

Diagnostic Utility of Fecal Calprotectin in Inflammatory Bowel Disease: A Cross-Sectional Study from Bangladesh

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Inflammatory bowel
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Ulcerative colitis,
Crohn's disease,
Cross sectional
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ABSTRACT:

Background: Fecal calprotectin (FC), a neutrophil-derived protein, serves as a valuable non-invasive biomarker for assessing intestinal inflammation. While extensively proven useful in Western cohorts, its clinical use in South Asian populations and specifically Bangladeshis, has not been fully explored.

Methods: This cross-sectional study included 90 patients: 23 diagnosed with Crohn's disease (CD), 22 with ulcerative colitis (UC), and 45 with irritable bowel syndrome (IBS), who served as a control group. Laboratory parameters analyzed comprised hemoglobin (Hb), erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and fecal calprotectin. An FC amount greater than 200 µg/g was considered above normal. Statistical analyses included the Wilcoxon rank sum test, Spearman's correlation, receiver operating characteristic (ROC) curve analysis, and chi-square tests to assess group differences and associations.

Results: Patients with IBD exhibited markedly higher median FC levels (UC: 459 µg/g; CD: 404 µg/g) than those with IBS (35 µg/g). None of the studies reported significantly different FC, CRP or ESR results between UC and CD subgroups. FC showed a strong positive correlation with CRP ($p = 0.704$) and a strong inverse correlation with Hb ($p = -0.687$), highlighting its alignment with systemic inflammation and anemia. Elevated FC (>200 µg/g) was significantly associated with increased CRP, ESR, and low Hb levels (all $p < 0.001$). ROC analysis demonstrated excellent diagnostic performance for identifying CRP-positive individuals (AUC ≈ 0.90).

Conclusion: Fecal calprotectin demonstrates robust diagnostic utility for differentiating IBD from IBS in Bangladeshi patients. Since it correlates well with usual inflammatory markers, it can support clinical monitoring when endoscopy is not possible.

INTRODUCTION

Inflammatory bowel diseases (IBD) that is Ulcerative colitis (UC) and Crohn disease (CD) are and are chronic, relapsing disorders admitting a history of gastrointestinal (GI) inflammation (1,2). Although traditionally it is known as the disease of the Western countries, increasing cases of IBD are also emerging in South Asia, such as Bangladesh where the awareness of the disease and the availability of diagnostic equipment are also growing factors in recognizing the disease (3,4). The precise assessment of the disease activity is essential to monitor the responsiveness to treatment and clinical management (5,6).

Endoscopy, despite being the gold standard of intestinal inflammation evaluation, is invasive, expensive, and it is not available everywhere, limiting its regular application in follow-up (7,8). Consequently, most clinicians tend to use the non-invasive forms of inflammatory markers, which include the rate of sedimentation of erythrocyte (ESR) and C-reactive protein (CRP) (9–11). Nonetheless, the sensitivity and specificity of these markers are inadequate to permit consistent circumvention of the disease activity in IBD (12–14). A more promising non-invasive measure is fecal calprotectin (FC) circulating an endogenous calcium-binding protein released by

activated neutrophils (15–17). The level of its concentration in stool is linked good to mucosal inflammation, and that creates a possible surrogate of endoscopic analysis (18,19).

Despite various research studies conducted in other western nations and regions of India showing the usefulness of FC as a diagnostic tool, researches are limited on information in Bangladesh (20,21). This disparity is of special significance in light of the fact that there is a high prevalence of infectious diarrheal diseases in this country (22,23). In addition, limited data existed in comparing FC with conventional markers including ESR, CRP, and hemoglobin (Hb) in the South Asian IBD populations.

The purpose of the cross-sectional study was to assess the fecal calprotectin in patients with IBD and compare it to the CRP, ESR, and Hb. Moreover, we looked into the value of FC at the differentiation between IBD and irritable bowel syndrome (IBS) a common functional disease exhibiting symptoms symbolizing both IBD and non-inflammatory. In this study, we tried to define the role FC had in the day-to-day IBD patients' evaluation within the Bangladesh clinical circles

METHODOLOGY:

We performed a retrospective, cross-sectional study comparing the patients assessed in a tertiary care hospital in Bangladesh with gastrointestinal symptoms from 2014-2019. Medical records and laboratory databases were used to collect data. Among the participants that were included in the study were patients with a documented record of having inflammatory bowel disease (IBD), either ulcerative colitis (UC) or Crohn disease (CD), and patients with irritable bowel syndrome (IBS), which was utilized as a control group.

