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The effect of Sinopharm COVID-19 vaccine on fecal calprotectin levels and clinical symptoms in patients with ulcerative colitis

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Abstract

Background: The ongoing COVID-19 pandemic has raised concerns regarding the safety and efficacy of vaccination in immunocompromised patients, including those with inflammatory bowel disease (IBD). In this study, we aimed to investigate the effect of the Sinopharm anti-COVID-19 vaccine on fecal calprotectin (fCP) levels and clinical symptoms in patients with ulcerative colitis (UC).

Methods: A total of 28 patients with UC (8 females and 20 males), with a mean age of 40.8 ± 9.7 years, were enrolled in the study. Most patients were receiving 5-aminosalicylic acid (5-ASA) agents. All patients received the Sinopharm anti-COVID-19 vaccine. Fecal calprotectin levels and clinical symptoms were assessed at baseline and at 2 and 12 weeks after vaccination. The Lichtiger score and Mayo score were used to evaluate clinical symptoms.

Results: No IBD-related adverse events were reported following vaccination. There was no significant difference in fCP levels between baseline and 2 weeks after vaccination. However, a significant decrease in fCP levels was observed at 12 weeks after vaccination compared to baseline and 2 weeks post-vaccination. Similarly, a significant improvement in clinical symptoms was noted at 2 and 12 weeks after vaccination compared to baseline, as evidenced by a reduction in the Lichtiger score. There was no association between vaccination and the clinical bleeding score (Mayo score). None of the other parameters, including location of injury, type of medication, or sex, were associated with fCP levels, Lichtiger score, or Mayo score.

Conclusion: The results of this study suggest that the Sinopharm anti-COVID-19 vaccine is safe for patients with IBD and does not lead to exacerbation of UC symptoms.

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Introduction

The COVID-19 pandemic, caused by SARS-CoV-2, emerged in December 2019 and rapidly spread worldwide, leading to significant morbidity and mortality. Severe cases often result in hospitalization, respiratory failure, or death, with reported case fatality rates ranging from 2.3% to 7.2%, particularly among individuals with comorbidities (1-7). Inflammatory bowel diseases (IBD), including Crohn's disease (CD) and ulcerative colitis (UC), affect millions of people globally. A major concern in patients with IBD is their increased susceptibility to infections due to immunosuppressive therapies (8-10). Paradoxically, these same immunosuppressive agents may reduce the risk of severe COVID-19 by mitigating cytokine storm-driven complications (11,12).

Given this complex interplay between immunosuppression and infection risk, vaccination remains a critical strategy for protecting patients with IBD against SARS-CoV-2. While COVID-19 vaccines have demonstrated efficacy in the general population, their safety and effectiveness in patients with IBD - particularly those receiving immunosuppressive regimens - require further investigation (13,14). The International Organization for the Study of Inflammatory Bowel Disease (IOIBD) strongly recommends vaccinating all patients with IBD as early as possible using any available vaccine type (mRNA, viral vector, inactivated, or recombinant), while acknowledging that immunosuppressants may reduce vaccine effectiveness (15).

However, reports of gastrointestinal (GI) side effects following mRNA vaccination - both in clinical trials (16,17) and among patients with IBD (18) - raise concerns about potential disease exacerbation. Patients with IBD commonly experience GI symptoms such as frequent stools, abdominal pain, and rectal bleeding (18). Since these symptoms are nonspecific, distinguishing between vaccine-related side effects and true IBD flare-ups is crucial. Fecal calprotectin (fCP), a well-established biomarker of intestinal inflammation, offers a noninvasive alternative to endoscopy for monitoring disease activity (19). Given its reliability, monitoring fCP levels before and after vaccination could help determine whether COVID-19 vaccines influence intestinal inflammation in patients with IBD.

The Sinopharm COVID-19 vaccine, an inactivated virus vaccine, has been widely administered worldwide. Despite its proven safety and efficacy in the general population, its effects on patients with IBD - particularly regarding intestinal inflammation and symptom progression - remain unclear. This study aimed to evaluate short- and long-term changes in intestinal inflammation (Measured by fCP) and clinical symptoms following Sinopharm SARS-CoV-2 vaccination in patients with IBD.

Methods

This pilot study was conducted at a single referral IBD center at Isfahan University of Medical Sciences. Adult patients with UC who voluntarily intended to receive the anti-SARS-CoV-2 vaccination between 1st April 2022 and 30 July 2022 were included in the study.

