the vaccine," said Melmed. "So, it's possible that you're not going to have as strong of a reaction to a vaccine if you're on medications that modulate parts of your <u>immune system</u>."

Patients with other types of immune-related conditions receiving these therapies would also likely experience fewer side-effects.

"We believe that our results will be applicable to patients with other immune-mediated inflammatory diseases as these drugs are widely used in dermatology, neurology, rheumatology and other disciplines," said Dermot McGovern, MD, Ph.D., study co-author and director of Translational Research in the Inflammatory Bowel and Immunobiology Research Institute and Joshua L. and Lisa Z. Greer Chair in Inflammatory Bowel Disease Genetics at Cedars-Sinai. "We will be working with our colleagues in oncology to understand effects of the vaccine on people receiving therapy for cancer and also with our partners in the health care workers study to understand if there are differences of outcomes from the vaccine that may be influenced by having an autoimmune disease."

Study expansion

Meanwhile, the current study of IBD patients is being extended for 5 years to help researchers determine whether—because their immune systems are being modulated by IBD treatment—they are receiving less protection from COVID-19 vaccines.

"What we do not yet know is whether these vaccines build lasting immunity to COVID-19 in patients with immune-mediated disease," said



study co-author Susan Cheng, MD, director of Public Health Research and Erika J. Glazer Chair in Women's Cardiovascular Health and Population Science at Cedars-Sinai. "Gathering this critically important information is the next step for our research team."

More information: Gregory J. Botwin et al, Adverse Events Following SARS-CoV-2 mRNA Vaccination, *American Journal of Gastroenterology* (2021). DOI: 10.14309/ajg.00000000001342

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