The inclusion criteria were that a patient had results with the fecal calprotectin (FC), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), hemoglobin (Hb), and demographic information (age, sex, diagnosis). The patients who had any of the needed laboratory data absent were excluded. To make statistical comparison between UC and CD, IBS patients were omitted. All the tests involved were done within one visit to the clinic so as to make them aligned both in time arguments to make clinical and laboratory data meet. The analysis of the Fecal Calprotectin (FC) is carried out applying a quantitative ELISA test. Level of results was in microgram per gram ($\mu\text{g/g}$) of stool. The definition of elevated FC was 200 $\mu\text{g/g}$ where a cut-off value of 200 $\mu\text{g/g}$ was adopted, in accordance with published literature, and prior surveys as illustrated. The measurement of the C-Reactive Protein (CRP) in serum is done with the help of common laboratory techniques. The elevated CRP was calculated as level $> 6 \text{ mg/L}$. Overall, the erythrocyte sedimentation rate (ESR) is stated in millimeters per hour (mm/hr), whereas the value that exceeds 20 mm/hr is regarded as high. Hemoglobin is abbreviated (Hb) or weighed in grams per deciliter (g/dL).

The characteristics of the patients and their laboratory readings were summarized using descriptive statistics. Continuous variables were presented as means or medians and interquartile ranges and categorical variables as frequencies and percentages. The non-parametric data were compared in groups between UC and CD via the Wilcoxon rank sum test. The relation of FC with CRP, ESR as well as Hb was determined using Spearman correlation. Area under the curve (AUC) was reported at receiver operating characteristic (ROC) runs to indicate the ability of FC to identify patients with elevated CRP ($> 6 \text{ mg/L}$). Patients were further grouped according to their FC levels ($<200 \text{ (micro)g/g}$ and more than 200 (micro)g/g) to compare inflammation markers among groups. All the statistical transformation and plotting were performed with R (version 4.0 or later). The p-value was set at <0.05 .

RESULTS:

A total of 90 patients were analyzed: 23 had Crohn's disease (CD), 22 had ulcerative colitis (UC) and 45 had irritable bowel syndrome (IBS). The average age among people in the study was 34.1 years with CD, 30.3 years with UC and 33.8 years with IBS. Compared to IBS, people with UC and CD had lower mean levels of hemoglobin: 9.76 g/dL for UC and 10.1 g/dL for CD. The ESR and CRP levels were significantly higher in patients with UC (45 mm/hr and 19.3 mg/L) and CD (42 mm/hr and 19 mg/L) when compared to those in IBS (15 mm/hr and 4.06 mg/L). UC and CD showed a high median level of fecal calprotectin (FC) (459 and 404 $\mu\text{g/g}$, respectively), much higher than what was found in IBS (35 $\mu\text{g/g}$).

To compare the changes in inflammatory markers between UC and CD, Wilcoxon rank sum tests were run without including results from IBS patients. There were no differences found in FC ($p = 0.364$), CRP ($p = 0.874$) or ESR ($p = 0.601$) between UC and CD patients. Every patient showed that FC was strongly associated with CRP ($p = 0.704$, $p < 0.001$) and was also moderately associated with ESR ($p = 0.563$, $p < 0.001$). The strong negative

correlation between FC and hemoglobin ($\rho = -0.687$ and p value was less than 0.001) points to a connection between inflammation in the small intestine and anemia.

The levels of fecal calprotectin in IBD (UC/CD) patients were found to be much greater than those of IBS patients. With a cut-off of 200 $\mu\text{g/g}$ to identify elevated FC, 40 out of the 45 patients with IBD showed elevated levels and IBS patients had no cases above this limit. When the data for inflammatory markers was analyzed, the difference between patients with FC $>200 \mu\text{g/g}$ and $\leq 200 \mu\text{g/g}$ was found to be highly significant. Patients with elevated FC levels had a much higher CRP ($p < 0.001$). People withsed highFC demonstrated much higher ESR compared to those with low FC($p < 0.001$).