Participants were sequentially and prospectively enrolled at the single institutional vaccination site. Exclusion criteria for vaccination included a history of allergic reaction to any previous vaccination, clinical signs of an acute infection at the time of vaccination, and systemic corticosteroid therapy at a daily dose exceeding 20 mg of prednisone administered for longer than 3 weeks prior to the first dose of the vaccine. Patient and disease characteristics were obtained from electronic medical records.

Fecal calprotectin (fCP) levels were measured prior to vaccination (Baseline) and at 2 and 12 weeks after the first dose. According to the manufacturer's instructions, fCP levels were determined using the Calprest NG kit, Lot No: 011895, Eurospital Diagnostic Company, Trieste, Italy. fCP, which is present in neutrophils and monocytes, correlates with the level of endoscopic and histological inflammatory activity in IBD, and its elevation in feces reflects intestinal inflammation (20).

At baseline and at 2 and 12 weeks following the initial dose, IBD severity scores (New onset or worsening of stool frequency, abdominal discomfort, or rectal bleeding) were assessed using the Lichtiger and Mayo indices. The Lichtiger index is a clinical tool for evaluating UC symptoms and comprises eight items: Nocturnal diarrhea, bowel movement frequency, fecal incontinence, rectal bleeding, abdominal pain/cramping, abdominal tenderness, general well-being, and use of anti-diarrheal medications. The total score (Lichtiger score) categorizes disease activity, with a score >10 indicating acute severe colitis (21).

The Mayo Score (Mayo Assessment of Clinical Activity Index) is a standardized measure of UC severity that evaluates four components: Stool frequency, rectal bleeding, endoscopic findings, and physician's global assessment. Each component is scored from 0 to 3, yielding a total score ranging from 0 to 12. Scores of 0 indicate remission, 3 - 5 mild activity, 6 - 10 moderate activity, and 11 - 12 severe disease (22). For this study, the partial Mayo score (Excluding endoscopy) was used, calculated by summing bowel movement frequency, rectal bleeding, and physician assessment.

Statistical analyses were performed using SPSS version 18 (SPSS Inc., Chicago, IL, USA). Normality of continuous data was evaluated using Q-Q plots and the Kolmogorov-Smirnov test, and data were examined for violations of normality, the presence of outliers, and missing values. Continuous variables were presented as mean ± SD or medians with ranges, and categorical variables were presented as percentages. Paired t-tests and Wilcoxon signed-rank tests were used to compare changes before and after vaccination. A two-sided P-value of 0.05 or less was considered statistically significant.

Ethical approval for the study was granted by the Ethics Committee of Isfahan University of Medical Sciences (IR.MUI.MED.REC.1400.417). The study was registered at clinicaltrials.gov as IRCT20210113050024N3-16.09.2021. Written informed consent was obtained from all participants.

Results

In total, 28 patients with UC were enrolled, including 8 females (28.6%) and 20 males (71.4%), with a mean age of 40.8 ± 9.7 years (Range: 24 - 57). Most patients were receiving 5-ASA agents (92.2%). All patients received the Sinopharm anti-COVID-19 vaccine.

No IBD-related adverse events were reported after vaccination. There was no difference in fecal calprotectin levels between baseline and 2 weeks after COVID-19 vaccination. However, a statistically significant decrease in fCP levels was observed at 12 weeks after vaccination compared with baseline and 2 weeks post-vaccination. A statistically significant decrease in clinical symptoms compared with baseline was also observed at 2 and 12 weeks after vaccination, as indicated by the Lichtiger score (Table 1). There was no association between vaccination and the clinical bleeding score (Mayo score). None of the other parameters, including location of injury, type of medication, or sex, were associated with fecal calprotectin levels, Lichtiger score, or Mayo score (P > 0.05).

Table 1. The levels of calprotectin, Lichtiger score and MAYO score at baseline and after 2 and 12 weeks of Anti COVID-19 vaccination

Variable	Baseline level (1)	2 weeks after vaccination (2)	12 weeks after vaccination (3)	P1,2	P2,3	P1,3
Calprotectin						
Mean±SD	302.9±318	267.8±407	102±143	0.27	0.02	< 0.001
Median (Min-Max)	179.7 (1.7-938)	36 (1-1122)	46.4 (1.1-457)			
Lichtiger Score						
Mean±SD	4.1±2.2	3±2.7	3.5±2.3	0.01	0.15	0.008
Median (Min-Max)	4 (1-9)	2 (1-10)	3 (1-8)			
MAYO Score						
Mean±SD	2.1±1	2.1±1	2±1	0.231	0.16	0.16
Median (Min-Max)	2 (1-3)	2 (1-3)	2 (1-3)			

P-values were derived from paired t-test and Wilcoxon nonparametric Rank

Discussion

Recent studies have demonstrated the importance of vaccinating patients with IBD against SARS-CoV-2 to prevent infection. However, concerns have been raised regarding the impact of vaccination on mucosal inflammation in these patients. The Sinopharm COVID-19 vaccine, an inactivated virus vaccine developed in China (23), has emerged as a potential immunization option for patients with IBD. To address this concern, we assessed fecal calprotectin (fCP) levels and clinical scores during the course of immunization with the Sinopharm vaccine. Our findings revealed no significant worsening effect of vaccination on intestinal inflammation or clinical outcomes in patients with IBD in both the short and long term. These results are consistent with previous studies that have reported a similar lack of adverse effects following vaccination in patients with IBD (24).

In a recent study by Pokryszka et al., a significant increase in fCP levels was observed in patients with IBD following standard two-dose vaccination with an mRNA vaccine. In that study, gastrointestinal adverse events were reported in 9.5% of patients with IBD after the first dose and in 4.8% after the second dose (19). However, it is important to note that the differences observed between our study and theirs may be attributed to the type of vaccine used. The Sinopharm COVID-19 vaccine, as an inactivated virus vaccine, has shown a favorable safety profile in patients with immune disorders (25).

The observed reduction in fCP levels and clinical symptoms at 12 weeks post-vaccination suggests potential immunomodulatory benefits. Although the underlying mechanism remains unclear, the vaccine-induced immune response may result in systemic immune regulation that indirectly improves intestinal inflammation. This may involve modulation of cytokine profiles or enhancement of regulatory T-cell activity; however, further research is required to confirm these hypotheses.

Immunocompromised individuals, including those with IBD, have expressed concerns about the potential risks associated with replication-competent vaccines. Various vaccine strategies, including live attenuated vaccines, standard inactivated virus vaccines, nucleic acid vaccines, and viral-vectored vaccines, have been developed to address these concerns (26). It is expected that patients with IBD will develop protective immunity from these vaccine strategies due to their capacity to mount antibody responses. Studies have shown that Spike protein antibody levels are significantly higher following mRNA vaccination, whereas the seroconversion rate is lower in patients who received non-mRNA vaccines (27). Several limitations should be considered when interpreting our findings. The relatively small sample size may limit the statistical power to detect subtle changes in inflammatory markers. In addition, the absence of a control group makes it difficult to distinguish vaccine-specific effects from natural fluctuations in disease activity. Future studies involving larger cohorts and longer follow-up periods are needed to validate these observations.

In terms of immunogenicity, inactivated vaccines such as Sinopharm appear to have lower immunogenicity compared with other vaccine platforms. However, they have been authorized for use in patients with IBD because of their favorable safety profiles (28). Potential risk factors for COVID-19 in patients with IBD include disease activity, corticosteroid treatment, nutritional status, and comorbidities (26). Interestingly, in our study, different IBD treatment modalities did not significantly influence changes in fecal calprotectin levels or disease activity following vaccination. Moreover, vaccination may have a beneficial effect on disease activity, as evidenced by a significant reduction in fCP levels and clinical symptoms at 12 weeks after vaccination compared with baseline. These findings suggest that patients with IBD receiving various treatments can safely receive the Sinopharm vaccine without compromising the safety or effectiveness of immunization.

Conclusion

This study provides evidence that the Sinopharm COVID-19 vaccine does not worsen intestinal inflammation or clinical outcomes in patients with IBD. These findings support the use of the Sinopharm vaccine as a safe immunization option for patients with IBD. Further research is warranted to explore the long-term effects and immunogenicity of the Sinopharm vaccine in this patient population.

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Ethical Statement

The study was approved by the Ethics Committee of Isfahan University of Medical Sciences (Protocol number 1400.417). This study was conducted in accordance with the principles of the Declaration of Helsinki. All methods were carried out in compliance with relevant guidelines and regulations. Written informed consent was obtained from all participants.

Conflicts of Interest

The authors declare that they have no competing interests.

Author Contributions

B. T., P. A., and M. R. K. contributed to the design of the study. M. R. K., K. Sh., and N. K. collected the data. N. K., H. M., and S. S. performed the statistical analyses and drafted the manuscript. All authors read and approved the final manuscript.

Data Availability Statement

All data generated or analyzed in this study are included in the article. Further inquiries can be directed to the corresponding author upon reasonable request.

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