The ROC curve was drawn to assess how well FC is able to identify people with high levels of CRP ($>6 \text{ mg/L}$). The AUC value was high which means FC is effective in spotting systemic inflammation.

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Table-1: The table shows the chi-square associations between demographic and clinical factors and indicators of inflammation. A significant association existed between FC elevation and CRP positivity, ESR increase and low hemoglobin levels ($p < 0.001$ for each relationship).

Table-1:

| Variable 1 | Variable 2 | χ^2 (df, N) | p-value |
|------------|--------------|---------------------------|----------|
| Group | FC High | $\chi^2(2, N=90) = 72.07$ | <0.001 |
| Sex | FC High | $\chi^2(1, N=90) = 0.02$ | 0.902 |
| Group | CRP Positive | $\chi^2(2, N=90) = 71.51$ | <0.001 |
| FC High | CRP Positive | $\chi^2(1, N=90) = 63.00$ | <0.001 |
| FC High | ESR High | $\chi^2(1, N=90) = 45.82$ | <0.001 |
| FC High | Hb Low | $\chi^2(1, N=90) = 48.07$ | <0.001 |

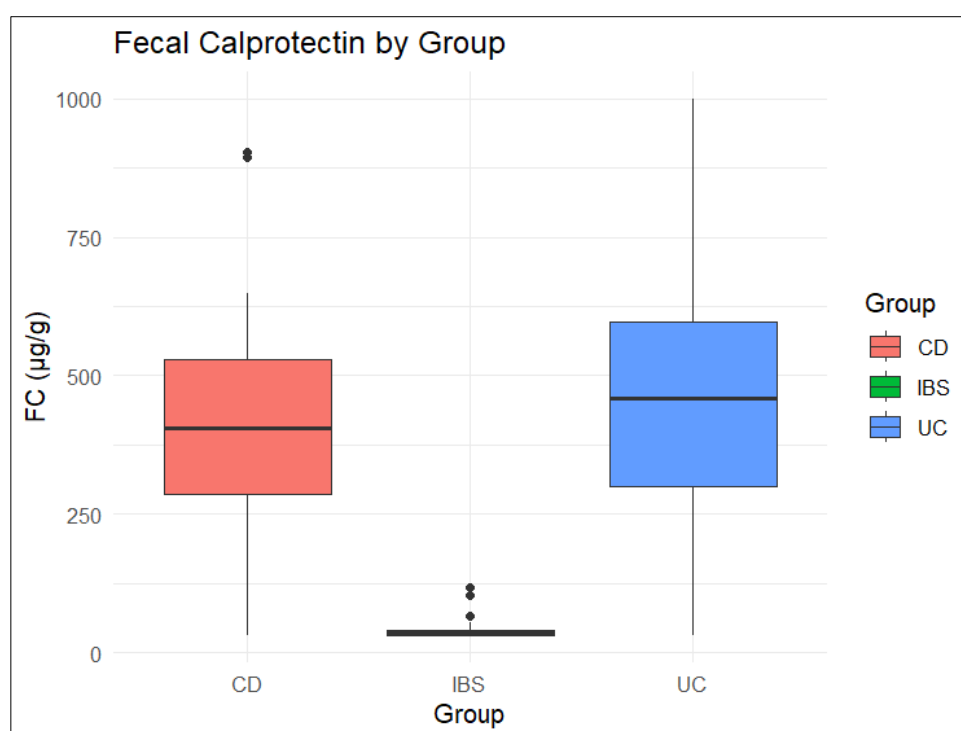


Figure-1:

Box plot presenting the fecal calprotectin levels (in micrograms per gram of feces) for patients diagnosed with Crohn's disease (CD), ulcerative colitis (UC) and irritable bowel syndrome (IBS), showing significantly higher levels of FC in IBD than in IBS.

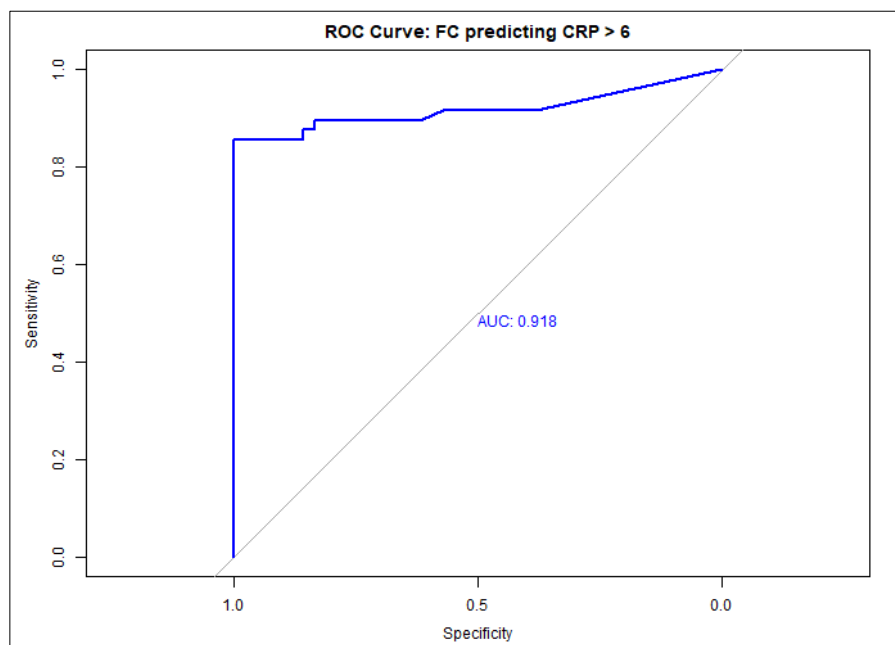


Figure-2:

The ROC curve illustrates the 0.918 AUC of fecal calprotectin for identifying elevated C-reactive protein (CRP) indicating its excellent accuracy in differentiating between cases and non-cases.

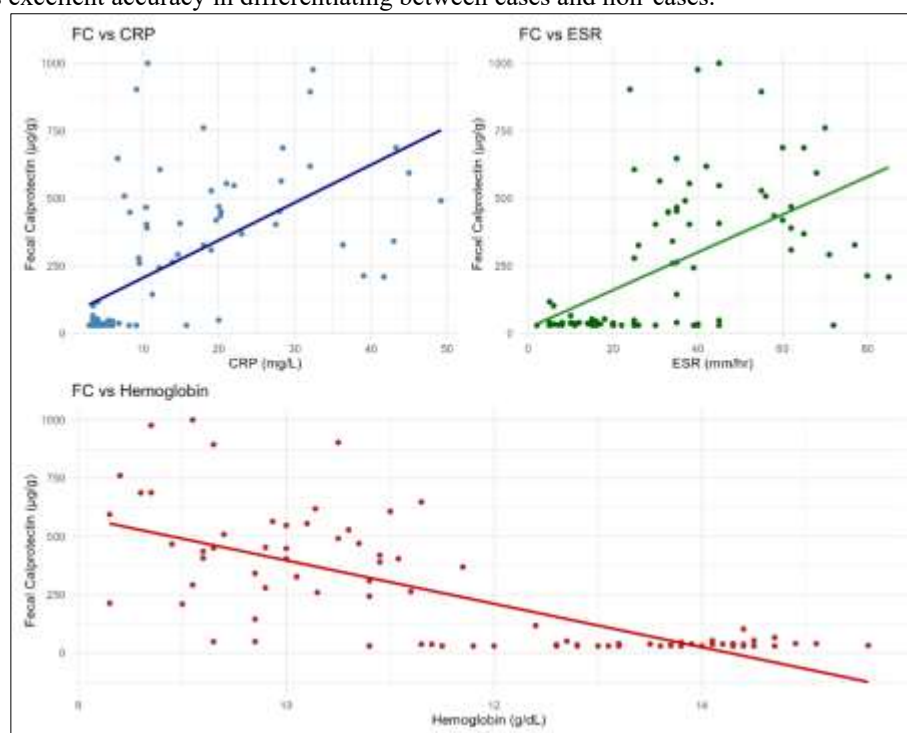


Figure-3:

The scatterplots showing positive relationship of FC with ESR & CRP and inverse relationship with Hb%

DISCUSSION:

In this study on Bangladeshi patients with IBD and IBS, we tested fecal calprotectin (FC) as a useful, non-invasive marker for identifying intestinal inflammation. From our analysis, patients with IBD have greatly elevated FC levels compared to those with IBS and these levels are strongly correlated with traditional systemic indicators of

inflammation—CRP and ESR. These findings align with evidence from other studies in this region, proving FC is helpful in monitoring IBD inflammation (24,25).

Despite higher FC levels in UC patients than in CD ones, this difference is not statistically significant. Like earlier studies, there are similar rises in FC with active disease in both types of IBD because, regardless of the type, FC indicates large numbers of neutrophils in the intestinal wall (26–28). Moreover, our findings reflect a strong association between FC and CRP ($p = 0.704$), a moderate link with ESR ($p = 0.563$) and a strong inverse relationship with hemoglobin ($p = -0.687$) which suggests that FC is linked to inflammation and anemia levels in this population.

Having a FC cut-off level of 200 $\mu\text{g/g}$ enabled the study to tell apart IBD from IBS. All the IBS patients showed FC values $<200 \mu\text{g/g}$, but approximately 89% of patients with IBD had FC levels over this figure. Patients with rising fecal calprotectin also had a higher level of both CRP and ESR, supporting the link between inflammation at multiple sites. The same has been found in an Indian study which concluded that FC performs better than CRP and ESR at revealing active disease in Indian UC patients (29). Based on our study, evidence now applies to Bangladeshi population and to people with both UC and CD.

According to ROC analysis, FC was shown to predict systemic inflammation accurately, as it presents a low error rate for high values of CRP above 6 mg/L. In other words, FC can be a helpful diagnostic tool for both diagnosis and following progress of the disease and treatment in routine clinical settings.

An important point of our study is that we used an IBS control group to make sense of FC results, demonstrating the differences between disease from infections and disease of the bowel. Also, the research has its limitations. The method does not fully confirm disease presence or activity, since tests like endoscopy or tissue samples are not done. As a result, we could not link FC with mucosal healing or scores used in endoscopies such as the Mayo score. On the other hand, the fact that the sample size is reasonable for initial analysis, it might limit any later comparisons in large groups.

In short, our research backs up the view that fecal calprotectin is a valuable and easy way to detect inflammation in IBD. It connects to common blood tests ($\text{ESR} < \text{CRP} < \text{HB\%}$), helps find diagnosis for IBD compared to IBS and may support decision-making about treatment in Bangladesh where endoscopies are not so easy.

CONCLUSION:

In people with inflammatory bowel disease, fecal calprotectin helps diagnose IBD in a non-invasive manner. FC values in the Bangladeshi cohort were strongly connected to CRP, ESR and hemoglobin, showing both overall and mucosal inflammation. The FC values were much higher in IBD than in IBS and using a cut-off value of 200 $\mu\text{g/g}$ allowed doctors to confirm whether the condition was organic or functional. As a result, FC is proven to be useful and sensitive for diagnosing and monitoring IBD in places where access to endoscopy is limited.

STRENGTHS AND LIMITATIONS OF THE STUDY:

This study has certain limitations. The way the study was conducted prevents the team from assessing causality or seeing how the disease changed over the years. Second, because endoscopic and histological findings were absent, it was not possible to link fecal calprotectin with direct signs of behavior or severity of the disease. Even though fecal calprotectin, CRP, ESR and hemoglobin levels were measured, prognostic indicators and scores based on bowel movements and pain were not recorded, so it is difficult to assess their relationship with clinical outcomes. As a fourth point, the number of patients in the study, though enough for initial examination, might not capture the small differences between UC and CD. Also, the study was carried out at only one center which may limit how useful the findings are for other patient groups in Bangladesh or countries with limited resources.

Implications of the Study Results:

The results can be used to improve health practices and interventions in areas facing resource limitations such as Bangladesh. Because Fecal Calprotectin is a reliable indicator of inflammation, it could be useful in routine IBD care, as some patients might not be able to have colonoscopy or histopathology done. FC testing can effectively tell apart inflammatory bowel disease from irritable bowel syndrome, preventing unwanted invasive treatments, cutting down on test wait times and allowing doctors to start the proper treatment sooner.

Furthermore, the clear relationship among increased FC values and markers like CRP, ESR and hemoglobin makes it all the more important to place FC in routine medical testing. By using FC, specialists can organize patients in outpatient clinics who will most likely require endoscopy. It affects the way patients are treated when a healthcare system is overloaded.

When FC testing is part of monitoring patients, changes in the disease can be noticed earlier, medications may be adjusted faster and costly imaging tests are needed less often. Taking these points into account, the study suggests

more widespread use of FC in both regular and specialist care and it also emphasizes that diagnostic tools should be tested on various populations for best results.

Recommendations for Future Research:

More research should use prospective, multi-center approaches to enroll larger and more varied IBD patients throughout Bangladesh. Having both endoscopic and histological analyses would help verify that fecal calprotectin is a valuable marker for measuring the healing of tissue and the severity of the disease. It is important to evaluate changes in FC over time in response to treatment, as such assessments may help to foresee clinical relapse, remission and the effectiveness of therapy.

Adding dependable clinical indices (such as Truelove-Witts and Harvey-Bradshaw Index) and reports from patients would create stronger connections between FC and the impact of the disease on patients. Researchers might also gain information on using combinations of biomarkers, for example lactoferrin in feces and cytokines in blood, to evaluate IBD. In addition, cost-effectiveness analyses should be conducted to assess the role of FC testing in resource-poor healthcare services and to encourage its regular use in South Asia.

Declaration of interest: All authors confirm they adopt no conflict of interest and would like to support the corresponding author for submission.

Informed Consent: The study followed the standards set by the Declaration of Helsinki. Permission for this study was granted by the Institutional Review Board (IRB) of BSMMU. Informed consent was collected from all participants before collecting data and participation was completely voluntary.

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Data sharing statement: As for the accessibility of the data of this study, the datasets are available from the corresponding author on reasonable request. Informed consent to use identifiable data was sought from the patient and in the exceptional circumstance that data is to be disclosed it will only be done after the patient's details are anonymized. Users' request should be combined with a declaration of the reasons why such request is made as well as a declaration of how the data is to be utilized. The data will be spread out in compliance with all the ethical scenarios from the study and the corresponding institutional guidelines

Ethical Considerations: We have taken IRB approval from & there is no conflict of interest regarding this article and all ethical rules are followed. The research paper here has been reviewed and all the data used in this work have been referenced appropriately.

Institutional Affiliation: BSMMU was the primary institution for this research, ensuring ethical guidance, protection of data and compliance with regulations.

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Registration: It's not applicable for this study.

Reporting Guideline: The manuscript was made according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) standards for cross-sectional studies.

Generative AI Use: For paraphrasing of citations and basic structure of outline, actually very limited use of Quillbot has been made and all have been edited properly after review.

Author contributions:

Dr. Mohammad Asadur Rahman, Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka: The clinical care of the patients during the period of this study was provided by Dr. Asad who was involved for both data acquisition process and for the first formation of this manuscript. He also took time to refine the manuscript and also assisted in the preparation of review of literature and writing of the manuscript and reviewing and editing of the manuscript.

Dr. Md. Fazlul Karim Chowdhury, Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka: The clinical care of the patients during the period of this study was provided by Dr. F.K Chowdhury who was involved for both manuscript revision and editing.

Dr. Mohammad Shoiab Chowdhury, Department of Gastroenterology, Bangabandhu Sheikh Mujib Medical University, Dhaka: The clinical care of the patients during the period of this study was provided by Dr. Chowdhury who was involved for both manuscript revision and editing.

Dr. Md. Deluwar Hussien, MBBS (Dinajpur Medical College, Dinajpur): Dr. Deluwar was involved in the formulation of the study, as well as the attainment of the data analysis and evaluation for the study. He also contributed to the writing of the review of literature and the manuscript and the review and editing of the manuscript.

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